UNIVERSITÀ DEGLI STUDI DI CAMERINO

Scuola di Giurisprudenza

International School of Advanced Studies

DOTTORATO DI RICERCA

XXXVII CICLO

AREA SCIENTIFICA

Legal and Social Sciences

CURRICULUM

Civil Law and Constitutional Legality

APPROVAL, LICENSING, AND MARKETING OF PERSONAL PROTECTIVE EQUIPMENT IN THE CONTEXT OF THE COVID-19 PANDEMIC OUTBREAK: EUROPEAN AND ITALIAN REGULATIONS BETWEEN DEROGATORY AND EMERGENCY MEASURES

APPROVAZIONE, AUTORIZZAZIONE E COMMERCIALIZZAZIONE DEI DISPOSITIVI DI PROTEZIONE INDIVIDUALE NEL CONTESTO DELLA PANDEMIA DI COVID-19: LA NORMATIVA EUROPEA E ITALIANA TRA MISURE DEROGATORIE ED EMERGENZIALI

RELATRICE

Chiar.ma Prof.ssa Giovanna Ricci

DOTTORANDO

Dott. Filippo Gibelli

Un obiettivo è un sogno con un punto d'arrivo

Duke Ellington

TABLE OF CONTENTS

LIST OF ABBREVIATIONS AND ACRONYMS

Abbreviation or acronym	*Meaning*
AD	Anno Domini
AENOR	Asociación Española de Normalización y Certificación (Spanish Association for Standardisation)
AFNOR	Association Française de Normalisation (French Association for Standardisation)
B2B	Business-to-business
B2C	Business-to-consumer
BFE	Bacterial filtration efficiency
BSI	British Standards Institution
CDC	Centres for Disease Control and Prevention
CEN	Comité Européen de Normalisation (European Committee for Standardization)
CENELEC	Comité Européen de Normalisation Électrotechnique
CFR	Code of Federal Regulations
CO_2	Carbon dioxide
COVID-19	Coronavirus Disease 2019
DIN	Deutsches Institut für Normung (German Institute for Standardisation)
DPCM	Decree of the President of the Council of Ministers
DVR	Documento di Valutazione dei Rischi (company's risk assessment document)
EEC	European Economic Community
EN	European Norm
ETSI	European Telecommunications Standards Institute
EU	European Union

EUDAMED	European Database for Medical Devices
EUIPO	European Union Intellectual Property Office
FFP	Filtering Face Piece
INAIL	Istituto Nazionale per l'Assicurazione contro gli Infortuni sul Lavoro e le Malattie Professionali (National Institute for Insurance against Accidents at Work and Occupational Diseases)
IPR	Intellectual Property Rights
ISO	International Organization for Standardization
ISS	Istituto Superiore di Sanità (National Institute of Health)
MD	Medical Devices
MDD	Medical Device Directive (EEC Directive 93/42)
MDR	Medical Device Regulation (Regulation EU 2017/745)
MISE	Ministry of Economic Development
N/A	Not applicable
NaCl	Sodium chloride
NIOSH	National Institute for Occupational Safety and Health
NLF	New Legislative Framework (Decision no. 768/2008/EC)
OECD	Organisation for Economic Co-operation and Development
OJEU	Official Journal of the European Union
OLAF	European Anti-Fraud Office
ÖNORM	Österreichische Norm (Austrian Standards International)
OSH	Occupational Safety and Health
OSHA	Occupational Safety and Health Administration
PFE	Particle Filtration Efficiency
PP	Polypropylene
PPE	Personal Protective Equipment

PPER	Personal Protective Equipment Regulation (EU Regulation 2016/425)
RAPEX	Rapid Alert System for dangerous non-food products
SN	Schweizerische Normen-Vereinigung (Swiss Association for Standardisation)
TB	Tuberculosis
TFUE	Treaty on the Functioning of the European Union
UDI	Unique Device Identification
UNI	Ente Nazionale Italiano di Unificazione (Italian National Unification Body)
USBM/BOM	United States Bureau of Mines
WHO	World Health Organization

INTRODUCTION

1. Respiratory personal protective equipment: birth and evolution in human history

Personal protective equipment (PPE) is used to prevent health and safety risks at work and in other aspects of daily life. It is firstly designed to prevent or minimize personal injury as a result of work or other activities or risks by protecting the individual from possible dangers through a barrier. Of all the PPE, respiratory protective equipment is the most important and has been the focus of technological development from the very beginning of the human history since the respiratory system is the main interface between people and their environment.

One of the earliest historical pieces of evidence of the adoption of respiratory protective devices can be found as early as ancient Rome. In the first century AD, Pliny the Elder (circa AD 23-79) described the use of masks made of animal bladder skins by workers in cinnabar mines to protect their respiratory tracts[1]. In the 16th century, Leonardo Da Vinci suggested placing damp cloths over the nose and mouth to limit injurious effects from inhaling harmful substances[2]. With the technological development of the 18th century, together with the emergence of the industrial revolution, there was a need to protect workers from the possible harm that could be caused by the new machinery. It was in the 19th century that the first personal protective equipment was designed, and this was targeted towards the protection of workers in the unhealthiest sectors, and mining was not exception.

---

[1] OSHA TECHNICAL MANUAL (OTM) – Section VIII: Chapter 2: *Respiratory Protection – Occupational Safety and Health Administration.* Available at: https://web.archive.org/web/20200328071605/https://www.osha.gov/dts/osta/otm/otm_viii/otm_viii_2.html#2 (last access: 21.01.2024)

[2] E.A. OGBUOJI, A.M. ZAKY, I.C. ESCOBAR, *Advanced research and development of face masks and respirators pre and post the coronavirus disease 2019 (COVID-19) pandemic: A critical review*, in *Polymers*, 2021, 13(12), p. 1998

In 1877, the British invented and patented the *"Nealy Smoke Mask"*, one of the first devices used by firefighters in an effort to protect themselves from fire smoke[3]. In 1910, in view of increasing frequency of mining disasters, the U.S. Bureau of Mines (USBM or BOM) was established in the United States with the charter to improve safety for workers engaged in the mining and processing of minerals[4]. In 1919, the USBM drew up Schedule 13, which described the *"Procedure for Establishing a List of Permitted Self-Contained Mine Rescue Breathing Apparatus"*[5], and Schedule 14, *"Procedure for Establishing a List of Permitted Gas Masks"*[6]. The first respirator approved by the USBM under Schedule 13 was, on 15 January 1920, the Gibbs respirator, which consisted of a closed circuit that operated with compressed oxygen and a soda-lime scrubber to remove carbon dioxide[7].

A new turning point in the development of personal respiratory protective equipment was the Hawks Nest Tunnel disaster, a case of mass occupational disease that occurred in the 1930s following the construction of the Hawks Nest Tunnel near Gauley Bridge, West Virginia, as part of a hydroelectric project. Due to exposure to silica dust without airway protection devices, many workers developed silicosis, and many of them died from the disease[8]. The catastrophe accelerated Schedule 21 standards for filtering respirators for dust/fume/mist[9]. Schedule 21, included within Title 30, Part 14, of the Code of Federal Regulations (30 CFR 14), represented the first standard of approval for dust/fume/mist respirators.

---

[3] D. SPELCE, T.R. REHAK, R.W. METZLER, J.S. JOHNSON, *Pre-World War I firefighter respirators and the US Bureau of Mines involvement in WWI*, in *J. Int. Soc. Respir. Prot.*, 2017, 34(2), p. 128

[4] *Ibidem*

[5] Schedule 13 would later go on to form Title 42 of the Code of Federal Regulations (CFR), Part 84

[6] S.J. PEARCE, *A Discussion of the Bureau of Mines Approval Schedules for Respiratory Protective Devices*, in *Am. Ind. Hyg. Assoc. J.*, 1958, 19(2), p. 126–129

[7] D. SPELCE, T.R. REHAK, R.W. METZLER, J.S. JOHNSON, *History of U.S. Respirator Approval*, in *J. Int. Soc. Respir. Prot.*, 2018, 35(1), pp. 35-46

[8] R.F. HOY, D.C. CHAMBERS, *Silica-related diseases in the modern world*, in *Allergy*, 2020, 75(11), p. 2805-2817

[9] CENTERS FOR DISEASE CONTROL AND PREVENTION, *Milestones in Respiratory Protection*. Available at: https://www.cdc.gov/niosh/npptl/pdfs/n95-timeline-508.pdf (last access: 28.01.2025)

A next important milestone took place in 1965, when Schedule 21 was updated for the second time (the first time had been in 1955, with the Schedule "21A"). The 1965 update (Schedule 21B, still within 30 CFR 14) provided for the extension of certification to devices capable of protecting against a wider range of respiratory insults, as well as imposing stricter safety standards[10]. In the exact words of the 1965 Schedule 21B: *"Extend certification of approval to respirators designed to protect against dusts, fumes, and mists that are significantly more toxic than lead; (2) permit certification of combinations of dispersoid-filter and other types of respirators; (3) revise current tests to realize accuracy and speed of testing; and (4) revise the fees for inspection and testing"*[11].

The year 1969 saw the third update of Schedule 21 – the so-called "Amended Schedule 21B"[12] (still within 30 CFR 14), which included the approval of permissible filters for protection against "radon daughters" and radon daughters attached to dust, where radon daughters are radioactive elements produced as a result of the disintegration of radon –, and the enactment of the Federal Coal Mine Safety and Health Act[13], which introduced regulations governing the certification and use of approved respirators in the mining industry, thereby improving the safety of miners against respiratory hazards.

The enactment of the Occupational Safety and Health Act of 1970[14] was a fundamental moment in the history of occupational safety in the United States. In fact, with the enactment of the so-called OSH Act, the National Institute for Occupational Safety and Health (NIOSH) and the

---

[10] S.J. PEARCE, *op. cit.*
[11] United States Department of the Interior – Bureau of Mines. 30 CFR Part 14 Filter-Type Dust, Fume, and Mist, Proposed Rulemaking, Federal Register Wednesday October 7, 1964, pages 13822–13827
[12] United States Department of the Interior – Bureau of Mines. Procedures for Testing Filter-Type Dust, Fume, Mist Respirators for Permissibility, 30 CFR PART 14 - Filter Type, Dust, Fume, and Mist Respirators, Schedule 21B, 19 June 1969
[13] United States. (1969). Coal Mine Safety and Health Act of 1969 (Public Law 91–173, December 31, 1969)
[14] United States. (1970). Williams-Steiger Occupational Safety and Health Act (OSH Act) of 1970. Public Law 91-596, December 29, 1970

Occupational Safety and Health Administration (OSHA) were also established, both of which were instrumental in the development of safety and health standards to protect American workers, including the implementation of standards for the use of respiratory personal protective equipment.

In March 1972, 30 CFR 11 replaced 30 CFR 14 and initiated a joint respirator approval process conducted by the U.S. Bureau of Mines and the National Institute for Occupational Safety and Health that continues today (in fact, prior to 1972, the USBM alone conducted respirator testing and approval). The initial framework had USBM conduct the testing on respirators with processing of application while NIOSH was supposed to handle quality assurance and control. A memorandum of understanding was signed in May 1972 by USBM and NIOSH to define the roles that each would play in the collection and analysis of information and to assign responsibility for applications and testing to NIOSH. The testing and application processes were also formally transferred from USBM to NIOSH by amendments made to 30 CFR 11 in March 1973[15].

The problem of personal respiratory protective equipment in healthcare thus rose to the surface with the outbreak of tuberculosis (TB) that happened in the 1990s[16]. In fact, TB as it is known highlighted the fact that respiratory protection is quite relevant in preventing infectious diseases from being transmitted between health personnel and patients, hence improving guidelines to incorporate respirator adoption into healthcare facilities.

[15] S.J. PEARCE, *op. cit.*
[16] J. BERNARDO, *Tuberculosis: A disease of the 1990s*, in *Hosp. Pract.*, 1991, 26(10), p. 195-222

A major revision to the respirator certification standards came in July 1995, when 30 CFR 11 was replaced by 42 CFR 84[17], and major changes were made in testing and safety requirements due to the advancement of technology and increased understanding of respiratory protection strategies. About the same time, in 1989, Europe enacted the PPE Directive (89/686/EEC) through the European Community, that established the essential health and safety requirements for the design and manufacture of PPE, including respiratory equipment.

The US Congress expressed further interest in the design, certification, and use of PPE (including respirators) when it established in 2001 the NIOSH National Personal Protective Technology Laboratory[18], a body that played an important role in ensuring that personal protective equipment attained the highest possible standards to offer protection, particularly in people exposed in high-risk occupations. The 9/11/2001 terrorist attacks shifted the focus toward respiratory protection for first responders, because during rescue and recovery operations first responders were exposed to hazardous substances, which was an indication that effective respiratory protection was absolutely needed. New standards and technologies have, therefore, been developed in line with safeguarding the health of first responders in disaster scenarios.

As we have seen so far, the evolution of respiratory PPE in the work context has been quite articulated and complex. At the same time – albeit at a different speed and pace – personal respiratory protective equipment also became established in medicine and public health. As far as medicine is concerned, in 1897 the Austrian surgeon Johann von Mikulicz Radecki had

---

[17] Occupational Health and Environmental Safety Division. (1995, August). Regulation update – 42 CFR 84 (Number 18)

[18] A.S. ANDREWS, J.R. POWERS, J.K. CICHOWICZ, C.C. COFFEY, M.L. FRIES, P.L. YORIO, M.M. D'ALESSANDRO, *Respiratory protection in a time of crisis: NIOSH testing of international respiratory protective devices for emergency use*, in *Health Secur.*, 2021, 19(4), p. 379-385

the idea of placing simple gauze over the mouth and nose in order to prevent droplets from falling into the operating field. In the same year, the French surgeon Paul Berger operated for the first time with a gauze mask. A few years later, at the beginning of the 20th century, mainly thanks to the American surgeon William Halsted, gloves and hair protection also began to be used[19,20]. In those years, surgical masks also began to be used to contain the spread of respiratory infections. Let's think for instance of the Spanish flu of 1918-1919, and even earlier of the plague in Manchuria in 1910-1911[21]. Photographs of the time show how the 'newborn' surgical masks were used in order to contain the contagion. Between the 1930s and the 1950s there was a technical improvement of surgical masks[22,23], and from the mid-1960s onwards, 'modern' surgical masks became widespread throughout the world as a means of preventing infectious diseases (both in healthcare and in epidemic settings)[24]. Their importance as a means of protection against the spread of infectious agents peaked, as already noted, with the spread of tuberculosis in the 1990s.

2. The emergence of COVID-19 and its impact on PPE demand

On 24 December 2019, an outbreak of a previously unknown aetiology of mysterious pneumonia was found in Wuhan-the capital of East-Central province Hubei, People's Republic of China. As the investigation

[19] J.A. GANDHI, J.J. CHURIWALA, P.H. SHINDE, S.N. CHAUDHARI, *Surgical Mask–the Saviour: from its Invention to the COVID-19 Era*, in *Indian J. Surg.*, 2020, 82, p. 278-279
[20] ABOUTPHARMA, *La lunga storia delle mascherine: da quelle a becco a quelle filtranti*, 16.04.2021. Available at: https://www.aboutpharma.com/scienza-ricerca/la-lunga-storia-delle-mascherine-da-quelle-a-becco-alle-filtranti/ (last access: 03.02.2025)
[21] S.N. MICHALEAS, K. LAIOS, M. KARAMANOU, N.V. SIPSAS, G. ANDROUTSOS, *The Manchurian pandemic of pneumonic plague (1910–1911)*, in *Le Infezioni in Med.*, 2022, 30(3), p. 464
[22] H. HABE, H. SCHULTZ, *Untersuchungen über Operationsschleier*, in *Chirurg.*, 1937, 9, p. 289-291
[23] O. KLEINSCHMIDT, *Allgemeiner Teil*, in *Operative Chirurgie*, Berlin, Springer, 1943, p. 12-13
[24] C. MATUSCHEK, F. MOLL, H. FANGERAU, J.C. FISCHER, K. ZÄNKER, M. VAN GRIENSVEN, J. HAUSSMANN, *The history and value of face masks*, in *Eur. J. Med. Res.*, 2020, 25, p. 1-6

unfolded, Wuhan Municipal Health Commission said the biggest outbreak to date seemed to be linked to a huge fish wholesale market in downtown Wuhan city. The disease shared some similarities to the SARS, or severe acute respiratory syndrome, epidemic that first gained traction in China and tore through 29 countries from 2002 to 2004, infecting more than 8,000 people and killing more than 800[25]. On 31 December 2019, the Chinese authorities sent a formal complaint to the World Health Organisation, which started an observation of how events were developing and issued a set of general operational guidelines[26].

The CDC of China – the Centres for Disease Control and Prevention of China – identified on 9 January 2020 a new, unknown, virus from the *Coronaviridae* family, provisionally named 2019-nCoV, as the aetiological agent of the disease. Health authorities in China's National Health Commission made an official release to announce that virus infection was transmitted from human to human in a press conference on 20 January 2020.

On 23 January 2020, the province of Hubei – 60 million people, 11 million of whom in Wuhan alone – was put under quarantine: citizens were not allowed to leave their houses, and the Chinese New Year festivities scheduled for the week of 24-30 February were abolished. Meanwhile, the whole world was alerted, and in late January the first confirmed cases outside China were reported: USA, Australia, Europe (France). On 11 February 2020, the World Health Organisation announced it had re-christened the virus (no longer 2019-nCOV, but SARS-CoV2), and that it had given the disease an official name: COVID-19, a name derived from an acronym for

[25] ISTITUTO SUPERIORE DI SANITÀ (O. PUNZO, A. BELLA, F. RICCARDO, P. PEZZOTTI, F.P. D'ANCONA), *Tutto sulla pandemia di SARS-CoV-2*, in *Epicentro*. Available at: https://www.epicentro.iss.it/coronavirus/sars-cov-2 (last access: 28.01.2025)

[26] WHO, *Pneumonia of unknown cause – China*. Available at: https://www.who.int/emergencies/disease-outbreak-news/item/2020-DON229 (last access: 28.01.2025)

CO (Coronavirus), VI (virus), D (disease) and 19 (2019, the year the virus was identified)[27].

By March 2020, COVID-19 had reached almost every part of the world, and it was on 11 March 2020 that the WHO officially declared the outbreak a pandemic. The rapid increase in the number of cases soon outweighed the capacity of healthcare, showing huge lapses in the processes of pandemic preparedness and response. Among all, the increased demand for personal protective equipment became a highly crucial issue. Masks, gloves, gowns, face shields, and other PPEs became indispensable in healthcare workers who were in the front line of this pandemic, as well as the people belonging to high-exposure environments such as public transportation and essential industries. The global supply chain of PPE was never designed to meet such sudden and unexpected surges in demand. Many countries had to deal with acute shortages, as manufacturing capacity lay concentrated in a few regions, notably in Asia, which itself was suffering the impact of the virus[28].

Panic buying combined with export restrictions by key producing nations increased shortage through a very competitive and at times chaotic global market. Delayed shipments, confiscated consignments and higher prices were almost the order of the day; some governments did extraordinary things to get supplies, including military airlifts, and direct negotiations with manufacturers. The shortage of PPEs was not only a logistical problem, but also a scourge on public health, because without adequate protection healthcare workers were often left reusing disposable items or making do with improvised alternatives, putting themselves at significantly increased

[27] LAB24, *La storia del coronavirus*, Il Sole 24 Ore. Available at: https://lab24.ilsole24ore.com/storia-coronavirus/ (last access: 28.01.2025)
[28] *Ibidem*

risk of infection[29]. It also increased the gap between the countries which were able to pay a high price for PPEs and the poor ones which could not be able to protect their citizens. These were met by the WHO and other international organizations by offering guidance on the prioritization and conservation of PPEs, and by recommending that it be used sparingly in high-risk settings and that solutions be found that could increase the supply of PPEs.

Many governments and private players took proactive steps to combat the crisis. Many countries increased their local production and converted certain industries to produce face masks and other protective equipment. 3D printing and other rapid manufacturing methods also proved very useful in making face shields and other PPE components. The campaigns to donate PPE and the creation of central distribution systems helped in channelizing the resources to where they were most needed[30].

However, these efforts to overcome the shortages also exposed the systemic vulnerabilities of the global supply chain and the lack of an effective international coordination mechanism. The crisis reopened the debate on diversification of the supply chain and the level of stockpiling of essential items with a view to future pandemic threats. It also portrayed the moral issue regarding access to lifesaving supplies and pressed for a greater need to have more appropriate distribution frameworks considering the need criteria rather than the wealth criterion[31].

---

[29] P. MEHROTRA, P. MALANI, P. YADAV, *Personal protective equipment shortages during COVID-19 –supply chain–related causes and mitigation strategies*, in *JAMA Health Forum*, 2020, I(5), p. e200553

[30] Y. YE, Q. ZHANG, Z. CAO, F.Y. CHEN, H. YAN, H.E. STANLEY, D.D. ZENG, *Impacts of export restrictions on the global personal protective equipment trade network during COVID-19*, in *Adv. Theory Simul.*, 2022, V(4), p. 2100352

[31] E.J. EMANUEL, G. PERSAD, R. UPSHUR, B. THOME, M. PARKER, A. GLICKMAN, J.P. PHILLIPS, *Fair allocation of scarce medical resources in the time of Covid-19*, in *N. Engl. J. Med.*, 2020, 382(21), p. 2049-2055

3. Aims and objectives of the thesis

This dissertation aims to fully reconstruct the changes that the personal protective equipment market has witnessed in the context of the COVID-19 pandemic outbreak, as of December 2019. In particular, the primary objective of this thesis is to study, from a juridical point of view, the ways in which the regulatory framework underpinning the approval and authorisation to market PPE has adapted to the emergency contingencies, while also assessing its bioethical and safety implications. In fact, the author's attempt will be not only to study from a purely legal point of view the derogatory measures introduced to cope with the PPE shortage – the primary objective of the thesis given the nature of the doctoral course – but also to analyze in a broader perspective the bioethical, social and communicative aspects related to the use of masks in the context of the first pandemic wave and the changes in the rules related to their marketing and distribution.

CHAPTER I

SCIENTIFIC BACKGROUND: BIOHAZARD, INTERHUMAN TRANSMISSION OF VIRAL RESPIRATORY DISEASES AND THE ROLE OF MASKS IN CONTAINING THEIR SPREAD

TABLE OF CONTENTS: 1.1 Biohazard: general and specific features of respiratory-transmitted viral infections – 1.2 PPE designated to protect against biohazard – 1.3 Biohazard protection: the specific role of masks

1.1 Biohazard: general and specific features of respiratory-transmitted viral infections

Biohazard refers to the probability of an individual coming into contact with biological agents that can cause harm to human health, animal health or the environment. Biological risk is potentially present in any living and working environment. In the public health context, bio-risk control and management are of paramount importance to prevent the spread of infectious diseases and protect the health of the population[32].

Biological risk agents include bacteria, viruses, fungi, parasites and prions that are capable of causing infectious diseases or intoxication. Briefly, bacteria are single-celled prokaryotic microorganisms of the size of 1 μm (micrometre, i.e. one millionth of a metre, i.e. one thousandth of a millimetre), viruses are infectious particles of submicroscopic size (of the order of 0.02-0.3 μm) that parasitise animal and plant eukaryotic cells, consisting essentially of proteins and nucleic acids (DNA or RNA), fungi are unicellular (yeasts) or multicellular (moulds) eukaryotic organisms, parasites are generally living beings of various kinds (protozoa, helminths and

[32] A.B. LE, A. SHKEMBI, A. TADEE, A.C. STURGIS, S.G. GIBBS, R.L. NEITZEL, *Characterization of perceived biohazard exposures, personal protective equipment, and training resources among a sample of formal US solid waste workers: A pilot study*, in *J. Occup. Environ. Hyg.*, 2023, 20(3-4), pp. 129-135

ectoparasites) that live and feed at the expense of other living beings, while prions are absolutely peculiar, protein-only infectious agents that owe their name to the acronym *"PRoteinaceous Infective ONly particle"*[33].

Figure 1 illustrates the size comparison between a PM 2.5 particle, which is an air pollutant with a diameter of less than 2.5 micrometers and can penetrate the lungs and enter the bloodstream, a Streptococcus, simply a type of bacteria, a bacteriophage, which is a type of virus that infects and replicates within bacteria, and a Coronavirus, known for causing respiratory infections including COVID-19.

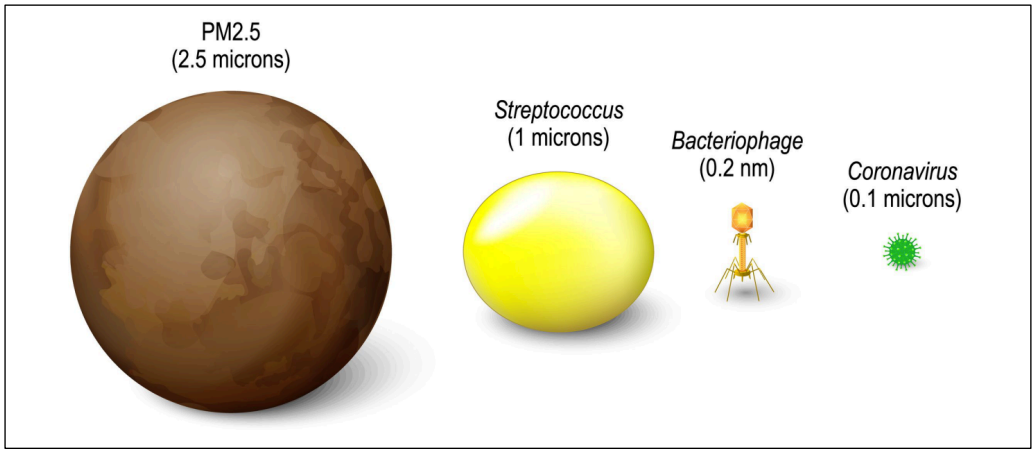

Figure 1. Size comparison of PM 2.5 particles, Streptococcus bacteria, bacteriophages, and the Coronavirus

The fundamental characteristics of pathogenic biological agents are essentially two: pathogenicity and virulence. Pathogenicity refers to the ability a pathogen has to cause a disease, while virulence refers to the extent of the severity of the disease transmitted. To give two examples, the viruses

[33] G. ANTONELLI, M. CLEMENTI, G. POZZI, G. ROSSOLINI, *Principi di microbiologia medica*, quarta edizione, Casa Editrice Ambrosiana, 2022

responsible for the common cold are very pathogenic but not very virulent, since contact with them leads very easily to the development of the disease, which is, however, of minimal severity, while the mycobacterium responsible for tuberculosis causes tubercular disease only under certain conditions and circumstances, but it causes a serious disease, and is therefore a micro-organism that we can define as not very pathogenic but very virulent[34].

The other important characteristic of biohazard agents is the inter-human transmissibility. It refers to the possibility that a biohazard agent might be transmitted from an infected person to another not infected. Contrary to what one might imagine, not all biohazard agents are inter-humanly transmissible. Examples include *Clostridium tetani*, a bacterium that causes tetanus, a disease contracted through open wounds coming into contact with bacterial spores present in the soil or on contaminated surfaces, but which is not transmitted inter-humanly, *Bacillus anthracis*, a bacterium responsible for anthrax, a disease contracted through direct contact with infected animals and/or their contaminated animal products but not transmitted via the human-to-human route, and the rabies virus, mainly transmitted via infected animals such as dogs or bats through either a bite or scratch, but never directly from one person to another. Since the transmission of the disease from one individual to another, biological agents have always raised high interest in public health because of the possibility of rapid spread of the infectious disease throughout a population[35].

The classification of a disease into being endemic, epidemic, or pandemic has to do with the way it spreads within its host population. A disease is said to be endemic when it is present in a community at a specified rate over a particular period, usually persisting in an area or population. An

---

[34] *Ibidem*

[35] M.P. CONTE, P. MASTROMARINO, *Microbiologia Medica. Batteriologia e Virologia*, Società Editrice Esculapio, 2019

endemic disease has a relatively constant level of prevalence and incidence, with only minor fluctuations over time. For example, malaria is endemic in certain parts of Africa: it occurs regularly in a predictable seasonal pattern. By contrast, an epidemic is the outbreak of an infectious disease, which leads to a sudden increase in the cases above the expected number for that population or area. It is most commonly applied to local outbreaks, but can also be used for widespread diseases spanning several continents. The 2014-2016 Ebola outbreak in West Africa is an example of an epidemic. A pandemic is an epidemic that extends between several countries or even continents, and it usually affects large numbers of people. Pandemics are characterised by the widespread transmission of a new infectious disease to which people have no immunity. The COVID-19 epidemic, declared a pandemic by the World Health Organisation (WHO) in March 2020, is the most recent example, but history is actually full of pandemics (to name the best known, the Justinian plague in 541-542 AD, the Black Death of 1347-1351 and the Spanish flu of 1918-1919)[36].

Figure 2 visually illustrates, through graphic simplification, the difference between endemic, epidemic and pandemic.

[36] M.P. FANTINI, L. DALLOLIO, G. FABBRI, F. BRAVI, *Igiene e Sanità Pubblica*, Società Editrice Esculapio, 2020

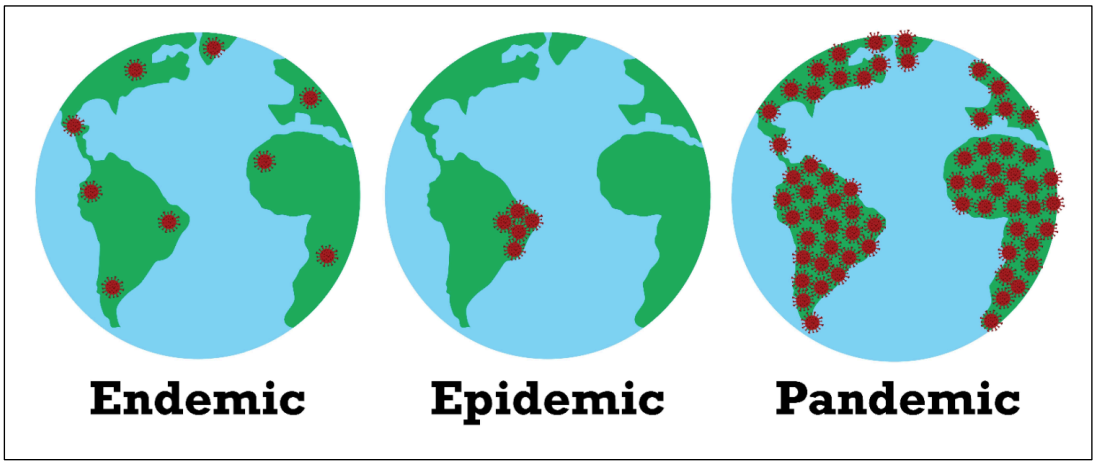

Figure 2. Schematic representation of the ways in which endemics, epidemics and pandemics spread

Biological agents that are transmissible via the human route can pass from an affected individual to an unaffected one essentially through five modes:

1. *Through direct contact*. It occurs when direct physical contact occurs between people, such as shaking hands, kissing or having sexual intercourse.
2. *Through indirect contact*. This occurs when an infectious agent is transmitted from one person to another through contact with a contaminated object or surface (fomites), such as door handles, kitchen utensils or electronic devices.
3. *Through oro-fecal transmission*. The faeces of an infected person, containing the biological agent, contaminate the water or food consumed by another person.
4. *By air*. There is a fundamental difference between airborne spread and droplet spread[37]:

[37] B. ATHER, T.M. MIRZA, P.F. EDEMEKONG, *Airborne precautions*, in StatPearls [Internet], Treasure Island (FL), StatPearls Publishing, 2025, updated to 13 March 2023

a. *Droplet spread*. Biological agents are encapsulated in relatively large saliva particles (formerly known as "Flügge droplets"), usually larger than 5 micrometres and smaller than 100 micrometres. These droplets tend to fall quickly to the ground due to their weight. The droplets can travel a limited distance, generally no more than 1-2 metres from the infected person. This limits transmission to situations where people are in close contact.

b. *Airborne spread*. The particles involved in airborne transmission are extremely small, generally less than 5 micrometres in diametre. These small particles, also known as "droplet nuclei" or "aerosols", can remain suspended in the air for long periods. Because of their small size, these particles can travel considerable distances, often well over 2 metres, allowing them to spread through ventilation systems and move from room to room.

Figure 3 illustrates the size difference between droplets and droplet nuclei (or aerosol particles) and the impact of this size difference on the distance travelled by the particles themselves.

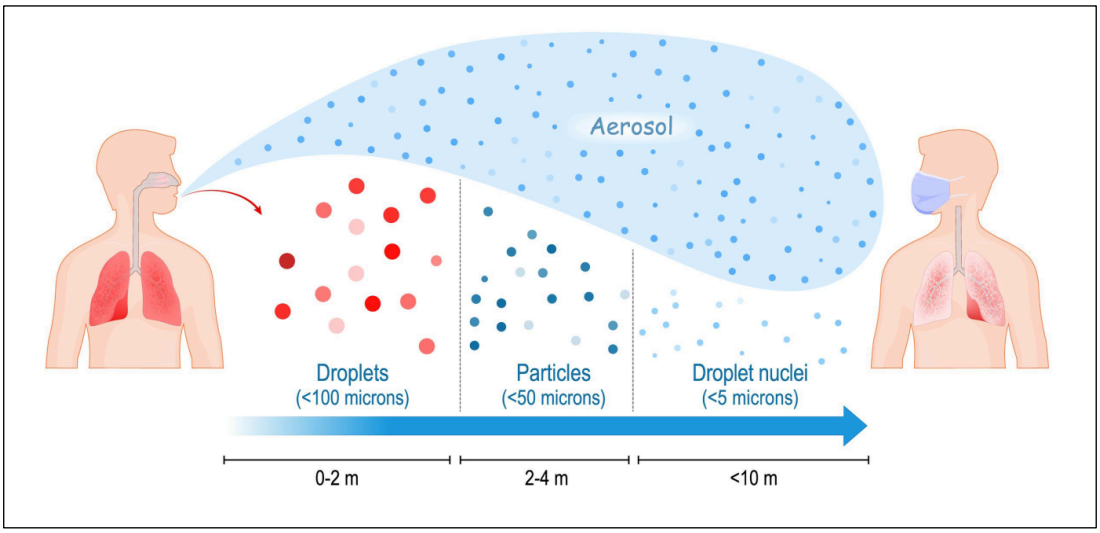

Figure 3. Schematic representation of droplets and droplet nuclei (aerosol particles)

1.2 PPE designated to protect against biohazard

In general terms, personal protective equipment is defined as any device that provides protection for an individual against one or more health and safety risks (the definition formalized by European legislation will be explained in section 2.1). Of particular interest in the present discussion are PPEs that protect against biological hazards: these protective tools are mainly used to prevent direct or indirect contact with the source of the pathogens.

Gloves are one of the most important PPE to be used, since they cover the hands and prevent them from coming into contact with body fluids and/or contaminated objects. This actually protects the wearer and the patient from pathogens in the meantime. Protective gowns and aprons are designed to prevent possible contamination of the torso, including clothing and skin, during the procedures which may lead to fluid release. Masks and respirators are most relevant for protection against respiratory diseases,

because a surgical mask can help prevent droplet transmission and a respirator, such as N95, can filter out aerosols. Goggles and face shields are designed to prevent splashes and droplets from affecting the eyes and face as well as other irritants, while head and shoe covers help prevent the spread of pathogens through the hair and footwear respectively. In more risky conditions, the whole-body suit is used. The described PPEs are used singly or in sets to protect the workers/users from chemical hazards in most cases. They are therefore the core of biohazard management protection system and are referred to as primary PPE in healthcare settings[38].

The essential characteristics of these primary PPE types are summarised in Table I.

[38] W. RICCIARDI, I.F. ANGELILLO, S. BOCCIA, S. BRUNO, S. BRUSAFERRO, R. BUCCI ..., P. VILLARI, *Igiene, Medicina Preventiva, Sanità Pubblica*, seconda edizione, Idelson-Gnocchi, 2013, pp. 1-965

Table I. Main PPEs to protect against biohazard

	Material	Purpose	Use cases
Medical gloves	Often made from nitrile, latex, or vinyl	To protect hands from contact with infectious agents or contaminated surfaces	Laboratory work, patient care, and cleaning
Gowns/aprons	They are made from disposable materials or reusable, washable fabrics that are impermeable to liquids	To protect the wearer's body and personal clothing from contamination	During procedures that are likely to generate splashes or sprays of infectious materials or in environments with high contamination levels
Masks and respirators	Extremely variable depending on the type of mask (discussed in detail below)	To protect the nose and mouth from airborne particles or infectious agents	Patient care, laboratory work, and areas with known airborne diseases
Goggles and face shields	Made from clear, impact-resistant plastic	To protect the eyes from splashes, sprays, and droplets of infectious materials	Situations where procedures may generate splashes or sprays, or during the examination of patients with infectious diseases
Head and shoe covers	Typically made from disposable, fluid-resistant materials	Head covers protect the hair and scalp from contamination Shoe covers protect footwear from contamination and help maintain a clean environment	In operating rooms, laboratories, or during the cleanup of biohazardous materials
Full body suits	Made from impermeable or semi-permeable materials	To offer full-body protection from airborne particles and liquid contamination	High-risk environments such as biocontainment laboratories and during the handling of highly infectious agents

1.3 Biohazard protection: the specific role of masks

As shown in figure 4, there are essentially three categories of face masks today. The first category includes the so-called "surgical masks", the second is represented by filtering face masks, which are indicated by the acronym FFP (Filtering Face Piece) if they have European certification, N95 if they have American certification, and KN95 if they have Chinese certification, and the third category includes cloth masks, washable and reusable.

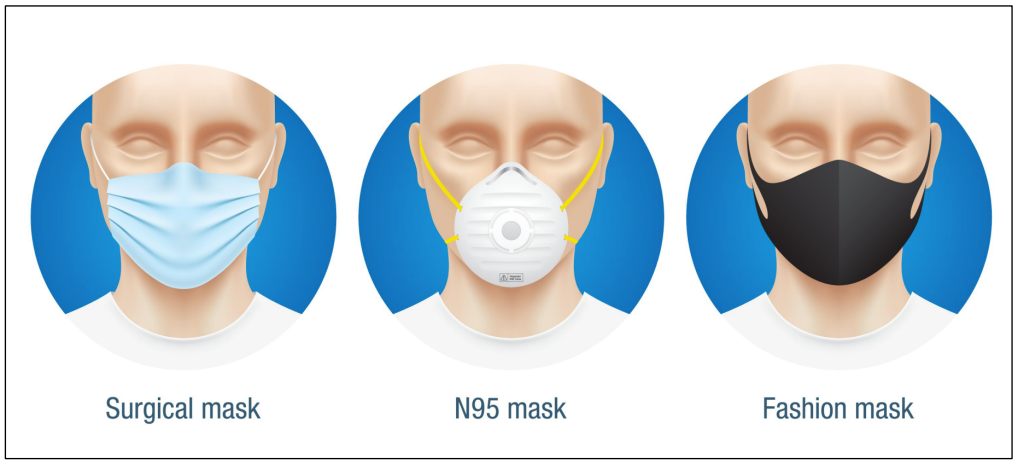

Figure 4. Schematics of various face mask types

The main characteristics of the three types of masks are shown in Table II.

Table II. Technical characteristics of surgical, FFP and cloth masks

	Surgical masks	**FFP masks**	**Cloth masks**
Preventing the spread of aerosols/drops from the wearer	Yes	Yes	Yes
Protection of the wearer from aerosols and external droplets	No	Yes	No
Components	Melt-blown polypropylene (PP)	Spun-bound polypropylene (PP) and other materials	Cotton, silk, nylon, etc.
Layers	Usually 3	4 to 5	Up to 3
Face adherence	Not designed to create a tight seal around the face	Suitable for creating a seal around the face	Variable fit depending on design and materials
Operating mechanism	Mainly mechanical filtration	Mechanical and electrostatic filtration	Mainly mechanical filtration
Filtering capacity	Variable; generally lower than N95	High: above 95% for particle sizes above 300 nm	Wide range, it depends on the materials used
Effectiveness against viruses	Moderate, depending on the specific construction of the mask and the fit	High, thanks to their ability to filter out small particles	Variable, however generally lower than N95 and surgical
Reusability	Disposable	Disposable, but can be reused under specific conditions following decontamination protocols	Reusable after washing

FFP masks are subdivided into 3 subcategories (FFP1, FFP2 and FFP3) depending on the PFE (particle filtration efficiency), which is a measure indicating the ability of a filtering material to block particles of a specific size present in the air. Specifically, PFE is measured by exposing the filter material to aerosolized NaCl (sodium chloride) with particle size distribution between 0.02 μm and 2 μm, to assess its filtration capacity against fine particles. The PFE value, expressed as a percentage, indicates the ratio between the number of particles filtered by the tested material and the total number of particles to which the material was exposed during the test.

Similar to the concept of PFE is the concept of BFE (bacterial filtration efficiency), which is instead determined by subjecting the material to be tested to particles of a different nature (bacteria/viruses suspended in aerosols) ranging in size from 0.65 μm to 7 μm. The BFE is used to classify surgical masks into three different subcategories (Type I, Type II and Type IIR, where the letter 'R' indicates that the mask is splash-resistant).

Table III shows the FPE and the BPE of the various types of masks[39,40].

Table III. Filtering effectiveness of the various types of masks, measured in terms of minimum guaranteed PFE and BFE, considering that 0.1 micrometres is the standard particle size used to determine PFE, while 3.0 micrometres is the particle size used to determine BFE

Type of mask		BFE (standard dimension of particles: 3.0 μm)	PFE (standard dimension of particles: 0.1 μm)
FFP masks	FFP1	N/A	≥ 80%
	FFP2	N/A	≥ 94%
	FFP3	N/A	≥ 99%
Surgical masks	Type I	≥ 95%	N/A
	Type II	≥ 98%	N/A
	Type IIR	≥ 98%	N/A
Cloth masks		70%	N/A

[39] CEN, the European Committee for Standardization EN 149:2001+A1:2009, Respiratory protective devices-Filtering half masks to protect against particles-Requirements, testing, marking, European Committee for Standardization 1–44 (2009) Available online at: https://standards.iteh.ai/catalog/standards/cen/f440f60a-91c1-497b-815e-4e9d46436256/en-149-2001a1-2009 (last access: 24.02.2024)

[40] CEN, European Committee for Standardization EN 14683:2019+AC:2019, Medical face masks-requirements and test methods, European Committee for Standardization 1–23 (2019) Available online at: https://standards.iteh.ai/catalog/standards/cen/4bdef56d-7660-4a66-ba96-8e287fbc7d8c/en-14683-2019ac-2019 (last access: 24.02.2024)

But how do masks work? A first and intuitive mechanism of functioning of the masks is the ability of the devices to form a physical barrier capable of reducing the emission of saliva droplets emitted by the subjects. These droplets can be emitted through actions such as breathing, talking, coughing or sneezing. Through talking, an individual emits an average of about 50 particles per second. With a sneeze, about 10^4 droplets are emitted, which can travel at a speed of 20 metres per second, while a coughing fit produces an average of 10 to 100 times fewer droplets, travelling at about 10 metres per second[41].

Figure 5 illustrates the transmission pattern of droplets expelled by breathing, coughing and sneezing.

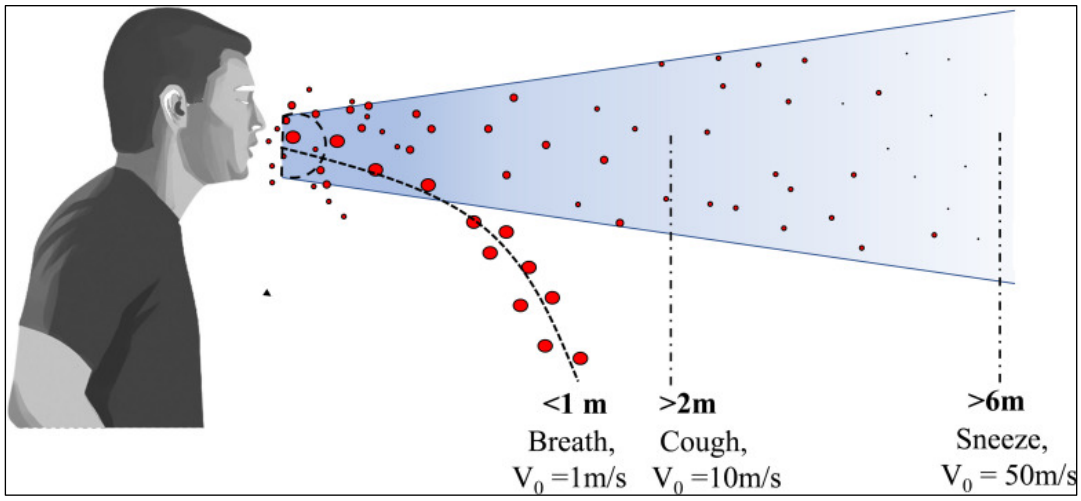

Figure 5. Transmission dynamics of droplets expelled by breathing, coughing and sneezing (image courtesy of Dr. P. Katre, S. Banerjee, S. Balusamy, K. Chandra Sahu, and AIP Publishing)

[41] P. KATRE, S. BANERJEE, S. BALUSAMY, K.C. SAHU, *Fluid dynamics of respiratory droplets in the context of COVID-19: Airborne and surfaceborne transmissions*, in *Phys. Fluids*, 2021, 33(8)

So, masks (of whatever type) significantly hinder the propagation of respiratory droplets and aerosols expelled through breathing, speech, coughing and sneezing. It is clear that this barrier function is largely influenced by the adherence of the mask to the subject's face: the greater the adherence, the fewer possible escape routes for droplets[42].

Beyond the mere barrier function (which virtually any object/material can exert), the protective potential of face masks is mainly expressed through two further, decidedly more sophisticated, mechanisms. These are filtration mechanisms of a mechanical nature (predominant in surgical and tissue masks) and/or of an electrostatic nature (predominant in FFP masks). A mechanical filtration is a set of features which mimic the physical interception of the particles in the flow during the attempt to penetrate through the material of the mask. The mechanisms involved in this al include inertial impaction, interception and diffusion. Inertial impaction is a mechanism where coarser particles due to their momentum turn out of the flow stream and strike the fibres of the mask. Interception, on the other hand, is where the medium size particles follow the flow stream and come into contact with the fibres and adhere to them. Diffusion, instead, a mechanism that is more dominant with smaller particles, is defined by the random movement of the particles in the airflow (Brownian motion) making them likely to hit the fibers. By contrast, electrostatic filtration works on the principle that electrostatic charge on the fibers of the mask can be used to attract and capture particles. This mechanism is especially effective against small aerosol particles than mechanical filtration alone may capture. Electrostatic force developed on the fibers attracts the particles and make them stick to the fibers without greatly affecting the flow resistance. This

[42] A. TCHARKHTCHI, N. ABBASNEZHAD, M.Z. SEYDANI, N. ZIRAK, S. FARZANEH, M. SHIRINBAYAN, *An overview of filtration efficiency through the masks: Mechanisms of the aerosols penetration*, in *Bioact. Mater.*, 2021, 6(1), pp. 106-122

dual filtration by mechanical and electrostatic forces makes face masks – especially surgical and FFP masks – to offer protection against different particle sizes including the respiratory droplets and other aerosols that may contain pathogens[43].

In particular, regarding the protective function of face masks with respect to viruses, their main role is to prevent the spread of droplets and aerosols, which are the main means of carrying the viral particles. Masks act as a barrier that blocks large droplets which are formed during activities like speaking, coughing or sneezing from getting to other people. Also, they limit the intake of fine aerosols that may contain viral particles, especially in close contact with others. The filtering capacity of the masks in terms of mechanical and electrostatic filtration is vital in the retention of viral particles in droplets or aerosols. Despite the fact that viruses are very small (on average between 0.02 and 0.3 micrometres, see figure 1), they are generally spread in the form of respiratory droplets or aerosols which masks are designed to filter, thus reducing the chances of being exposed or infected[44].

[43] J.T. JU, L.N. BOISVERT, Y.Y. ZUO, *Face masks against COVID-19: Standards, efficacy, testing and decontamination methods*, in *Adv. Colloid Interface Sci.*, 2021, 292, p. 102435

[44] M. LIANG, L. GAO, C. CHENG, Q. ZHOU, J.P. UY, K. HEINER, C. SUN, *Efficacy of face mask in preventing respiratory virus transmission: A systematic review and meta-analysis*, in *Travel Med. Infect. Dis.*, 2020, 36, p. 101751

CHAPTER II

PERSONAL PROTECTIVE EQUIPMENT: PRE-PANDEMIC STANDARDS, PANDEMIC PREPAREDNESS, AND REGULATORY CONTEXT IN EUROPE AND ITALY

TABLE OF CONTENTS: 2.1 From workplace safety to public health: the significance of PPE – 2.2 The evolving role of personal protective equipment in pandemic preparedness and response – 2.3 Regulatory frameworks for PPE in Europe: from Directive 89/686/EEC to Regulation (EU) 2016/425 – 2.4 Regulatory frameworks for medical devices in Europe: from Directive 93/42/EEC to Regulation (EU) 2017/745 – 2.5 Regulatory framework for PPE in Italy

2.1 From workplace safety to public health: the significance of PPE

In the field of security, it is important to make a clear distinction between "prevention" and "protection" measures. The purpose of preventive measures is to reduce the probability of a harmful event occurring. Protective measures, on the other hand, have no effect on the probability of a harmful event occurring, but rather limit the harmful consequences of the event itself, and therefore essentially serve to limit the severity of a damaging event.

Protection measures are distinguished into "passive" and "active". The former do not require human intervention or the operation of a system, while the latter do. For example, with reference to fire protection measures, safety signs are an example of a passive measure, while a fire extinguisher is an example of an active measure.

Among protective measures, the most important are personal protective equipment, the general and technical characteristics of which have

been explained in previous chapters. With reference to the European context, the European Directive 89/686/EEC is one of the first pieces of legislation in which an official definition of PPEs was provided in the European Union. The Directive, which was adopted on 21 January 1989, defined PPEs as *"any device or appliance designed to be worn or held by an individual for protection against one or more health and safety hazards"*[45]. Interestingly, the definition states that PPEs, in order to qualify as such, must necessarily be "worn" or "held" (it is no coincidence that most PPEs are worn, being clothing, footwear, headgear or gloves).

In addition to providing a comprehensive definition of PPEs, Directive 89/686/EEC also defined the contours of the regulatory framework for the approval and marketing of PPEs, defining different categories of PPEs according to the level of risk protected, setting out the essential safety requirements necessary to place PPEs on the market, providing precise conformity assessment procedures, indicating the technical documentation necessary to certify the conformity of devices, defining the responsibilities of the manufacturers, indicating the obligation of market surveillance by member states, and calling for cooperation between member states in order for the legislation to be fully implemented.

Despite being repealed and replaced by Regulation (EU) 2016/425 of the European Parliament and of the Council – which came into force on 21 April 2016 but was in fact only operative as of 21 April 2018 – Directive 89/686/EEC represented the first organic and structured legislative act in the European context relating to the regulation of PPE, and from it directly descended Legislative Decree 4 December 1992, no. 475, which represented its transposition in the Italian regulatory context.

[45] Council Directive no. 89/686/EEC, 21 December 1989, in OJEC L 399, 30.12.1989, pp. 18-38

Legislative Decree no. 475 of 4 December 1992 (*"Implementation of Council Directive 89/686/EEC of 21 December 1989 on the approximation of the laws of the Member States relating to personal protective equipment"*), in force since 24.12.1992, outlined the conformity requirements of PPE, which were later referred to in Legislative Decree no. 81 of 9 April 2008 (the Unified Law on Health and Safety at Work), in Article 76 (*"PPE requirements"*). The Legislative Decree no. 475/1992 was adapted to the provisions of Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 through Legislative Decree no. 17 of 19 February 2019[46], as will be discussed in detail in paragraph 2.5.

As illustrated in the previous chapters, personal protective equipment plays an important role in safeguarding individuals from occupational hazards and ensuring compliance with health and safety regulations. In the last analysis, PPE is the final protective barrier when other controls including those done by engineering, administration or through work practices are not feasible. PPE works by providing a physical barrier between the person and the hazard to reduce contact with the hazard that may cause harm. It is used in almost all industries including construction, healthcare, manufacturing, agriculture and even in emergency response among others. For example, in the healthcare sector, PPE like gloves, face masks, gowns, and face shields has become crucial in the prevention of disease transmission during epidemics. In the same way, in construction and industrial activities, helmets, safety glasses, and high visibility jackets are vital to prevent injuries from falling objects, chemical splashes, or inadequate illumination[47].

---

[46] Legislative Decree 4 December 1992, no. 475, adjusting national legislation to the provisions of Regulation (EU) no. 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC

[47] G. BARTKOWIAK, K. BASZCZYŃSKI, A. BOGDAN, A. BROCHOCKA, R. HRYNYK, E. IRZMAŃSKA, ... J. ŻERA, *Use of personal protective equipment in the workplace*, in *Handbook of human factors and ergonomics*, 2012, p. 895 ss

The first key aspect of PPE is the fit and feel of the protective gear. Low-quality PPE also provides poor protection and may actually decrease the probability of wearing them properly, which in turn may increase the risk of exposure to dangers. For this reason, standards such as Regulation (EU) 2016/425 also address the ergonomics of the product and the user in the selection process[48]. However, training and education on the correct usage, maintenance and limitation of PPE is as important, since improper or inadequate use or care can render even the best equipment useless. Currently, new technologies are also changing the PPE market and products with better materials, integration with other systems, and real-time monitoring are appearing. Modern helmets equipped with sensors can measure fatigue and other hazards of the environment and can demand the attention of the worker and the supervisor frequently. New age materials such as nanotechnology-based fabrics and lightweight composites have enhanced the strength, lightness and usability of the PPE, thus making it more efficient and comfortable to use[49].

Another major problem concerning PPE is fulfilling the requirements for safety criteria of the product and at the same time minimizing the adverse impact on the environment. The usage and the disposal of the PPE, especially the single-use items such as masks and gloves have become a major concern[50]. Efforts are being made to create bio-degradable and recyclable products and also to implement the concept of circular economy for PPE[51]. The ISO and CEN are still developing PPE harmonized standards in order

---

[48] K. SZCZECIŃSKA, K. ŁĘŻAK, *Review of research studies of ergonomic aspects of selected personal protective equipment*, in *Int. J. Occup. Saf. Ergon.*, 2000, 6(sup1), pp. 143-151

[49] S. MÁRQUEZ-SÁNCHEZ, I. CAMPERO-JURADO, J. HERRERA-SANTOS, S. RODRÍGUEZ, J.M. CORCHADO, *Intelligent platform based on smart PPE for safety in workplaces*, in *Sensors*, 2021, 21(14), p. 4652

[50] F. A. MAZAHIR, A. M. AL QAMARI, *Personal protective equipment (PPE) and plastic pollution during COVID-19: strategies for a sustainable environment*, in *Rev. Environ. Health*, 2022, 37(3), pp. 321-325

[51] L. LYU, M. BAGCHI, N. MARKOGLOU, C. AN, *Innovations and development of sustainable personal protective equipment: a path to a greener future*, in *Environ. Syst. Res.*, 2024, 13(1), p. 22

to facilitate free movement of the products and to ensure that PPE sold in the market meets the required safety standards. In the European Union, Regulation (EU) 2016/425 specifies the conformity assessment procedures, the CE marking, and the responsibilities of economic operators to guarantee that the PPE introduced to the market fulfils the essential health and safety requirements. However, although a lot of progress has been made, the use of PPE in the workplace remains a challenge due to factors such as cost, negative perception of the scheme by the workers, and unequal access to good PPE. These problems can only be solved if everyone works together: employers, employees, regulatory bodies, and manufacturers to foster safety culture and focus on the health of workers[52].

In fact, there is no way of overstating the importance of PPE in the protection of workers. But its success depends on this being part of a wider safety management approach that includes hazard identification, risk assessment and the adoption of control measures in the hierarchy of controls. It is only through this all-encompassing approach that PPE can be fully optimized to protect the health and safety of people.

The COVID-19 pandemic, like previous global health crises, has elevated the discussion around PPE beyond the confines of workplace safety, bringing it to the forefront of societal consciousness and highlighting its critical importance in all areas of daily life, as will be further explored in the subsequent sections of this thesis.

[52] N. KARIM, S. AFROJ, K. LLOYD, L. C. OATEN, D. V. ANDREEVA, C. CARR, ... K. S. NOVOSELOV, *Sustainable personal protective clothing for healthcare applications: a review*, in *ACS Nano*, 2020, 14(10), pp. 12313-12340

2.2 The evolving role of personal protective equipment in pandemic preparedness and response

Pandemic preparedness and response have been a core part of the public health for years, as societies have fought to control and lessen the effects of the spread of disease. Outbreaks from the bubonic plague in the 14th century to the influenza pandemic of 1918 have shown the need for coordinated efforts to avoid the devastation that such outbreaks can bring[53]. Quarantine, social distancing, and hygiene practices were some of the initial measures taken to control infection but the use of PPE in preventing the spread of infectious agents became more evident in the 20th century with the help of microbiology and pathogen transmission[54].

The 1918 influenza pandemic is one of the earliest known uses of basic PPE like cloth masks by healthcare workers and the community. Being fairly ineffective by today's standards, this period showed that PPE can be a barrier against airborne and droplet transmission. Subsequent pandemics such as the SARS outbreak of 2002 2003 and the H1N1 influenza pandemic of 2009 also highlighted the importance of properly designed PPE as a part of the pandemic preparedness and response. For example, in the SARS outbreak, the use of N95 respirators and other high-filtration masks was standardized in healthcare facilities and was followed up in subsequent outbreaks[55].

The COVID-19 pandemic is the most significant pandemic that has highlighted the importance of PPE in infection control and prevention in the world. The pandemic-like crisis created a supply chain disruption to affect the production and distribution of PPE. Healthcare workers who were at the front line of the fight were lacking basic needs like masks, gowns, and gloves,

[53] J. PIRET, G. BOIVIN, *Pandemics throughout history*, in *Front. Microbiol.*, 2021, 11, p. 631736
[54] *Ibidem*
[55] A. PAJEL, *Using PPE correctly and safely*, in *Kai Tiaki Nurs. N. Z.*, 2020, 26(9), pp. 26-28

which only reinforced the need for strong preparedness measures. Outside of the healthcare setting, PPE became almost synonymous with daily life, with masks and hand protection being taken by the general population to prevent the spread of the virus[56].

The use of PPE during the COVID-19 pandemic has also led to the improvement of the design, production, and regulation of PPE. The advancement in the area of material science and manufacturing processes has enabled better and more sustainable PPE to be developed. In order to adapt to the current public health emergencies, regulatory frameworks were also adapted to expedite the approval of new products[57,58]. The WHO and other international organizations gave direction on proper PPE use, stating that PPE should be used in combination with the other mitigation measures (mainly testing, contact tracing, and vaccination).

The experiences from the COVID-19 pandemic have once again shown that PPE should be an integral part of pandemic readiness plans. Stockpiling, supply chain resiliency, and building local manufacturing capacity have been identified as important approaches to guarantee the timely and equitable distribution of PPE in the event of future health crises. Moreover, the pandemic has showed the significance of the public's knowledge and information about PPE, since its use and compliance with the rules is crucial[59].

In general, the role of PPE in pandemic control has increased with each generation of technology. Its effectiveness cannot be overemphasized

---

[56] T. M. COOK, *Personal protective equipment during the coronavirus disease (COVID) 2019 pandemic – a narrative review*, in *Anaesthesia*, 2020, 75(7), pp. 920-927

[57] A. ZIMMERLING, X. CHEN, *Innovation and possible long-term impact driven by COVID-19: manufacturing, personal protective equipment and digital technologies*, in *Technol. Soc.*, 2021, 65, p. 101541

[58] B. BLAKELY, W. ROGERS, J. JOHNSON, Q. GRUNDY, K. HUTCHISON, R. CLAY-WILLIAMS, ... G. MADDERN, *Ethical and regulatory implications of the COVID-19 pandemic for the medical devices industry and its representatives*, in *BMC Med. Ethics*, 2022, 23(1), p. 31

[59] A. PAJEL, *op. cit.*

as a key component of infection control when used as part of a wider public health approach. The further development of measures for pandemic preparedness and response will determine the further evolution of PPE and its essential role in the protection of population's health.

2.3 Regulatory frameworks for PPE in Europe: from Directive 89/686/EEC to Regulation (EU) 2016/425

As mentioned in a previous section, the two reference regulations in the European pre-pandemic era were Directive 89/686/EEC, in force until 21.04.2018, and Regulation (EU) 2016/425, in force since 20.04.2016. The period between 20.04.2016 and 21.04.2018 was in fact a transitional period in which Directive 89/686/EEC had not yet been officially repealed and EU Regulation 2016/425 had officially entered into force (figure 6).

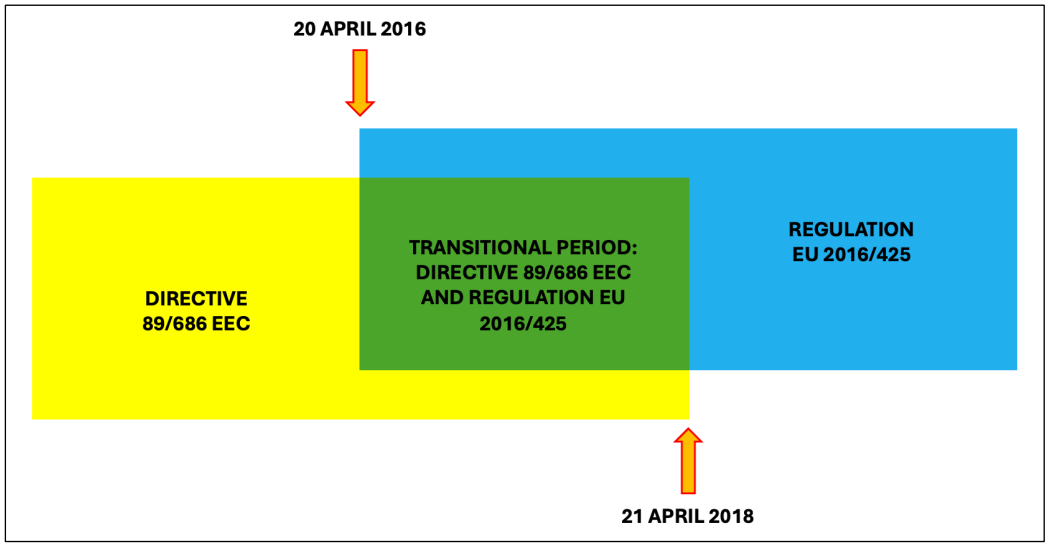

Figure 6. Succession in time of Directive 89/686/EEC and Regulation (EU) 2016/425

In more detail, Articles 46, 47 and 48 of the Regulation EU 2016/425 clarify three points regarding intertemporal issues:

- Despite the fact that Directive 89/686/EEC would have been repealed on 21 April 2018, products complying with the Directive could still be placed on the market until 20 April 2019
- Despite the fact that the full applicability of Regulation 2016/425 was foreseen from 21 April 2018 (Art. 48), Articles 20 to 36 (on notified bodies) and Article 44 (on the committee) would have been valid from 21 October 2016, and Article 45 (penalties) from 21 March 2018
- EEC type-examination certificates and type-approval decisions issued under the Directive 89/686 EEC would remain valid until 21 April 2023 (unless they expire before that date)

The updating of the 1989 legislation became necessary for several reasons, including the transition from the European Economic Community (EEC) to the European Union (EU) in 1992 with the Maastricht Treaty, the progression of the level of cooperation between Member States in the area of market surveillance, technological and technical progress, and increasingly stringent market requirements. More importantly, there was also a need to align with the "New Legislative Framework" (NLF) (Decision no. 768/2008/EC)[60].

While both the pieces of legislation aimed to ensure product safety and free movement within the European single market, the former was a Directive, while the latter was a Regulation. It is worth mentioning that the European Union, as provided for in Article 288 of the Treaty on the

[60] Decision no. 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC

Functioning of the European Union (TFUE)[61], can adopt five different types of legal acts: Regulations, Directives, Decisions, Recommendations and Opinions. Directives set objectives to be achieved by all Member States, but leave the member states free to act on the means to achieve them. Regulations, on the other hand, establish uniform rules that are directly applicable and binding in each Member State. As far as implementation is concerned, directives require the Member States to adopt national measures to give effect to the objectives of the directive through their own legal system, within a specified time limit, whereas regulations do not require any national implementing legislation, and enter into force on a specified date, applying automatically in each Member State. Failure to comply with a directive means that the Member State may be subject to infringement proceedings, whereas the non-application of a regulation may have direct effects on citizens and businesses, which may find themselves in a position of immediate legal non-compliance.

In concrete terms, the EU Regulation 2016/425 (also called "PPER", that is PPE Regulation) introduced 9 essential changes:

1. **Change in categorisation**: whereas the Directive 89/686/EEC based the categorisation of PPE more on the product itself, the Regulation changed this approach by focusing on the risks. Thus, instead of classifying PPE based on the type of product, the regulation provided for classification based on the level of risk they protect. Table IV presents the comparison between the old classification (Directive 89/686/EEC) and the new classification of PPE (EU Regulation 2016/425). Table V shows

[61] Article 288 (ex Article 249 TEC), in the consolidated version of the Treaty on the Functioning of the European Union, OJ C 326, 26.10.2012, p. 171-172. ELI: http://data.europa.eu/eli/treaty/tfeu_2012/art_288/oj (last access: 10.02.2025)

which PPEs are explicitly included in each of the individual categories according to the two regulatory sources.

Table IV. The categorisation of PPEs according to Directive 89/686/EEC and Regulation (EU) 2016/425

		Directive 89/686/EEC	***Regulation (EU) 2016/425***
Principle underlying categorisation		PPEs design and complexity	Risk level against which PPEs provide protection
Categories	*Category I*	Simple design PPEs	Minor risks
	Category II	Intermediate design PPEs	"Other" risks
	Category III	Complex design PPEs	Life-threatening or irreversible risks

Table V. PPEs included in the individual categories of Directive 89/686/EEC and Regulation EU 2016/425 (PPEs that have moved from Class II – Directive 89/686/EEC – to Class III – EU Regulation 2016/425 – are highlighted in bold)

	Category I	Category II	Category III
Directive 89/686/EEC	PPEs that protect the wearer from: • Mechanical action with superficial effects (example: gardening gloves, thimbles) • Mild cleaning materials (example: gloves for diluted detergent solutions) • Moderate heat handling: protection from temperatures up to 50 °C without severe impacts (example: gloves, professional aprons) • Normal weather conditions: protection from non-extreme atmospheric elements (example: headgear, seasonal clothing, footwear) • Minor impacts and vibrations: protection for non-vital body parts, preventing irreversible damage (example: light helmets, gloves, light footwear) • Sunlight (example: sunglasses)	PPEs not covered by either Category I or Category III	• Respiratory filtering devices (those offering protection against aerosols, irritant, hazardous, toxic or radiotoxic gases) • Full insulation respiratory devices (those that completely isolate from the atmosphere, including diving gear) • PPEs offering partial defense against chemical substances or ionizing radiation • High-temperature emergency equipment (gear for environments with temperatures around or exceeding 100 °C, potential exposure to infrared radiation, flames, or molten material) • Low-temperature emergency equipment (PPEs for extreme cold with temperatures around or below –50 °C) • Equipment designed to prevent injuries from falls • PPE offering protection against electrical hazards and high voltages, including isolation devices for electrical work • Motorcycle helmets and visors
Regulation EU 2016/425	PPEs that protect against the following risks: • Superficial mechanical injuries • Contact with weak-acting cleaning materials or prolonged contact with water • Contact with hot surfaces not exceeding 50 °C • Eye damage due to exposure to sunlight (not while sunbathing) • Non-extreme weather conditions	PPEs not covered by either Category I or Category III	PPEs that protect against the following risks: • Substances and mixtures hazardous to health • Oxygen-deficient atmospheres • Harmful biological agents • Ionising radiation • High-temperature environments whose effects are comparable to those of an air temperature of at least 100 °C • Low-temperature environments whose effects are comparable to those of an air temperature of –50 °C or lower • Falls from a height • Electric shock and live working • **Drowning** • **Cuts caused by hand chainsaws** • **High-pressure jets** • **Bullet or knife injuries** • **Harmful noises**

2. **Reclassification of certain product categories**: some product categories were reclassified. A number of PPE previously placed in Class II were placed in Class III (highlighted in bold in Table V), and in particular the following: PPEs to protect against drowning, PPEs to protect against chainsaw cuts, PPEs to protect against high-pressure jets, PPEs to protect against projectile or knife wounds, and PPEs to protect against harmful noises.

3. **Introduction of new European certification tools**: the certification rules for PPE classification were not changed by Regulation EU 2016/425, which did, however, introduce new European certification tools, as shown in table VI.

Table VI. PPE certification rules and corresponding certification tools in accordance with Directive 89/686/EEC and Regulation EU 2016/425

Classification	Manufacturer's obligations	European certification tools provided by Directive 89/686/EEC	European certification tools provided by Regulation EU 2016/425
Category I	• PPE technical file • Instructions • Declaration of conformity • CE marking	Manufacturers self-declaration	Internal production control (module A) set out in Annex IV
Category II	As category I + EC/EU-type examination by a notified body	Article 10 (EC-type examination by a notified body)	Module B (Annex V – EU-type examination by a notified body) + Module C (Annex VI – internal production control)
Category III	As category II + annual conformity checks by the notified body	Article 10 (EC-type examination) + either of the following (quality control system of the production process): • Article 11A for conformity to type based on internal production control and supervised product checks at random intervals • Article 11B for conformity to type based on quality assurance of the production process	Module B (Annex V – EU-type examination) + either of the following (quality control system of the production process): • Module C2 (Annex VII) for conformity to type based on internal production control and supervised product checks at random intervals • Module D (Annex VIII) for conformity to type based on quality assurance of the production process

4. **Clear definition of economic operators and their obligations**: Regulation EU 2016/425 provided for a clearer definition of the economic operators involved in the process of production, distribution and marketing of PPEs, which is shown in table VII. The provisions concerning the economic operators involved and their responsibilities, explained in Articles 8-13, are mainly taken from NLF (Decision no. 768/2008/EC).

Table VII. Economic operators and their obligations in accordance with Regulation EU 2016/425

Economic Operator	Definition	Responsibilities
Manufacturer	Any natural or legal person that manufactures or has PPEs designed or manufactured and markets them under its own name or trademark	• Ensure that PPE has been designed and manufactured in compliance with essential health and safety requirements • Draw up the technical documentation and carry out the applicable conformity assessment procedure • Retain the technical documentation and declaration of conformity for 10 years after the PPE has been placed on the market • Ensure that series production remains compliant with this standard • Perform, if necessary, sampling tests on PPE available on the market and keep a record of complaints and recalls of non-compliant PPE • Indicate their name, registered trademark and postal address on the PPE or its packaging • Provide clear, legible and easily understandable instructions and information • Inform the market surveillance authorities immediately if the PPE presents a risk
Authorised representative	Any natural or legal person that performs the manufacturer's obligations on his behalf and under his responsibility, provided that he is formally delegated	• Be appointed by written mandate from an approved PPE manufacturer • Perform the tasks specified in the mandate received from the manufacturer • Keep the EU declaration of conformity and the technical documentation at the disposal of national market surveillance authorities for 10 years • Provide the authorities with all the information and documentation necessary to demonstrate the conformity of the PPE • Cooperate with the competent authorities on any action taken to eliminate the risks presented by the PPE
Importer	Any natural or legal person established within the EU who places PPEs from a third Country on the EU market	• Only place compliant PPE on the market • Ensure that the manufacturer has carried out the correct conformity assessment and drawn up the technical documentation • Indicate their name, registered trademark and postal address on the PPE or its packaging • Ensure that the PPE is accompanied by the required instructions and information • Keep the technical documentation and EU declaration of conformity for 10 years • Perform, if deemed appropriate, sampling tests on PPE available on the market and keep a record of complaints and recalls of non-compliant PPE
Distributor	Any natural or legal person in the supply chain (other than the manufacturer or importer) that makes PPEs available on the market	• Act with due diligence in relation to the requirements of this regulation when making PPE available on the market • Ensure that the PPE bears the CE marking, is accompanied by the required documents and instructions and information • Ensure that, while the PPE is under their responsibility, storage or transport conditions do not compromise its conformity

5. **Clarification on the use of harmonised standards**: in Article 14 (*"Presumption of conformity of PPE"*) the Regulation states *"PPE which is in conformity with harmonised standards or parts thereof the references of which have been published in the Official Journal of the European Union shall be presumed to be in*

conformity with the essential health and safety requirements set out in Annex II covered by those standards or parts thereof". Harmonised standards are European standards developed by a recognised European standardisation body: CEN (European Committee for Standardization), CENELEC (Comité Européen de Normalisation Électrotechnique) or ETSI (European Telecommunications Standards Institute), and are drawn up following a specific request from the European Commission to one of these bodies.

Harmonised standards are listed in a document called the Official Journal of the European Union (OJEU) which is available online at the following website: *https://single-market-economy.ec.europa.eu/single-market/european-standards/harmonised-standards_en*.

The adoption of harmonised European standards is absolutely optional in order to comply with legal requirements. Harmonised standards contain specific technical solutions that can be followed to meet legal requirements, and when such solutions are adopted, there is a presumption of conformity of the PPEs. In other words, the very fact that the harmonised standard (present in the OJEU) has been observed provides evidence that the device complies with the legislation. However, manufacturers are not necessarily obliged to follow the harmonised standard: it is up to them not to do so, but in that case, they will have to demonstrate that the alternative technical solution applied is adequate to ensure the compliance of the product with the applicable legal requirements.

The harmonised European standards are indicated by the acronym "EN" (European Norm). The allocation of numbers starts with EN 1 (Flued oil stoves with vaporizing burners). The following numbers follow the following convention depending on the issuing body.

Since standards require periodic updates to remain relevant (typically, they undergo a review to assess their applicability every five years), often the EN number is followed by the year of revision preceded by a colon (for example, EN 12102:2018).

Upon the adoption of an EN standard by a national standards organization, it assumes the role of a national standard within that country's standards framework, for instance the following: the International Organisation for Standardisation (ISO), the German Institute for Standardisation (Deutsches Institut für Normung – DIN), the Austrian Standards International, (Österreichische Norm – ÖNORM), the Swiss Association for Standardisation (Schweizerische Normen-Vereinigung – SN), the British Standards Institution (BSI), the French Association for Standardisation (Association Française de Normalisation – AFNOR), the Italian National Unification Body (Ente Nazionale Italiano di Unificazione – UNI), and the Spanish Association for Standardisation (Asociación Española de Normalización y Certificación – AENOR). Consequently, the national abbreviation precedes the standard's name (e.g., DIN EN, ÖNORM EN, etc.), and the number assigned to the European standard is generally retained, as seen in examples like DIN EN ISO 2338:1998 or ÖNORM EN ISO 9001:2000.

6. **New rules for the appointment of regulatory bodies (accreditation requirement for certification activities)**: in accordance with EU Regulation 2016/425, notified bodies must demonstrate their conformity with the requirements set out in Regulation (EC) No 765/2008[62] and the

[62] Regulation, E.U. (2008). Regulation (EC) No 765/2008 of 9 July 2008 on the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93. Official Journal L, 218(13/08), 0030-0047

relevant harmonised standards. This includes the competence of personnel, impartiality of operations and consistency of assessments. Notified bodies must also demonstrate that they have the necessary qualifications to assess the specific category of products for which they have been designated. Enhanced supervision by national authorities is envisaged to ensure that notified bodies maintain their standards. This includes regular audits and assessments. The regulation also facilitates a more coordinated approach to the monitoring of notified bodies at EU level, including the possibility of joint assessments by several Member States. Notified bodies are also required to make public the certificates they issue, in order to ensure maximum transparency. The new regulation also aims to increase the reliability of the certification process by ensuring that notified bodies are subject to peer review and that their work can be examined by other bodies and authorities.

7. **Harmonisation of market control by Member States**: Regulation (EU) 2016/425 facilitates the harmonisation of market surveillance by Member States in several ways, particularly in the areas of market surveillance, certification processes, risk management, quality control standards and compliance monitoring. First, the regulation sets clear requirements for the design and manufacture of PPE. Secondly, the regulation introduces specific rules for the CE marking of PPE and for the accreditation of conformity assessment bodies. Thirdly, in terms of risk management, Regulation (EU) 2016/425 requires manufacturers to ensure that PPEs have been designed and manufactured in accordance with the necessary health and safety requirements and sets out the specific responsibilities also of other economic operators, as explained above. With regard to quality control standards, the regulation requires that PPEs be

accompanied by instructions and contact details in the language of the user and that conformity assessment is an obligation of the manufacturer, which also applies to imported PPEs. This ensures that the quality of PPEs is maintained and controlled in a consistent manner throughout the EU. Finally, with regard to compliance monitoring, the regulation makes the entire supply chain responsible, not just the employers as in the previous directive, as explained at length above. This comprehensive approach to compliance monitoring contributes to a harmonised standard of market surveillance within the EU.

8. **Definition of a maximum validity period of five years for EU type certificates**: new EU certificates of conformity issued under Regulation 2016/425 are valid for a maximum of 5 years. This introduces an element of time control, which is used for the purpose of ensuring that safety standards are not violated.

9. **Unification of declarations of conformity and traceability of PPE on the market**: PPER has specific requirements to guarantee the authenticity and to verify that each PPE is fit for its intended use and meets the essential health and safety requirements. The new regulation identifies the other important feature is the provision of the postal address of the manufacturer on the PPE to link the product with the manufacturer and hence the traceability of the product. In addition, the regulation provides for the ability to trace the PPE from its declaration of conformity e.g. through the use of the batch number or the date of manufacture. This is important in the identification of particular items in the event of a recall or safety recall.

In addition, the regulation introduces a new template for the declaration of conformity, which must be easily accessible to all, either via the Internet or in paper form. This standardisation ensures that all PPE products comply with the regulations. This standardisation ensures that all PPE products marketed in the EU adhere to a uniform set of requirements regarding their declaration of conformity, facilitating verification of compliance by users and authorities.

Table VIII schematically illustrates the main differences between Directive 89/686/EEC and Regulation (EU) 2016/425.

Table VIII. Main differences between Directive 89/686/EEC and Regulation (EU) 2016/425

Aspect	Directive 89/686/EC	Regulation (EU) 2016/425
Categorisation of PPE	PPEs are divided into three categories according to design and complexity: simple design (Category I), intermediate (Category II) and complex (Category III)	The three-category system is retained, but the categorisation criteria are revised: it is not so much the design, but the level of risk associated with the PPE category that counts
Classification of certain product categories	PPE categories are classified according to the available standards	Certain PPEs are moved into different groupings based on a more comprehensive risk assessment. For instance, hearing protectors have been transferred from category II to category III
Definition of economic operators and their obligations	Primarily focused on the obligations of manufacturers	Expands the definition of economic operators to cover importers and distributors, specifying obligations on each type of economic operator to ensure compliance of PPE throughout the supply chain
Adherence to harmonised standards	Adherence to harmonised standards is encouraged, but not compulsory	It places more emphasis on adherence to harmonised standards, linking compliance more directly to the application of those standards
Rules for the appointment of regulatory bodies	It provides a framework for Member States to appoint bodies responsible for PPE certification, but places little emphasis on accreditation	Introduces more rigorous accreditation criteria for the regulatory bodies that are involved in the certification of PPE in order to guarantee a similar level of capability and excellence throughout the EU
Market control by Member States	It requires Member States to monitor the market, but offers limited guidance on coordination and enforcement	It emphasises the strengthening of market surveillance and control by Member States, including more specific provisions for cooperation and exchange of information between national authorities
Definition of a maximum validity period for EU type certificates	No specific maximum period of validity is given for EU examination certificates	A maximum validity period of five years is introduced for EU type-examination certificates, after which a new certification is required
Unification of declarations of conformity and traceability of PPE on the market	Requires declarations of conformity, but with less emphasis on traceability	Requires a single EU declaration of conformity for each PPE and strengthens traceability requirements, facilitating the traceability of PPE through the supply chain

2.4 Regulatory frameworks for medical devices in Europe: from Directive 93/42/EEC to Regulation (EU) 2017/745

The EEC Directive 93/42 on medical devices, published on 14 June 1993[63] (so-called "MDD", Medical Device Directive), is a document outlining the general criteria to be adopted in the design and manufacture of certain categories of medical devices (MDs), in force in the states of the European Union. It is in fact a Directive, thus setting objectives to be achieved by all Member States, but leaving them free to choose the best means to achieve them. In Article 1 some basic definitions are explained, including that of medical device: *"medical device means any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of: diagnosis, prevention, monitoring, treatment or alleviation of disease; diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap; investigation, replacement or modification of the anatomy or of a physiological process; control of conception"*.

It is important to note that, again in Article 1, it is specified that the Directive does not apply to personal protective equipment covered by Directive 89/686/EEC. It is also specified that *"In deciding whether a product falls under that Directive or the present Directive, particular account shall be taken of the principal intended purpose of the product"*.

Article 9 outlines the classification of medical devices into four classes: I, IIa, IIb, and III. The classification is based on the potential risks associated with the manufacture and use of these devices. Annex IX outlines the criteria necessary to assign the MD to its correct class. These criteria include duration of use, invasiveness, whether the device is 'active' or 'passive', whether it has

[63] Directive, C. (1993). Council Directive 93/42/EEC of 14 June 1993 concerning medical devices. Official Journal L, 169(12/07), 0001-0043

diagnostic or therapeutic purposes, and whether it acts on particular body systems and apparatuses.

Article 11 (*"Conformity assessment procedures"*) explains the procedures for conformity assessment, which are more or less rigid and complex depending on the class to which the device belongs. The Directive stipulates that conformity assessments and EC type-examination (with the exception of class I MDs) are delegated to particular bodies called "notified bodies". If the checks are successful, the medical device receives the CE marking, which is mandatory on essentially all devices (except in certain specific cases).

Directive 93/42/EEC was repealed by Regulation (EU) 2017/745 of 5 April 2017[64] (so-called "MDR", Medical Device Regulation), which entered into force on 25 May 2017 but was not fully effective until 26 May 2021, i.e. one year later than originally planned, by virtue of EU amending Regulation 2020/561 of 23 April 2020[65], which was adopted to enable EU Member States and their authorities and institutions to prioritise the fight against the COVID-19 pandemic.

Regulation (EU) 2017/745 came into being with several objectives, including standardising practices regarding the approval and marketing of medical devices in the EU Member States, tightening up the monitoring of companies by notified bodies, tightening up post-market surveillance, ensuring better identification and tracking of medical devices, and guaranteeing faster marketing of the most innovative products (e.g. those based on hybrid technologies).

[64] Regulation, E.U. (2017). Regulation (EU) 2017/745 of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC. Official Journal L, 117(05/05), 0001-0175

[65] Regulation, E.U. (2020). Regulation (EU) 2020/561 of 23 April 2020 amending Regulation (EU) 2017/745 on medical devices as regards the dates of application of certain of its provisions. Official Journal L, 130(24/04), 0018-0024

Regulation (EU) 2017/745 is first and foremost a Regulation, and therefore much more stringent and binding than Directive 93/42/EEC. In terms of substance, the innovations introduced by the Regulation are numerous and characterised by a high degree of complexity. Briefly, the main changes introduced by the new European Regulation can be summarised as follows:

1. **Stricter classification of medical devices**: the MDR introduced stricter rules for the classification of medical devices.

2. **More stringent conformity assessment**: the Regulation (EU) 2017/745 provided for more stringent and complex conformity assessment procedures, including more scrupulous supervision of higher risk devices by notified bodies.

3. **Post-marketing surveillance**: the MDR has enhanced the responsibility for post marketing surveillance by demanding that manufacturers collect and analyze performance and safety data of devices from the time they are on the market up to their expiry.

4. **Provision of a Unique Device Identification (UDI) System**: the new Regulation has also brought in the obligation to use a Unique Device Identification System (UDI) in an effort to enhance the traceability of medical devices, help with the recall of defective products and enhance the management of adverse event reports.

5. **Increased transparency and accessibility of information**: the MDR ensured greater transparency with regard to publicly available information on medical devices, including the creation of a European Database for

Medical Devices (EUDAMED), with the aim of collecting and disseminating information on the market, device registration, certificates issued, clinical studies and vigilance.

6. **Extended responsibilities for economic operators**: Regulation (EU) 2017/745 provided for an extension of responsibilities also to importers and distributors (in addition to manufacturers), who are obliged to ensure that the devices they make available on the EU market comply with the requirements of the regulation.

7. **Inclusion of devices without a medical purpose**: the MDR ordered the regulation of devices without an explicit medical purpose, such as non-corrective lens filters and lipofilling devices.

8. **More stringent requirements for clinical studies**: the new Regulation set out detailed requirements for the conduct of clinical studies, including ethical approval and study registration. It also stipulated that more clinical evidence on efficacy and safety was mandatory for certain devices.

Table IX schematically illustrates the main differences between Directive 93/42/EEC and Regulation (EU) 2017/745.

Table IX. Main differences between Directive 93/42/EEC and Regulation (EU) 2017/745

Aspect	Directive 93/42/EEC (MDD)	Regulation (EU) 2017/745 (MDR)
Rigidity of the classification system for medical devices	Relatively loose. The MDD provides for four main classes (I, IIa, IIb and III) based on risk, but the criteria are relatively loose	Stricter. The MDR maintains the same device classes, but includes more detailed classification rules and criteria, resulting in some devices being classified in a higher risk class
Rigidity of conformity assessment	Relatively lax. Conformity assessments under the MDD can often be carried out by the manufacturers themselves for certain classes of devices	More stringent. The MDR requires greater involvement of notified bodies in the conformity assessment process, even for certain lower-class devices
Post-marketing surveillance	The MDD requires manufacturers to have an incident reporting system, but is less specific about continuous surveillance	More comprehensive: the MDR requires a more systematic and proactive post-market surveillance system, including regular safety update reports for all classes of devices
Provision of a Unique Device Identification (UDI) System	Not required	Mandatory: MDR requires devices to be labelled with a UDI to improve traceability throughout the life cycle of the device
Transparency and accessibility of information	Limited. Information on devices is less accessible to the public under MDD	Implemented. The MDR provides for the establishment of a European Database on Medical Devices (EUDAMED)
Responsibilities for economic operators	Defined relatively unclearly: the MDD describes in detail the responsibilities of manufacturers, but less clearly those of importers and distributors	More clearly defined: the MDR clearly specifies the responsibilities of manufacturers as well as importers and distributors, tightening the responsibilities of all parties involved
Devices without a medical purpose	Not explicitly covered. The MDD focuses on devices intended for medical purposes	Explicitly included. The MDR also applies to certain devices without a medical purpose (e.g. cosmetic contact lenses, some dermal fillers), which must meet similar safety and performance requirements
Requirements for clinical studies	Relatively loose. Clinical evaluations are required within the MDD, but the criteria and process are not very detailed	More stringent. The MDR imposes stricter requirements for clinical evaluations and investigations, including the need for more detailed documentation and justification for not conducting clinical trials in certain cases.

2.5 Regulatory frameworks for PPE in Italy

As noted above, in Italy the reference law relating to personal protective equipment is Legislative Decree no. 475 of 4 December 1992, implementing Council Directive 89/686/EEC of 21 December 1989, amended in 2019 through Legislative Decree no. 17 of 19 February 2019 to adapt national legislation to the provisions of Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016.

The decree defines the coverage and fundamental concepts in line with the European regulation so that all types of PPE come under the standards. Among the most relevant changes introduced, there are those concerning harmonised standards and the presumption of conformity of PPE. The decree provides that, in developing the harmonised standards, the Italian standardisation bodies shall involve the employers' and workers' trade unions in advance, therefore ensuring the involvement of all interested parties.

As for the essential safety requirements, the decree provides that PPE shall only be made available on the market if it meets certain indications to ensure a high level of protection of the users. The CE marking is provided for PPEs that are compliant with European safety standards. The manufacturer or his authorised representative, if they are based in the territory of the Union, must be able to provide the necessary documentation that proves that the product is conform to the standard when asked by the authorities. The legislative decree also provides for a conformity assessment procedure that the manufacturer must carry out before making PPEs available on the market, and this procedure is essential to ensure that the devices comply with the essential safety requirements and are therefore safe for use.

Another important aspect concerns market surveillance and control of PPEs. The Ministry of Economic Development and the Ministry of Labour and Social Policy act as market surveillance authorities, in cooperation with other entities such as the Customs and Monopolies Agency and Chambers of Commerce. The market inspectors are to ensure that the PPEs in the market are up to the required safety standards, these are the authorities.

The decree also provides for penalties and penal sanctions for the manufacturers, importers and distributors of the PPEs that will be processed and or placed on the market without meeting the set criteria. The penalties are classified according to the type of PPE and the level of non-fidelity and could lead to fines and, in the most severe cases, imprisonment.

In addition, the decree includes provisions for the adaptation of national legislation to the provisions of Regulation (EU) No 2016/425 and the delegated and implementing acts of the same European regulation. This includes the adoption of further provisions necessary to ensure full adaptation to European standards.

Finally, the decree sets out the burdens relating to the procedures for conformity assessment of PPEs, authorisation of conformity assessment bodies and for market surveillance. These charges are borne by the economic operators concerned and the applicants, and are determined on the basis of the actual cost of the service.

In conclusion, Legislative Decree no. 475 of 4 December 1992 (amended through Legislative Decree no. 17 of 19 February 2019 to adapt national legislation to the provisions of Regulation 2016/425) represents a fundamental step in the harmonisation of Italian legislation with European legislation on personal protective equipment. By defining essential safety requirements, conformity assessment procedures, market surveillance and

penalties for non-compliance, the decree aims to ensure a high level of protection for workers and users of PPE, thus helping to promote safer and healthier working environments.

Table X shows the main amendments to Legislative Decree no. 475 of 4 December 1992 introduced by Legislative Decree no. 17 of 19 February 2019.

Table X. The main innovations to the Italian PPE legislation introduced by Legislative Decree no. 17 of 19 February 2019 (implementing Regulation 2016/ 425)

Aspect	Modification	Comment
Definition of PPE	Revision of the definition	The definition of PPE has been updated to align with EU Regulation 2016/425: it now includes all devices designed to protect the user against one or more health and safety hazards
PPE categories	Reclassification	PPE is divided into three categories according to the level of risk: Category I (minimal risks), Category II (intermediate risks) and Category III (fatal or serious risks). This ensures that PPE is designed and certified to offer an adequate level of protection
Obligations for economic operators	More responsibilities	The role of manufacturers, importers and distributors is clarified. They must ensure that PPE placed on the market complies with the essential health and safety requirements, is accompanied by the technical documentation and bears the CE marking
Conformity assessment	Updating procedures	Conformity assessment procedures have been modified to include more stringent checks. Category III PPE requires the involvement of notified bodies to verify conformity before it is placed on the market.
Market Surveillance	Stricter supervisory measures	Market surveillance is strengthened with the introduction of mechanisms to quickly identify and recall non-compliant PPE. Competent authorities now have additional tools to monitor the safety of products on the market.
Technical Documentation	New requirements	Manufacturers must provide detailed technical documentation for each piece of PPE. This includes the risk assessment, design characteristics, materials used and conformity tests.
CE marking	More stringent requirements	CE marking becomes mandatory for all PPE placed on the market. It must be clearly visible, legible and indelible, demonstrating that the product meets the essential safety requirements of the regulation.
Instructions for use	More details required	PPE must be accompanied by detailed instructions in a language that the end user understands, containing information on the correct use, maintenance, cleaning and disposal of the product.
Transitional period	Timing of implementation	Transitional periods have been introduced to allow economic operators to adapt to the new requirements. PPE that already complies with the previous regulations can be placed on the market until the end of the transitional period, subject to verification of compliance.
Penalties for non-compliance	Strengthening of sanctions	Penalties for non-compliance have been tightened to ensure greater compliance. This includes significant fines and a ban on marketing non-compliant PPE.

CHAPTER III

EUROPEAN RESPONSE TO COVID-19 AND PPE

TABLE OF CONTENTS: 3.1 PPEs specifically designed to protect against biohazard: European frame of reference and harmonised standards – 3.2 Emergency measures taken to deal with the pandemic outbreak: from EU Recommendation 2020/403 of 13 March 2020 to Commission Implementing Decision (EU) 2020/668 of 18 May 2020 – 3.3 Impact on the supply chain and manufacturing

3.1 PPEs specifically designed to protect against biohazard: European frame of reference and harmonised standards

Most of the PPEs shown in Table V fall within the scope of the PPER, but there are actually some, such as surgical (medical) masks, medical gloves and certain types of gowns that belong to the category of medical devices, and thus fall within the scope of Regulation (EU) 2017/745.

Table XI helps to clarify the point, also indicating which category the PPEs belong to (categories I-II-III if under PPER and classes I, IIa, IIb and III if under MPR) and which European harmonised standards are the reference.

Table XI. Regulatory reference at European level of the main PPEs and medical devices for the containment of biological risk and related European harmonised standards

PPE/medical device		Legal Reference Framework	Category/Class	European harmonised standards
Gloves	Working gloves	Regulation EU 2016/425	Category I (gardening gloves), II (for mechanical risks), or III (for chemical risks)	ANSI/ISEA 105; EN ISO 374-1; EN ISO 374-5; EN 388; EN 407; EN 421; EN 511; EN 659; EN 1082; EN ISO 10819; EN ISO 11393-4; EN 12477; EN 13594; EN ISO 13997; EN 14328; EN 16027; EN 16350; EN 16523; EN 16778; EN 18889; EN ISO 21420:2020
	Medical gloves	Regulation EU 2017/745	Class I (examination gloves)	EN 21171:2006; EN 455-2000; EN 455:2-2015; EN 455:3-2015; EN 455:4-2009
			Class IIa (surgical sterile gloves)	
Masks	FFP2 masks	Regulation EU 2016/425	Category III	DIN EN 149:2001+A1:2009
	Surgical masks	Regulation EU 2017/745	Class I	DIN EN 14683:2019-10; EN ISO 10993-1; EN ISO 11737-1
	Cloth masks	/	/	/
Gowns	Surgical gowns	Regulation EU 2017/745	Class II	EN 13795:2019
	Surgical isolation gowns	Regulation EU 2017/745	Class II	
	Non surgical gowns	Regulation EU 2017/745	Class I	
	Disposable isolation gowns	Regulation EU 2016/425	Category III	EN 14126; EN 13034
Protective eyewear (goggles and face shields)		Regulation EU 2016/425	Category II	EN 166

The PPE categorization under either the PPER or the MDR is based on their intended use and the associated risks. PPE is designed to provide specific protection against potential risks to the health or safety of the user. As presented in Table XI, examples include working gloves, FFP2 masks, disposable isolation gowns, and protective eyewear. This regulation is enforced through the use of European harmonized standards that give a presumption of conformity. For instance, EN 149:2001+A1:2009 lays down requirements for filtering half masks for protection against particles. On the other hand, medical gloves, surgical masks and surgical gowns are categorized as medical devices in the MDR. The standardized standards present the minimum performance standards that the device must meet, as well as the testing methods that should be done in order for the device to be safe and effective in clinical practice. For example, EN 14683:2019 defines requirements for surgical masks. The CE marking shows that a product meets the relevant EU laws and has gone through the right conformity assessment procedures. For lower risk categories this may be an internal declaration of conformity by the manufacturer, but for the higher risk categories like some of the medical devices, the involvement of a Notified Body is compulsory to clear the conformity assessment before the product can be sold in the EU. It is important to note that there are some products which are both PPE and medical devices at the same time and hence have to satisfy the needs of both PPER and MDR.

3.2 Emergency measures taken to deal with the pandemic outbreak: from EU Recommendation 2020/403 of 13 March 2020 to Commission Implementing Decision (EU) 2020/668 of 18 May 2020

The COVID-19 pandemic began with isolated cases towards the end of January 2020, with the first three cases reported in France on 24 January and the first two cases in Italy (Rome) on 31 January. Other cases were subsequently detected in Austria, Croatia, Greece, North Macedonia, San Marino and Switzerland, as well as in other previously affected countries[66]. From the second half of February to mid-March 2020, the number of confirmed daily cases of 0 per million inhabitants increased to almost 90 (0.02 on 16 February, 0.21 on 23 February, 3.08 on 1 March, 18.44 on 8 March, 89.38 on 15 March), as illustrated in figure 7. By 17 March 2020, all European states had reported at least one case of COVID-19[67].

[66] Lab24, La storia del coronavirus, Il Sole 24 Ore, *op. cit.*

[67] Our World in Data; data source: WHO COVID-19 Dashboard. Available at: https://ourworldindata.org/coronavirus (last access: 24.01.2025)

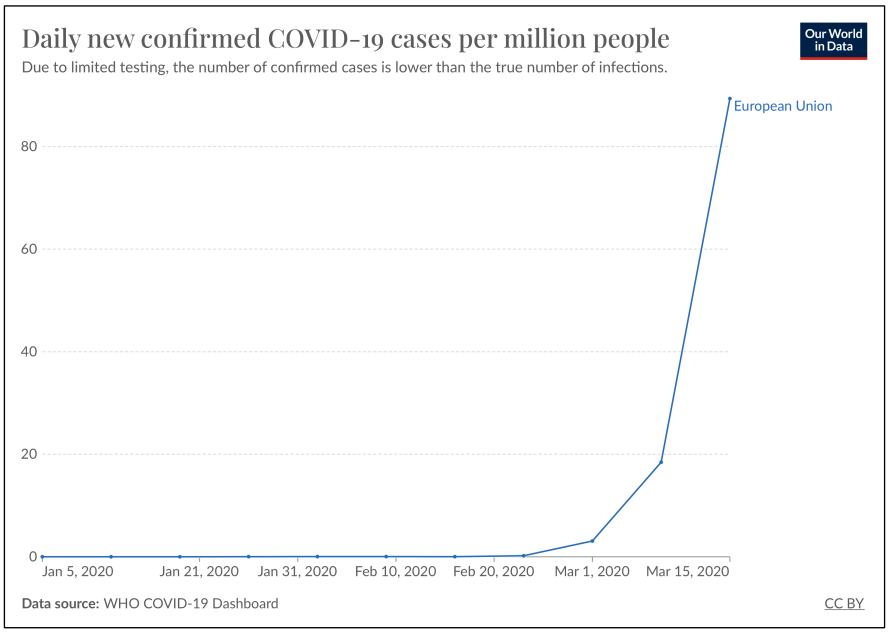

Figure 7. Daily new confirmed COVID-19 cases per million people in the European Union in the period between 5 January 2020 and 15 March 2020 (source: Our World in Data; data source: WHO COVID-19 Dashboard)

The ever-increasing pressure of the pandemic threat on Europe, coupled with an ever-increasing demand for personal protective equipment (especially face masks, gloves and gowns), led the European Commission to draw up Recommendation 2020/403 of 13 March 2020 *"on conformity assessment and market surveillance procedures within the context of the COVID-19 threat"*[68]. It is in fact a Recommendation, thus not a Directive nor a Regulation, and as such not binding (like the Opinion, the other non-binding legislative act that the European Commission can issue). The purpose of the Recommendations is to enable the European institutions to make known their positions on issues of particular interest and relevance and to suggest courses of action, without imposing legal obligations on the addressees.

[68] Recommendation, C. (2020). Commission Recommendation (EU) 2020/403 of 13 March 2020 on conformity assessment and market surveillance procedures within the context of the COVID-19 threat. Official Journal L, 77(16/03), 0001-0009

Of particular interest is the opening of the aforementioned recommendation, which explains the epidemiological reasons behind the need for a specific piece of legislation: *"In the context of the current COVID-19 global outbreak as well as the rapid spread of the virus across various regions of the EU, the demand for personal protective equipment (hereinafter 'PPE') such as face masks, gloves, protective coveralls or eyewear protection, as well as for medical devices such as surgical masks, exploration gloves and some gowns, has seen an exponential growth. In particular, the supply chain of certain types of PPE such as the disposable face masks is under severe strain, due to the exponential growth of the demand both via existing as well as via new channels. In addition, the global supply chain of such products has also sustained significant disruptions, which have induced repercussions on the EU market as well"*[69].

In no less than two places in the space of a few lines there is talk of "exponential growth" in demand for PPE. In fact, according to Eurostat, the official website of the European Union, comparing the first half of 2019 with the first half of 2020, the value of imports of face masks into the EU actually saw an exponential growth from € 800 million to € 14 billion, which means an increase of 1.800%[70] (the figures quoted refer to the first six months of 2020, while the recommendation was issued on 13 March 2020, but the exponential trend was already evident). Strikingly, China was the EU's biggest trading partner for mask imports in the first half of 2020, providing 92% of masks imported during this period, which was 30% more than in the first half of 2019. This also shows the EU relied significantly on Chinese supplies to satisfy increasing demand for the products[71].

The demand for PPEs grew exponentially during the COVID-19 pandemic, hence the European Commission had to put in place certain

[69] *Ibidem*
[70] EUROSTAT NEWS, EUROPEAN UNION, *Which Country Imported the Most Face Masks?* Available at: https://ec.europa.eu/eurostat/web/products-eurostat-news/-/ddn-20201006-1 (last access: 01.02.2024)
[71] *Ibidem*

measures in order to overcome the shortage of these essential protective equipments. Among these measures, Commission Recommendation (EU) 2020/403 of 13 March 2020 was also involved in this process. Although this Recommendation was not binding, it offered valuable guidance to Member States on procedures for conformity assessment and market surveillance of PPE and medical devices during the COVID-19 pandemic. It also recommended flexibility in applying EU conformity assessment rules, meaning that PPE without the CE marking could be placed on the market temporarily under specific circumstances.

To comply with Recommendation 2020/403, the following criteria had to be met:

1. Adequate safety standards: the equipment had to meet an appropriate level of health and safety as set by the essential requirements of EU legislation.
2. Critical need justification: the equipment had to be intended only for the response to the COVID-19 outbreak.
3. Targeted usage: the use of such equipment was restricted to healthcare workers and other first responders.

Additionally, the Recommendation stressed the importance of Member States ensuring proper checks and controls to verify the safety and efficacy of such products before deployment.

Building on these recommendations, the European Commission adopted Regulation (EU) 2020/561 of 23 April 2020, amending Regulation (EU) 2017/745 on medical devices (MDR). This amendment postponed the full application of the MDR by one year, from 26 May 2020 to 26 May 2021.

The delay was aimed to alleviate the burden on healthcare systems and medical device manufacturers by allowing them to continue to focus on the pandemic response. It also addressed potential market disruptions due to the inability to meet the new rules during a health emergency during the COVID-

19 pandemic. The European Commission also supported these actions through Commission Implementing Decision (EU) 2020/668 of 18 May 2020, that established general conditions for the acceptance of PPE that did not fully comply with the EU harmonized standards but met the essential safety and health requirements. This decision provided for the expedited evaluation and approval of PPE imported from third countries if it offered the necessary level of protection.

The emergency framework also relied on the following:

1. Article 11(13) of Directive 93/42/EEC (Medical Devices Directive - MDD): this article permitted national authorities to permit the marketing of medical devices that had not been through the normal conformity assessment processes where their use was in the public interest.
2. Article 59 of Regulation (EU) 2017/745 (MDR): this article permitted Member States to grant exemptions from the requirements of the MDR in extraordinary circumstances, which allowed the approval of medical devices that did not meet all the MDR requirements but were necessary for public health.

The use of these provisions and emergency measures together was critical in ensuring that PPE and medical devices were available to the European region at speed. For example, national authorities were enabled to allow the use of products that did not meet the necessary standards but which met essential safety requirements and which healthcare workers needed.

Beside the regulatory flexibility, the EU put in place strong surveillance systems to prevent substandard or counterfeit PPE. The Member States worked closely with the Commission and used RAPEX – the Rapid Alert System for dangerous non-food products – to share information on non-compliant products and respond to them promptly.

These measures reflect the capacity of the EU's regulatory frameworks to address hitherto unencountered threats, and to do so in a way that safeguards the public's health, maintains the integrity of the market, and takes into consideration pressing public health needs at a time of a severe public health crisis.

3.3 Impact on the supply chain and manufacturing

The COVID-19 pandemic has caused a supply chain and manufacturing disruption of personal protective equipment and medical devices and revealed critical weaknesses in the global production and distribution systems. Before the pandemic, the European Union had a large reliance on importing PPE from countries outside of the European Union, particularly from China[72]. But as the outbreak intensified, international trade was greatly affected with many countries, especially the exporting countries, imposing restrictions on the export of the necessary goods to meet the first, the domestic need. This left Europe with a dramatic shortage of PPE and desperate measures were required to address the supply chain and increase manufacturing capacity[73].

The first and one of the most immediate responses to these challenges was the reorganization of supply chains for PPE sourcing from a variety of suppliers. Efforts were made to assure alternate supply chain and guarantee that PPE was available from regional sources within the EU. European governments and institutions were working closely with manufacturers and logistics providers to simplify and accelerate the import process, decrease

[72] J. COHEN, Y. VAN DER MEULEN RODGERS, *Contributing factors to personal protective equipment shortages during the COVID-19 pandemic*, in *Preventive Medicine*, 2020, 141, p. 106263
[73] U. JAIN, *Risk of COVID-19 due to shortage of personal protective equipment*, in *Cureus*, 2020, 12(6)

bureaucratic delays and guarantee the rapid distribution of critical supply. Also, the European Commission provided recommendations and guidelines for the simplification of the movement of goods across Member States in order to minimize the impact of national border controls and restrictions. At the same time, there was an attempt to increase the domestic production of PPE and medical devices[74]. Many manufacturers across other industries also switched their production lines to create necessary items such as face masks, gowns and ventilators. This change was also helped by the fact that automotive, textile and electronics industries were able to modify their facilities and knowledge to help in the production of medical supplies. This shift, in addition to helping to meet urgent needs, also helped to overcome reliance on PGE imports from third countries, which increased the EU's self-sufficiency[75].

The PPE market also experienced an unprecedented number of new entrants due to the crisis. New small and medium enterprises, and new start-ups began to create PPE or did so with the help of government incentives or funding programs. To this surge in production, temporary derogations like Recommendation 2020/403 to sell products not CE marked were brought forward for limited time. This regulatory flexibility was important for allowing new manufacturers to quickly enter the market and provide much needed equipment[76].

The demand for PPE during the pandemic led to innovation and technological improvements in the manufacturing of the products. Indeed, companies also invested in automation and enhanced production

[74] C.P. BOWN, *How COVID-19 medical supply shortages led to extraordinary trade and industrial policy*, in *Asian Economic Policy Review*, 2022, 17(1), pp. 114-135
[75] WORLD ECONOMIC FORUM (V. VECCHI, N. CUSUMANO), *COVID-19: lessons from Italy on public-private healthcare procurement*, in *World Economic Forum*, 12.05.2020
[76] M.S. SINHA, F.T. BOURGEOIS, P.K. SORGER, *Personal protective equipment for COVID-19: distributed fabrication and additive manufacturing*, in *American Journal of Public Health*, 2020, 110(8), pp. 1162-1164

technologies to increase output speed without compromising on quality. However, digital tools like blockchain[77] and artificial intelligence were also being increasingly used to improve supply chain transparency and traceability to only good and compliant products reach the market[78].

Overall, COVID-19 pandemic has driven a shift towards greater resilience, diversification, and regionalization in the supply chain and manufacturing landscape of PPE. The adaptations made were not only to solve the problems that arose from the pandemic but also to create a better and more sustainable system that can withstand any future crisis.

[77] Blockchain is a distributed digital ledger that stores transactions across many computers in a way that is secure, transparent, and almost impossible to alter. They are known as blocks and are linked chronologically, and then cryptography is used to validate each transaction and make it nearly unchangeable, all without the use of intermediaries

[78] A. ZIMMERLING ET AL., *op. cit.*

CHAPTER IV

THE ITALIAN APPROACH TO PPE DURING THE FIRST WAVE OF COVID-19

TABLE OF CONTENTS: 4.1. Emergency legislation in the Italian legal system – 4.2 The first pandemic wave in Italy – 4.3 National Health System and PPE preparedness – 4.4 Emergency legislation and measures – 4.5 The effects of derogatory measures – 4.6 The constitutionality of derogatory measures: Constitutional Court ruling no. 198 of 22.09.2021 – 4.7 The reports of the derogatory mask validation activities by INAIL – 4.8 The report of the derogatory mask validation activities by ISS

4.1. Emergency legislation in the Italian legal system

In the introduction, it is noted how emergency legislation was born – in general and also in Italy – in wartime contexts, having developed as a regulatory tool to deal with extraordinary situations that endangered the stability of the state. It should also be underlined how the most extensive use of emergency legislation was made by states with a strong imperialist vocation, while Italy, characterised by a legal system less inclined to authoritarian solutions, made more circumscribed use of it[79].

One of the fundamental theoretical references on the subject of emergency decrees is Carl Schmitt's work "Political Theology", in which the author writes the well-known motto *"Sovereign is he who decides on the state of exception"*[80]. This expression, often evoked in the context of the COVID-19 pandemic, emphasises the extraordinary decision-making power of executive

[79] C. LATINI, *Emergenze e democrazia: alcune riflessioni in prospettiva comparata*, in *Solidarietà ed emergenze*, Editoriale Scientifica, 2022, pp. 7-16

[80] B. GULLÌ, *The sovereign exception: Notes on Schmitt's word that sovereign is he who decides on the exception*, in *Glossator: Practice & Theory of the Commentary*, 2009, 1

power in contexts of crisis. However, it should be emphasised that Schmitt is a controversial figure due to his involvement in National Socialism, which means that his thinking should always be interpreted with caution. Another important text for understanding emergency decrees is the Weimar Constitution (1919)[81], which is the perfect historical example of how emergency regulations can be used to suspend fundamental rights and facilitate authoritarian drifts (e.g. Article 48: *"The president may take the measures necessary for the restoration of public order and security when they are disturbed or threatened to a considerable extent, and, if necessary, intervene with armed force"*). Similarly, article 16 of the French Constitution (1958): *"When the institutions of the Republic, the independence of the Nation, the integrity of the territory or the fulfilment of international commitments are seriously and immediately threatened and the regular functioning of the constitutional public powers is interrupted, the President of the Republic adopts the measures required by such circumstances, after consultation with the Prime Minister, the Presidents of the Assemblies and the President of the Constitutional Council"*.

Before discussing the evolution of emergency decrees in Italy, it is necessary to define the concept of the "state of siege", which refers to the temporary suspension of the effectiveness of part of the Constitution in the presence of extraordinary events that threaten the security of the State or public order. It can take two main forms: the "military state of siege" (applied in contexts of war or insurrection) and the "political state of siege" (used in situations of internal emergency). Having said this, we can talk about the Messina and Reggio Calabria earthquake of 28 December 1908, an event that marked the beginning of a systematic reflection on the legal management of emergencies. On that occasion, in fact, the Prime Minister (Giovanni Giolitti)

[81] In force since 11 August 1919, it was the first democratic statute in German history, guiding Germany from the end of World War I to the rise of Hitler in 1933

issued a decree-law signed by the king (Victor Emmanuel III), recognising the "political state of siege", which led to the intervention of the Savoy army. This practice, although not new (similar previous cases had occurred in 1894 and 1898 to quell riots), was for the first time applied to a natural cataclysm, due to the fact that the army had the necessary resources and organisation to deal with emergency situations that the civil authorities were unable to handle independently.

The last case of a declaration of a state of siege in Italy dates back to 1922, with the Facta Decree, issued by Prime Minister Luigi Facta to counter the Fascists' March on Rome, but it was not signed by king Victor Emmanuel III, so it remained unimplemented. Due to the king's refusal to approve the decree, Facta resigned, and the fascist government of Benito Mussolini began. A controversial aspect of the emergency decree in the pre-Republican period is its legitimacy. The statuto albertino of 1848 (the pre-Republican constitution) did not explicitly provide for the instrument of emergency decrees, but had a 'flexible' nature, in that it allowed constitutional guarantees to be overridden by ordinary laws, exactly the opposite of the 1948 Republican constitution, which was 'rigid' and overridden by ordinary laws[82]. Well known to experts in the field is the position of the jurist Santi Romano (1875-1947), who elaborated the theory of the emergency as a source of law, implemented by emergency ordinances and administrative acts, even in derogation of primary sources of law and constitutionally protected rights. In other words, Romano justified the state of siege on the basis of the principle of "necessity" (*necessitas non habet legem*), believing that emergency decrees were legitimate as long as they were limited in time[83].

---

[82] M. FIORAVANTI, *Lo statuto albertino*, in *Dallo statuto albertino alla costituzione repubblicana*, in *Atti del seminario, Roma, palazzo della Consulta, 25 novembre 2011*, Giuffrè, 2012, pp. 19-38

[83] S. ROMANO, *Sui decreti-legge e lo stato di assedio in occasione del terremoto di Messina e di Reggio-Calabria*, in *Rivista di diritto pubblico*, 1909

A few years after Santi Romano's theoretical elaboration, the decision of the French Council of State of 28 June 1918 to validate the dismissal without notice of a civil servant under the theory of "exceptional states" caused a stir (the Heyriès case)[84,85].

A turning point in the regulation of emergency decrees in Italy was Law No 100 of 31 January 1926[86], with which the fascist regime formally regulated the use of the decree-law, which until then had no precise regulation. This text represents the direct precedent of the current Article 77 of the Constitution[87]. However, Law 100/1926 provided for extremely long conversion times (up to two years), effectively nullifying parliamentary control and allowing wide abuse of the decree-law, thus in fact not solving the problem of emergency decrees but exacerbating it[88]. The current maximum validation period (60 days) was defined in the 1948 Republican Constitution, Article 77.

To sum up, we could say that the evolution of emergency management in Italy can be divided into three main phases. In the first period, up to the First World War, the State adopted a 'paternalistic-assistential' approach, intervening only a posteriori. In the second period, with the advent of the fascist regime (from 1922), the emergency became a pretext for the centralisation of power and the socialisation of private interests. In the third period, starting in 1948, there was a progressive institutionalization of the

---

84 C. LATINI. *La regola e l'eccezione. Necessità ed emergenza tra passato e presente*, in *Iurisdictio*, 2023, pp. 1-14

85 CE, 28 juin 1918, Heyriès, req. n° 63412. Available at: https://www.conseil-etat.fr/fr/arianeweb/CE/decision/1918-06-28/63412 (last access: 10.02.2025)

86 Law no. 100 of 31 January 1926, "Provisions on the organization of the Government and the central administration" (Gazzetta Ufficiale, no. 26, 2 February 1926)

87 *"The Government may not, without delegation from Parliament, issue decrees that have the force of ordinary law. When, in extraordinary cases of necessity and urgency, the Government adopts, under its responsibility, provisional measures with the force of law, it shall on the same day present them for conversion to the Houses of Parliament, which, even if dissolved, shall be specially convened and shall meet within five days. Decrees lose their effectiveness from the outset if they are not converted into law within sixty days of their publication. The Chambers may, however, regulate by law the legal relationships that have arisen on the basis of the unconverted decrees"*

88 C. LATINI. *La regola e l'eccezione. Necessità ed emergenza tra passato e presente*, *op. cit.*

Civil Protection, culminating in law 996 of 1970, which assigned the coordination of disaster intervention to the Ministry of the Interior. Subsequently, in 1982, the Civil Protection Department was established at the Presidency of the Council of Ministers and, finally, with Law 225 of 1992, the Civil Protection became an official body with precise competences. The current regulatory definition of emergency is contained in the Civil Protection Code (Legislative Decree 2/2018, Articles 2 and 24), aimed at ensuring greater consistency and uniformity in crisis management.

4.2 The first pandemic wave in Italy

A brief overview of the main stages of the first pandemic wave in Italy is provided below[89]. The first alarm was raised on January 31, 2020, when the Italian government imposed a six-month national emergency after identifying two cases of the virus in Rome. But it was not until February 21, when the first case of community transmission was recorded in Lombardy that the government's response was ramped up. Measures were enforced first, on February 23, in some areas of Lombardy and Veneto, and then extended to other regions, i.e. Emilia Romagna and Liguria. By early March, as the cases were reported in different parts of the country, the government enforced more stringent measures. All schools and universities were closed across the country on March 4, and the lockdown of northern Italy was extended to the whole country by March 9. Other measures that were put in place in mid-March to limit the spread of the virus saw to it that the country was in total lockdown by March 22. The healthcare system was therefore put under a lot of pressure and the number of daily deaths peaked on March 27.

[89] Lab24, La storia del coronavirus, Il Sole 24 Ore, *op. cit.*

As the healthcare system struggled to cope with the influx of patients, the government launched economic support packages, such as the "Cura Italia" decree on March 17, which aimed to strengthen the national health system, support employment, and suspend certain fiscal obligations. Factories began reopening on May 4 under strict safety protocols, and by May 18 bars, restaurants, and shops resumed operations. Inter-regional travel was allowed again starting June 4, with further relaxation of restrictions on June 15 as recreational activities were permitted to resume[90].

A more detailed summary of the events that characterised the first wave of the pandemic is offered in table XII.

[90] I. BOSA, A. CASTELLI, M. CASTELLI, O. CIANI, A. COMPAGNI, M.M. GALIZZI, M. VAINIERI, *Response to COVID-19: was Italy (un)prepared?*, in *Health Economics, Policy and Law*, 2022, 17(1), pp. 1-13

Table XII. Summary of the main phases of the first pandemic wave in Italy

Date	Event
31.01.2020	In response to the identification of the first two confirmed COVID-19 cases in Rome (Chinese tourists visiting from Wuhan) the Italian Council of Ministers enacts a six-month national emergency. Responsibility for coordinating the country's efforts against the virus is delegated to the Head of the Civil Protection Department
21.02.2020	The first Italian patient testing positive for COVID-19 is identified in Lombardy, and soon after, additional infections are reported in the nearby regions of Emilia Romagna and Veneto
23.02.2020	The government designates two areas in Lombardy and Veneto as 'red zones', initiating the first set of lockdown measures. Residents are required to remain at home unless they had valid reasons, such as medical needs, work obligations, or essential activities like buying groceries
25.02.2020	Additional restrictions are enforced across Emilia-Romagna, Friuli-Venezia Giulia, Liguria, Lombardia, Piemonte, and Veneto. In Friuli Venezia Giulia, Lombardia, and Veneto, schools are closed indefinitely, while in the other mentioned regions, as well as in Calabria, educational institutions are only shut down for one week
27.02.2020	A nationwide monitoring system, led by the ISS, is implemented to manage the daily reporting and aggregation of data from various regions and from the ISS's National Laboratory for SARS-CoV-2. This system is facilitated through an online platform to ensure streamlined data collection and coordination
01.03.2020	'Red zones' are established in 10 municipalities across Lombardy, including Codogno, which was the first town to be placed under lockdown. In Veneto, Vo' becomes the first area to face similar restrictions. Additional provinces in Emilia Romagna, Marche, and Liguria are also subjected to these stringent containment measures
04.03.2020	Schools and universities throughout the country are closed
08.03.2020	The lockdown is extended to Lombardy and other areas in northern Italy
09.03.2020	Partial lockdowns are extended to the entire Italian peninsula
11.03.2020	Restaurants, bars, and pubs are closed
17.03.2020	Decree no. 18/20 ('Cura Italia'), which includes measures to strengthen the national health service, support employment and suspend certain tax obligations, comes into effect
22.03.2020	All activities throughout the country are suspended: it's total lockdown
27.03.2020	The peak of daily deaths is recorded (969)
30.04.2020	Conversion into law, with amendments, of the Cura Italia decree, the decree-law No. 18 of 17 March 2020 (Law no. 27 of 24 April 2020)
04.05.2020	It reopens most factories and various wholesale activities in accordance with established health safety protocols

18.05.2020	Bars, restaurants, shops and some social activities reopen
04.06.2020	The possibility of moving between regions is granted without restrictions
15.06.2020	Recreational activities reopen
29.07.2020	The state of emergency is extended to 31 October

4.3 National Health System and PPE preparedness

When the COVID-19 pandemic broke out (late February and early March 2020), Italy found itself in an extremely vulnerable situation with regard to the availability of PPEs, also due to the fact that it was the first Western country to be hit by the pandemic[91]. The national health system, like many others in Europe, was not prepared to face a health emergency of this magnitude, especially in terms of procurement and distribution of essential materials such as PPEs. This situation highlighted some major structural and organisational deficiencies that were already present in the system and became particularly serious with the outbreak of the health crisis. In fact, the COVID-19 pandemic hit the country after years of strict expenditure review and cost containment measures initiated in the wake of the 2008 economic crisis. These measures significantly reduced the resources allocated to the healthcare system, including the capacity of hospitals. As a result, the financial burden of healthcare has been increasingly shifted to households, in particular through increased user fees. This coincided with tighter budgetary constraints on public pharmaceutical spending, exacerbating

[91] D. BEZZINI, I. SCHIAVETTI, T. MANACORDA, G. FRANZONE, M.A. BATTAGLIA, *First wave of COVID-19 pandemic in Italy: data and evidence*, in *Coronavirus Therapeutics–Volume II: Clinical Management and Public Health*, Cham, Springer International Publishing, 2022, pp. 91-113

existing socio-economic inequalities in access to and financing of healthcare[92].

Before the outbreak of the pandemic, strategic planning for the management of healthcare resources and, in particular, PPEs, had not been sufficiently thorough in Italy. Available stocks were limited, and in many cases obsolete, and there was no adequate reserve to cope with a sudden and massive increase in demand. This deficit became clear in the early days of the pandemic outbreak, when the first outbreaks of COVID-19 hit northern Italy, particularly Lombardy and Veneto. The head of Civil Protection, Angelo Borrelli, quantified the need for masks at around 90 million units per month. In an interview on 24 March 2020, indeed, he said *"... Regarding the most serious problem right now, we should be able to buy intensive care ventilators in supermarkets and masks on every corner, but instead we are struggling. We are especially lacking surgical ones for doctors ..."*[93].

As a matter of fact, the shortage of PPE had direct repercussions especially on healthcare personnel, who found themselves on the front line without adequate protection[94]. Hospitals, many of which were already under pressure from years of funding cuts and structural deficiencies, faced a sudden increase in the number of infected patients, while PPE supplies were rapidly depleted. At the national level, there was no well-defined contingency plan to purchase and distribute PPE on a large scale, and health authorities were not prepared to handle a crisis of this magnitude. Moreover, the deficient masks, were precisely those most useful in containing the spread of

---

92 G. CITONI, D. DE MATTEIS, M. GIANNONI, *Disuguaglianze socioeconomiche in salute, equità nell'accesso e nel finanziamento dei servizi sanitari in Italia: quale evoluzione in tempi di SARS-COV-2?*, in *Sistema Salute*, 2020, 64(3), pp. 204-221

93 IL SOLE 24 ORE (A. CARLI), *Da Miroglio a Menarini: Fabbriche che si riconvertono contro il coronavirus.* 31 Mar 2020. Available at: https://www.ilsole24ore.com/art/da-miroglio-menarini-fabbriche-che-si-riconvertono-contro-coronavirus-ADLIFdD (last access: 09.09.2024)

94 F. TESSAROLO, G. NOLLO, D. MANIGLIO, M. RIGONI, L. BENEDETTI, F. HELFER, N. PAONE, *Testing surgical face masks in an emergency context: the experience of Italian laboratories during the COVID-19 pandemic crisis*, in *Int. J. Environ. Res. Public Health*, 2021, 18(4), p. 1462

infection, i.e. FFP2 and FFP3. On 14 March 2020, in fact, the National Institute of Health (Istituto Superiore di Sanità – ISS) issued guidelines detailing the practices for rationalising resources in terms of masks, so as to save FFP2 and FFP3 as much as possible[95].

Another significant factor was the PPE import dependence of the country during the pandemic. Protective equipment used in the country prior to COVID-19 was imported in majority from China and other Asian countries. This supply model that had been sustainable under normal conditions was clearly unsustainable in a global crisis situation. It was impossible for Italy to build a domestic production network to meet the increasing demand for PPE as international demand increased and producing nations closed their borders[96].

This put further pressure on already struggling international supply chains, adding to Italy's problems. The absence of national strategic stockpiles thus made it quickly apparent that the healthcare system was dependent on imports, which could not satisfy the increasing demand. Many hospitals and healthcare institutions were left with no choice but to restrict the usage of PPE or, in some cases, to operate without proper protection, which in turn, increased the risk of infection for healthcare workers. This context has been the impetus for the conversion of many industries (mainly fashion, but not only) to mask producers as of March 2020.

---

[95] ISTITUTO SUPERIORE DI SANITÀ – PREVENZIONE E CONTROLLO DELLE INFEZIONI, *Indicazioni ad interim per un utilizzo razionale delle protezioni per infezione da SARS-CoV2 nelle attività sanitarie e socio-sanitarie (assistenza a soggetti affetti da COVID-19) nell'attuale scenario emergenziale SARS-CoV2*, 14 Mar. 2020. Available at: https://www.sigg.it/wp-content/uploads/2020/03/MIN-SAL-INDICAZIONI-AD-INTERIM.pdf (last access: 09.09.2024)

[96] THE NEW YORK TIMES, *China Dominates the Market for Medical Face Masks, but Some Countries Can't Depend on It*, in *The New York Times*, 13 March 2020. Available at: https://www.nytimes.com/2020/03/13/business/masks-china-coronavirus.html (last access: 25.01.2025)

Fippi spa in Rho, a nappy manufacturer in Lombardy, was the first company to agree to convert part of its production to masks[97]. Clearly, this conversion represented a challenge both from a technical and regulatory point of view, i.e. the production of legally suitable and certified protective masks, which will be discussed in detail in the following chapters.

Another severe issue regarding the PPE problem in Italy during the COVID-19 outbreak was the fragmentation of the healthcare system, which is organized at the regional level (there are essentially 20 different health systems, one per region). The healthcare resources and PPE procurement were all the sole responsibility of each region and there was virtually no coordination from the central government, and this fragmentation led to a very uneven situation across the country, since obviously some regions were better equipped than others. Nevertheless, even in the more developed health systems' regions, such as Lombardia – which was one of the first and the most affected regions – the lack of personal protective equipment was a major issue. Lack of a national rapid response plan, coupled with poor coordination between the regions, only made the competition for the limited resources more challenging. Since the crisis had to be managed by each region on its own, the management of protective equipment was delayed and ineffective[98].

4.4 Emergency legislation and measures

In the Italian context, the two main regulations that allowed derogations from the usual methods of purchasing and marketing personal

[97] IL SOLE 24 ORE, *Mascherine, Italia Spa: ecco tutte le aziende in pista e i volumi di produzione*, 14 Apr. 2020. Available at: https://www.ilsole24ore.com/art/mascherine-italia-spa-ecco-tutte-aziende-pista-e-volumi-produzione-ADHvCuG (last access: 11.09.2024)
[98] F.G. SANTERAMO, M. TAPPI, E. LAMONACA, *On the management of COVID-19 pandemic in Italy*, in *Health Policy*, 2021, 125(8), pp. 995-1001

protective equipment in the context of the first pandemic wave were decree-law no. 9 of 2 March 2020 (DL 'Gualtieri', *"Urgent support measures for families, workers and enterprises related to the COVID-19 epidemiological emergency"*)[99] and the subsequent decree-law no. 18 of 17 March 2020 (DL "Cura Italia", *"Measures to strengthen the National Health Service and provide economic support for families, workers and businesses related to the epidemiological emergency from COVID-19"*)[100].

The first one (DL 'Gualtieri') in Article 34 authorised, on the one hand, the Civil Protection to purchase individual protection devices and other medical devices until the end of the emergency period, as well as to arrange advance payments for the entire supply, and, on the other hand, it allows the use of surgical masks as a suitable device to protect healthcare workers, particularly permitting the use of masks without the CE mark, subject to assessment by the Istituto Superiore di Sanità.

The following is the text of Article 34 of the decree ("Provisions to facilitate the acquisition of protective and medical equipment"):

> *"… 1. The Civil Protection Department and the implementing entities identified by the Head of the Civil Protection Department among those referred to in the order of the same dated 3 February 2020 no. 630, are authorised, within the resources available for the emergency management, until the end of the state of emergency of the resolution of the Council of Ministers on 31 January 2020, to acquire personal protective equipment (PPE) as identified by Ministry of Health Circular no. 4373 of 12 February 2020 and other medical devices, as well as to arrange advance payments for the entire supply, by way of derogation from Legislative Decree no. 50 of 18 April 2016.*
>
> *2. In relation to the emergency referred to in this Decree, until the end of the state of emergency referred to in the resolution of the Council of Ministers on 31 January 2020, the use of personal protective equipment of similar protective effectiveness to that envisaged for personal protective equipment provided for by the regulations in force. The effectiveness of such devices is evaluated in advance by the Scientific Technical Committee referred to in*

[99] Decree-law no. 9 of 2 March 2020, "Urgent measures to support families, workers, and businesses affected by the epidemiological emergency caused by COVID-19" (Gazzetta Ufficiale, No. 53, 2 March 2020)

[100] Decree-law no. 18 of 17 March 2020, "Measures to strengthen the National Health Service and provide economic support for families, workers, and businesses related to the COVID-19 emergency" (Gazzetta Ufficiale, no. 70, 17 March 2020)

Article 2 of the Order of the Head of the Department of Civil Protection Department of 3 February 2020, no. 630.

3. In relation to the emergency referred to in this decree, in consistency with the guidelines of the World Health Organisation Health Organisation guidelines and in accordance with current scientific evidence, it is permitted to use surgical masks, as a suitable device for protecting healthcare workers; also masks without CE marking may also be used, subject to evaluation by the Istituto Superiore di Sanità …".

The subsequent decree-law no. 18 of 17 March 2020 ("Cura Italia" decree, converted with amendments into Law no. 27 of 24 April 2020) established evaluation procedures as an exception to the ordinary procedure for the certification of medical devices, in order to speed up the production and marketing of masks. In essence, Article 15 of the decree-law established that manufacturers and importers of masks could request the activation of a 'fast-track' procedure for the assessment of compliance with the technical standards of the masks, based on self-certification of conformity. This self-certification, transmitted to the Istituto Superiore di Sanità, had to be followed by the sending, within 3 days, of the results of the technical tests carried out to support the declared requirements. Within a further 3 days, the Istituto Superiore di Sanità would provide an opinion on the possibility of producing and marketing the product. The favourable opinion of the ISS was a fundamental requirement for the possibility of marketing the product (not producing it, since production could be started even in the absence of the ISS authorisation).

Below is the text of Article 15 of the decree ("Extraordinary provisions for the production of surgical masks and personal protective equipment").

"… 1. Without prejudice to the provisions of Article 34 of decree-law no. 9 of 2 March 2020, no. 9, for the management of the COVID-19 emergency, and until the end of the state of emergency referred to in the resolution of the Council of Ministers of Ministers on 31 January 2020, it is permitted to produce import and market surgical masks and personal protective equipment as an exception to current provisions.

2. Manufacturers and importers of surgical masks referred to in referred to in paragraph 1, and those who place them on the market who intend to intend to make use of the derogation provided for therein, shall send to the Istituto Superiore di Sanità a self-certification in which, under their own their own exclusive responsibility, certify the technical characteristics technical characteristics of the masks and declare that they comply with all safety requirements of the regulations in force. Within and not no later than 3 days after the aforementioned self-certification, manufacturers and importers must also transmit to the Istituto Superiore di Sanità any useful element for the validation of the surgical masks surgical masks. The Istituto Superiore di Sanità within 3 days from the receipt of what is indicated in this paragraph, shall pronounce on the conformity of the surgical masks surgical masks to the standards in force.

3. Manufacturers, importers of personal protective equipment referred to in paragraph 1 and those who place them on the market who intend to avail themselves of the derogation provided for therein, shall send INAIL a self-certification in which, under their own exclusive responsibility, certify the technical characteristics of the mentioned devices and declare that they comply with all the safety requirements of the regulations in force. Within and not no later than 3 days after the aforementioned self-certification, manufacturers and importers must also transmit to INAIL any element useful for the validation of the personal protective equipment object of the same. INAIL, within 3 days from the receipt of what is indicated in this paragraph, shall decide on the compliance of the personal protective equipment with the standards in force.

4. If, at the outcome of the assessment referred to in paragraphs 2 and 3, the products do not comply with the standards in force, without prejudice to the application of the provisions on self-certification, the manufacturer shall immediately cease production and the importer is prohibited from placing the product on the market …"

The "explanatory note' to Article 15 of the "Cura Italia" decree, entitled "Procedure for the exemption production of face masks for medical use", is also absolutely fundamental. The document essentially indicates in clear and practical terms the instructions to be followed by those who intend to produce, import and market face masks for medical use in derogation of the provisions in force at the time (non-CE marked products) as provided for by the combined provisions of decree-law of 2 March 2020 no. 9 (art. 34, paragraph 3) and decree-law of 17 March 2020 no. 18 (art. 15). These are summarised for ease of reading in Table XIII.

Table XIII. Arrangements for the production and marketing under derogation of masks as established by the combined provisions of decree-law no. 9 of 2 March 2020 (Art. 34, paragraph 3) and decree-law no. 18 of 17 March 2020 (Art. 15) and clarified by the "explanatory note" to Art. 15 of decree-law no. 18 of 17 March 2020

Procedure element	*Description*
Scope	Applies to manufacturers, importers, or distributors of medical masks not CE-marked due to emergency conditions (as per Decree March 2, 2020, no. 9)
Submission requirements	Manufacturers (Proponents) must submit a self-certification and derogatory assessment request via PEC to the Istituto Superiore di Sanità (ISS). All communication is to be directed to the specified PEC address
Preliminary submission	Before submission, the Proponent must specify the product's intended use, following the guidelines of Article 15 of Law Decree. If applicable, Article 16 of the Decree does not involve the ISS
Additional documentation	Proponents must provide technical documents showing compliance with UNI EN 14683 (current revision) and ISO 10993-1, and evidence of a quality management system. This should include bacterial filtration efficiency (BFE), bioburden, splash protection, differential pressure, and labeling
Evaluation timeframe	3 days are given by the ISS to review the documentation that has been received. A favorable or unfavorable opinion is provided within this timeframe. If positive, production or distribution can be made to follow
Responsibility	When manufacturers submit missing or incomplete test results at the time of submission, they are solely responsible for the products and must be able to document it later. It can work on that basis
Non-compliance actions	If ISS gives an unfavorable opinion, then production and marketing must cease immediately, and the products must be recalled from the market. Any temporary approvals that have been issued by ISS can be easily revoked
Sample retention	Manufacturers should not submit product samples, except for one representative sample for archival purposes at the ISS, which must be accompanied by relevant documentation
Product requirements	Products must comply with current UNI EN 14683 standards, especially in terms of filtering capacity (Type I, Type II, Type IIR), breathability, biocompatibility, and labeling. Tests for biocompatibility include cytotoxicity, skin irritation, and sensitisation
Quality management system	A certified quality management system is not mandatory, but production and final product controls must adhere to defined procedures. Traceability procedures for raw materials and finished products must be in place
Biocompatibility tests	Tests must follow ISO 10993-1 guidelines based on the duration and nature of skin contact. Medical masks classified as "surface medical devices" are tested for cytotoxicity, skin irritation, and sensitization

Documentation of compliance	Proponents must provide detailed technical and product data including, but not limited to, the product code, description, layers, materials, chemical composition, and any certifications such as UNI EN 14683 or ISO 10993 compliance
Labeling requirements	The label must include the manufacturer's name, product identification, batch/serial number, use-by date, sterility information (if applicable), and specific usage warnings or conditions
Post-approval actions	After initial approval, the manufacturer must provide additional proof of compliance as soon as it becomes available. ISS may revoke approval if subsequent documentation does not meet requirements
Key ISO standards	UNI EN 14683: Medical face masks – Requirements and test methods UNI EN ISO 10993-1: Biological evaluation of medical devices – Part 1
Product withdrawal and notification	If non-compliance is determined, the Proponent must stop production immediately and recall distributed products from the market

Article 16 of the "Cura Italia" decree ("Additional protective measures for workers and the community") is also relevant:

> *"… 1. To contain the spread of the COVID-19 virus, until the end of the state of emergency referred to in the resolution of the Council of ministers on 31 January 2020, on the entire national territory, for workers who in the performance of their activities are objectively unable to maintain the interpersonal distance of one metre, are considered personal protective equipment (PPE), referred to in Article 74, paragraph 1, of Legislative Decree 9 April 2008, n. 81, commercially available surgical masks, the use of which is regulated by Article 34, paragraph 3, of decree-law no. 9 of 2 March 2020.*
>
> *2. For the purposes of Paragraph 1, until the end of the state of emergency of referred to in the resolution of the Council of Ministers dated 31 January 2020, individuals on the entire national territory are authorised to use filtering masks without the CE mark and produced by way of derogation from the current marketing regulations …"*

Article 16, paragraph 1, as can be seen, defines which type of mask workers must wear according to their occupational risk, as shown in table XIV.

Table XIV. Types of masks to be worn by different categories of workers in accordance with Article 16, paragraph 1, of decree-law no. 18 of 17 March 2020

Type of worker	*Mask*	*Character of the provision (ordinary/derogatory)*
Worker exposed to occupational risk for the ordinary task performed in accordance with the company's risk assessment document (DVR – Documento di Valutazione dei Rischi) (regardless of the pandemic situation)	CE-marked PPE, FFP2 and/or FFP3 (also valid for containing COVID-19-related biohazard)	Ordinary
Worker only exposed to the biohazard from COVID-19 because he is less than 1 metre away from others in his ordinary job	CE surgical masks until 31 July 2020 (Art. 16, first paragraph)	Derogatory
Worker exposed neither to occupational risk nor to biological risk from COVID-19, as he is always more than 1 metre away from other workers	Filtering masks without the CE marking and produced in derogation of the current marketing regulations (Art. 16, second paragraph)	Derogatory

Article 16, paragraph 2, instead, specifies that the face masks for the community (generic masks, neither surgical nor FFP) can be used by all individuals present on the national territory even if they do not have the CE mark and are produced in derogation of the current regulations on placing on the market, as confirmed and clarified by the important circular of the Ministry of Health no. 0003572-P of 18 March 2020 ("… *The provision in question* – author's note: the text refers to article 16, paragraph 2, of the Cura Italia decree – *allows all individuals present on the national territory, who are in any case required to respect the provisions on social distancing and the other precautionary rules introduced due to the COVID-19 emergency, to use, as a precautionary measure, filtering masks which, due to their intended use, are not classified as medical devices or personal protective equipment. It is understood that these masks cannot be used on the job by*

healthcare workers or by other workers for whom the use of specific safety devices is prescribed. Also in relation to the aforementioned case, it is important to remember that it is absolutely necessary that the manufacturers of the aforementioned masks guarantee that they do not cause damage or additional risks for users according to the intended use specified by the manufacturers. The evaluation procedures referred to in Article 15 of Legislative Decree no. 18 of 17 March 2020 do not apply to these products …")[101,102]. Still with reference to generic masks, we cannot fail to mention the circular of the Ministry of Economic Development (MISE) no. 107886 of 23 April 2020, which provided indications regarding the production, import and marketing of these devices, in particular: absence of CE marking, clear labelling (with explicit indication that they are not MD or PPE), warnings regarding use (specifying that they do not guarantee protection of the wearer's respiratory tract and that they cannot be used when the use of MD or PPE is prescribed), and manufacturer's declaration that they do not cause harm and do not create additional risks for users[103].

In order to make the exemption regulations clearer, it is considered useful to summarise the regulatory framework in Table XV[104] (it should be noted that the derogation validation procedure summarised in the table was not applicable to products already bearing the CE marking).

[101] Italian Ministry of Health, Circular no. 3572 of March 18, 2020
[102] INAIL. *Report delle attività di validazione straordinaria dei dispositivi di protezione individuale*. 5 aprile 2020. Available at: https://www.certifico.com/component/attachments/download/17308 (last access: 20.09.2024)
[103] Italian Ministry of Economic Development (MISE), Circular no. 107886 of April 23, 2020
[104] G. ARPEA, *Maschere DM, DPI e per la collettività: disciplina e deroga COVID-19*, in *Ius in itinere*, 26 marzo 2020. Available at: https://www.iusinitinere.it/maschere-dm-dpi-e-per-la-collettivita-disciplina-e-deroga-covid-19-31659 (last access: 16.09.2024)

Table XV. Summary of the derogatory regulations concerning the approval and marketing of masks in Italy in the context of the first pandemic wave

Mask type	**Surgical masks**		**FFP2/FFP3 masks**	
Legal framework	Medical Devices (Regulation EU 2017/745)		Personal Protective Equipment (Regulation EU 2016/425)	
Type	Regularly CE-marked DM	DM put on the market under derogation	Regularly CE-marked PPE	PPEs put on the market under derogation
Regulatory reference	Directive 93/42/EEC[105]	Decree-law no. 18 of 17 March 2020	Regulation EU 2016/425 Decree no. 17 of 19 February 2019 (penalties)	Decree-law no. 18 of 17 March 2020 Regulation EU 2016/425
Technical production standards	UNI EN 14683:2019 UNI EN ISO 10993.1:2010 (or equivalent)	UNI EN 14683:2019 UNI EN ISO 10993.1:2010 (or equivalent)	UNI EN 149:2009 (or equivalent)	UNI EN 149:2009 (or equivalent)
Body Notification	No	No	Yes	No
Application for derogation	No	Art. 15, paragraph 2, Decree-law no. 18 of 17 March 2020 (until 31.07.2020)	No	Art. 15, paragraph 3, Decree-law no. 18 of 17 March 2020 (until 31.07.2020)
Information that must be present on the packaging	CE marking (Annex XIII of MD 93/42) Name of manufacturer Name of authorised representative (if non-EU manufacturer) Information referred to in Annex I, Chapter III, point 13 (above all, see point 13.3) of MDD 93/42	Information listed under 'Minimum content of the labelling affixed on the primary/secondary packaging) of the document "Technical documentation: ISS specifications".	CE marking (Art. 16 and 17 of Regulation 2016/425) Information (Art. 17 of the Regulation 2016/425)	Information that is absent from the INAIL website
Documents to be checked for purchase	EC Declaration of Conformity (Annex VII of MDD 93/42)	Application for derogation assessment ISS positive opinion (optional)	EC Declaration of Conformity (Annex IX of Regulation 2016/425)	Application for derogation assessment INAIL positive opinion (optional)

[105] Directive 93/42/EEC was repealed by Regulation (EU) 2017/745 of 5 April 2017 (so-called 'MDR', Medical Device Regulation), which entered into force on 25 May 2017, but it did not enter into force until 26 May 2021, i.e. one year later than originally planned, by virtue of the EU Amendment Regulation 2020/561 of 23 April 2020, which was adopted to enable EU Member States and their authorities and institutions to prioritise the fight against the COVID-19 pandemic. Thus, at the time of the first pandemic wave, the reference legislation at European level was still Directive 93/42/EEC

	Instructions for Use (Annex I, Chapter II, point 13.6 of MDD 93/42)	Technical documentation required for validation (including material data sheet, technical test report, Quality System certification documents) as per document 'Technical documentation: ISS specifications'	EC type-examination certificate (issued by Notified Body) Information Notice (with instructions and information, referred to in Annex II, Chapter I, point 1.4, of the RDPI 2016/425)	Technical documentation required for validation (including material data sheet, technical test reports performed, Quality System attestation documents) referred to in the document 'INAIL Operating Instructions of 19 May 2020'

Table XVI gives a complete overview of the exemption measures provided for each type of mask.

Table XVI. Derogatory measures regulating the validation of different types of masks in the context of the first pandemic wave in Italy

Mask type	Derogatory procedure for validation
Non-CE marked surgical masks (qualifying as MDs)	Necessary, managed by the Istituto Superiore di Sanità
Non-CE marked FFP2/FFP3 masks (qualifying as PPEs)	Necessary, managed by the INAIL
CE-marked masks (any type)	Not necessary
Non-CE marked masks that do not qualify either as MDs or as PPEs, not intended either for the use of healthcare professionals nor for the protection of workers	Not necessary (but the producer must certify that the masks are safe and not harmful, see Ministry of Health Circular no. 3572/2020 and Ministry of Economic Development Circular no. 107886/2020)

A further major derogatory measure occurred with Article 66-bis of Law no. 77 of July 17, 2020, converting decree-law no. 34 of May 19, 2020. This measure introduced significant amendments to Article 15 of decree-law no. 18 of 2020, with particular reference to the importation and marketing of surgical masks and personal protective equipment, revising the competencies of ISS and INAIL, respectively, in relation to the state of epidemiological emergency.

It was indeed established that the Institute (and ISS for surgical masks) would remain in charge of the evaluation exclusively of requests submitted by manufacturers based in a European Union country of personal protective equipment, while for those submitted by importers it was envisaged that they would pass into the sphere of responsibility of the Regions and the establishment of a technical committee to define simplified validation criteria, as an exception to current regulations, that would ensure the protective efficacy suitable for the specific use until the end of the state of emergency. As of August 4, 2020, therefore, requests for extraordinary validation, pursuant to Article 15, paragraph 3, of decree-law no. 18 of 2020,

could only be submitted to the Institute by manufacturers based in a country of the European Union. The extraordinary and derogatory validation was declared valid until the end of the state of emergency, scheduled for October 15, 2020.

4.5 The effects of derogatory measures

The regulatory simplifications brought about by the 'Cura Italia' decree enabled many Italian companies, some of them from sectors completely different from the medical sector (such as the fashion industry and the textile industry), to convert their production to manufacture masks. The use of self-certification and the temporary elimination of the need to obtain CE certifications, indeed, made it possible to supply the domestic market in record time, avoiding further delays due to imports and international bureaucracy. Within a few weeks, numerous Italian companies were able to produce and distribute large quantities of masks.

The footwear company "Baldinini", in San Mauro Pascoli (in the province of Forlì Cesena, Emilia-Romagna), assigned the first masks produced following the conversion to employees and family members. It later distributed them to the police forces of the municipalities of San Mauro Pascoli and Savignano sul Rubicone, who were at the forefront of the implementation of social containment measures[106].

The famous "Calzedonia" (with administrative headquarters in Dossobuono, in the province of Villafranca di Verona, in Veneto) also converted some of its factories to the production of masks (and gowns). The

[106] VOGUE ITALIA (I. PANTANO), *Mascherine antivirus e moda: Gucci, Prada e le altre maison in prima linea nella produzione*, 30.03.2020. Available at: https://www.vogue.it/moda/article/mascherine-antivirus-moda-produzione-gucci-prada (last access: 28.012025)

conversion made it possible to produce a minimum number of 10.000 masks per day, which were donated to the hospital of Verona and the municipality of the same city[107].

The Turin fashion house "Carlo Pignatelli" distributed free masks made from the production conversion to local authorities, who distributed them to the population of the capital of Piemonte (Turin)[108].

"Fabi", a historic footwear manufacturer in the Marche region, also converted its production, supporting the Marche region in managing the first pandemic wave[109].

"Lanificio F.lli Cerruti" collaborated with "Cittadellarte"[110] and "Consulta per le Persone in difficoltà"[111] to produce 100.000 masks for civilian use destined for the Italian Red Cross and 10.000 CE-marked three-layer surgical masks destined for the Biella Hospital. The initiative was also supported through a crowdfunding campaign[112].

"Pellemoda", a company founded in 1979 in Empoli specialising in the production of leather clothing and accessories, started production of 100.000 masks and gowns destined for health associations in the municipality of Empoli. The company also declared itself willing to make masks and gowns for anyone who requested them[113].

The Padua-based fashion company "Plissè" donated some 15.000 masks and 1.000 gowns to local health authorities in the first week of the

---

107 *Ibidem*
108 *Ibidem*
109 *Ibidem*
110 "Cittadellarte" is a cultural centre in Biella (Piemonte), founded in 1998 by Michelangelo Pistoletto, an Italian artist, that promotes social art, collaborative projects and innovative community and contemporary art initiatives
111 The "Consulta per le persone in difficoltà" is a non-profit organisation based in Turin that supports people in conditions of discomfort, disability or social disadvantage, promoting inclusion and breaking down physical and cultural barriers. Its services include social assistance, accompaniment for dependent persons and awareness-raising projects on disability and equal opportunities
112 VOGUE ITALIA, *op. cit.*
113 *Ibidem*

conversion alone. It was also willing to accommodate supply requests from local companies[114].

The eyewear company "Safilo", of Padua, also converted its production, distributing the first 10.000 masks to healthcare facilities in Bergamo, Seriate, Padua, Latina and Brescia[115].

In addition to the rapid production conversion of Italian companies, the regulatory simplifications introduced by the 'Cura Italia' decree had a significant impact in terms of innovation and quality of the products manufactured as a result of the conversion. As it has turned out, the option of using self-certification has encouraged many companies to explore new materials and technologies and thus to design more comfortable and high-performance masks. This not only fulfilled the requirement of the moment but also helped to create conditions for further innovation in the field of personal protection equipment[116].

Another important factor was the support of small and medium-sized enterprises that were able to adjust to new market demands without having to wait for bureaucratic procedures to be over. This conserved jobs and prevented company deaths during a period of unprecedented economic crisis. Moreover, collaboration between companies from different industries has shown a strong and adaptable character of the Italian economy and created cross collaborations that may be useful in future[117].

From the social point of view, producing masks domestically has led to a reduction of the country's dependence on imports, which in turn has ensured security in the supply chain and time delivery of the masks. This has ensured that the masks were distributed equally and on time to the areas that

---

[114] *Ibidem*
[115] *Ibidem*
[116] A. ZIMMERLING ET AL., *op. cit.*
[117] S. CERULLO, *Cura Italia: Italy's Covid-19 Emergency Decree*, in *PAF9181 Spring 2020 Blog*. Baruch College. Available at: https://blogs.baruch.cuny.edu/paf9181spring2020/?p=251 (last access: 19.09.2024)

were most affected by the pandemic. Furthermore, many companies also chose to donate some part of their production to local authorities and health facilities, thus enhancing the spirit of community and solidarity during the crisis[118].

Last but not least, the experience of the first pandemic wave helped to accumulate important practices for emergency management and the effective cooperation between the public and private sectors, since the best practices that emerged helped improve the country's preparedness for possible future health emergencies, consolidating a model of rapid and effective response.

4.6 The constitutionality of derogatory measures: Constitutional Court ruling no. 198 of 22.09.2021

Although not directly related to the derogatory measures concerning face masks, the Constitutional Court's ruling no. 198 of 2021 is of particular interest, as it rejected the question of constitutional legitimacy of the so-called "pandemic regulatory system", based to a large extent on the instrument of the decree-law[119].

The Constitutional Court was called upon to rule on the constitutional legitimacy – with reference to articles 76, 77, and 78 of the Constitution – of some provisions of the decree-laws adopted to deal with the epidemiological emergency from COVID-19, in particular with regard to the alleged delegation of legislative function to the Government through the adoption

[118] WORLD ECONOMIC FORUM, *From perfume to hand sanitiser, TVs to face masks: How companies are changing track to fight COVID-19*, in *World Economic Forum*. 24 mar 2020. Available at: https://www.weforum.org/agenda/2020/03/from-perfume-to-hand-sanitiser-tvs-to-face-masks-how-companies-are-changing-track-to-fight-covid-19/ (last access: 19.09.2024)

[119] M.C. SPECCHIA, *Le fonti dell'emergenza nella crisi pandemica. Riflessioni di sintesi*, in *DPCE Online*, 2021, 50(Sp). Available at: https://www.dpceonline.it/index.php/dpceonline/article/view/1554 (last access: 11.02.2025)

of Decrees by the President of the Council of Ministers (DPCM). The contested decree-laws were decree-law no. 6 of 23 February 2020 ("Urgent measures regarding the containment and management of the epidemiological emergency from COVID-19"), converted, with amendments, into law no. 13 of 5 March 2020, and decree-law no. 19 of 25 March 2020 ("Urgent measures to deal with the epidemiological emergency from COVID-19"), converted, with amendments, into law no. 35 of 22 May 2020. The Court declared the questions relating to the first decree-law inadmissible due to lack of relevance, since in the specific case a subsequent decree should have been applied (being the specific fact, relating to a citizen who had violated the ban on leaving his home, which occurred on 20 April 2020, therefore when decree-law no. 19 of 2020 was in force, repealing the previous one). On the other hand, it examined the merits of the issues concerning the second decree-law, stating that it did not improperly delegate the legislative function to the Government, but simply provided for 'standardised' containment measures, leaving their implementation to the Prime Minister according to criteria of adequacy and proportionality. The judges therefore ruled out any violation of the principle of legality, and indeed held that the regulatory mechanism adopted was in accordance with the constitution, since the restrictive measures were defined by law and implemented by executive administrative measures, without this constituting an undue delegation of regulatory power.

There was no lack of criticism of this interpretation, such as that of Specchia[120], who considers the decision of the Constitutional Court to be wrong because, in his opinion, it did nothing more than circumvent the main problem, that is, the reservation of law in the matter of fundamental rights. The Court, in fact, maintained that the DPCM (Decree of the President of

[120] M.C. SPECCHIA, *op.cit.*

the Council of Ministers) were legitimate because they derived from decree-laws approved by Parliament, therefore formally in line with the principle of legality, but focusing only on the correctness of the 'chain of legal sources' (i.e. the relationship between decree-laws and DPCM) without assessing whether the power exercised by the Government was compatible with the separation of powers and the rule of law. In other words, according to Specchia's criticism, the Court should have asked itself whether it was right that measures that limit fundamental rights (such as the ban on movement) were decided by the Government instead of Parliament. Similar reflections to those proposed by Specchia could indeed be made in relation to the decree-laws concerning face masks that we discussed in the previous chapters, since the focus of the discussion regarding the emergency decree is the evaluation of the constitutional legality of the Government's right to legislate.

4.7 The reports of the derogatory mask validation activities by INAIL

As illustrated in the previous section, INAIL (Istituto Nazionale per l'Assicurazione contro gli Infortuni sul Lavoro e le Malattie Professionali – National Institute for Insurance against Accidents at Work and Occupational Diseases) was in charge of handling requests for extraordinary validation of PPEs (basically FFP2 and FFP3). In order to quickly manage the validation files and to ensure a rapid conclusion of the proceedings, INAIL set up a task force of about 40 people with different professional technical and administrative professionals from three sub-organisations of the Institute (CONTARP; DIMEILA; DC Ricerca), established a special section in the INAIL web portal, from which all useful information for submitting the

request for validation request, and activated a certified e-mail box dedicated exclusively to sending validation requests[121].

On 5 April 2020, INAIL released a first report on the evaluated procedures[122]. Out of a total of 840 files[123], only 35 (about 4%) were approved, almost all of them submitted by importers. The remaining 805 dossiers (96%) were assessed as non-conforming. Of the rejected dossiers, in 57% of the cases the reason was the technical unsuitability of the masks (not sufficiently protective), while in 43% of the cases the reason was the absence of the prerequisites for INAIL to proceed with the conformity assessment (25%: products not classifiable as PPEs; 17%: products classifiable as surgical masks, and therefore assessable by the Istituto Superiore di Sanità; 1%: products already CE marked and therefore not in need of re-validation).

INAIL released a second report on 4 May 2020[124]. Out of a total of 2.458 files, only 96 (about 4%) were approved, again almost all of them submitted by importers. The remaining 1.653 dossiers (96%) were assessed as non-conforming. Of the rejected dossiers, in 73% of the cases the reason was the technical unsuitability of the masks (not sufficiently protective), while in 27% of the cases the reason was the absence of the prerequisites for INAIL to proceed with the conformity assessment (15%: products not classifiable as PPEs; 12%: products classifiable as surgical masks, and therefore assessable by the Istituto Superiore di Sanità).

---

121 INAIL, *Report delle attività di validazione straordinaria dei dispositivi di protezione individuale. Op. cit.*
122 *Ibidem*
123 Requests received since the entry into force of the 'Cura Italia' decree, 17 March 2020
124 INAIL. Report delle attività di validazione straordinaria dei dispositivi di protezione individuale. Report delle attività aggiornato al 4 maggio 2020. Available at: https://www.certifico.com/component/attachments/download/17706 (last access: 20.09.2024)

INAIL released a third report on 4 August 2020[125]. Out of a total of 9.359 submissions, including multiple entries, document integrations, and information requests, 7.284 cases underwent technical evaluation. Among these, 6.867 resulted in finalized communications. Only 600 cases (approximately 8%) were approved, nearly all submitted by importers. The remaining 6.267 cases (92%) were deemed non-compliant. Among the rejected submissions, the primary reasons for rejection were as follows: in 70% of cases, the lack of complete or valid test reports for the products was identified; 20% involved certificates issued by non-accredited entities, making them unsuitable for evaluation; and 10% failed to clearly specify the product models or manufacturers.

Again, INAIL released a fourth report on 4 October 2020[126]. Out of a total of 9.438 submissions, including multiple entries, document integrations, and information requests, 7.433 cases were subjected to technical assessment. Among these, 7.032 resulted in final communications. Only 670 cases (approximately 9%) were approved, the vast majority submitted by importers. The remaining 6.362 cases (91%) were found to be non-compliant. The primary reasons for rejection were as follows: 65% lacked complete or valid test reports for the devices; 25% involved certificates issued by non-accredited entities, making them invalid for evaluation; and 10% failed to provide clear information about product models or manufacturers.

[125] INAIL. Report delle attività di validazione straordinaria dei dispositivi di protezione individuale. Report delle attività aggiornato al 4 agosto 2020. Available at: https://www.certifico.com/component/attachments/download/17706 (last access: 13.01.2025)
[126] INAIL. Report delle attività di validazione straordinaria dei dispositivi di protezione individuale. Report delle attività aggiornato al 4 ottobre 2020. Available at: https://www.certifico.com/component/attachments/download/17706 (last access: 13.01.2025)

4.8 The report of the derogatory mask validation activities by ISS

As illustrated in the previous section, ISS (Istituto Superiore di Sanità – National Institute of Health) was in charge of handling requests for extraordinary validation of surgical masks. On the ISS website, a single document was found showing the status of all files processed until 23 July 2021[127]. Looking at the table and examining the results, and admitting that no mistakes were made by the writer (who counted the results manually), the following emerged.

The document contains information on 643 validation requests that were approved, including their geographic characteristics, mask type, proposed use, model and the 38 cases where an initial positive opinion was recommended for production before the definitive license for commercialization and use. The approved requests were made from different areas and the distribution was not equally distributed. The regions that had the greatest number of approvals were Lombardia (117), Campania (84) and Toscana (72). Other regions with a high number of approved requests include Piemonte (54), Lazio (47), Puglia (47), and Veneto (45). Emilia-Romagna had 42 approvals, Marche and Abruzzo each had 28. Calabria had 16 approved requests, and Trentino-Alto Adige, Umbria and Sicilia had 12 each. Sardegna had only 3. Liguria and Basilicata had 8 each, and Friuli Venezia Giulia had 5. Molise and the Republic of San Marino each contributed one approval, while India was the only country from outside Europe in the dataset. In regard to mask type, the most frequent use was that

[127] ISS, *Procedura di produzione di maschere facciali ad uso medico in deroga secondo quanto previsto dall'art.15, comma 2, del Decreto-legge del 17/03/2020 n.18, convertito con modificazioni dalla Legge del 24/04/2020, n. 27 e modificato dalla Legge del 17/07/2020 n. 77.* Available online at: https://www.iss.it/documents/20126/0/20210723+Autorizzazioni+Rilasciate.pdf/e67a7096-abce-be0e-6faa-e5aeb2958d48?t=1627269827289 (last access: 26.01.2025)

of type I masks with 249 instances, and type II masks came in second with 242 approvals. Type IIR masks were less common, with 152 approvals. In terms of use, masks that were for single use were the most approved at 586. Reusable masks were approved 43 times, and only 12 masks were designed with replaceable filter. Two approvals were also for transparent single-use masks. As for the model, the majority of the approvals were for adult masks, 609 times. Pediatric masks were documented 33 times, and only one approval did not include the model type. In the last place, 331 out of the total 643 approved requests were granted a preliminary favourable opinion for production, which is a prerequisite for obtaining the final approval for large-scale production, marketing and use.

CHAPTER V

MARKETING AND DISTRIBUTION OF PPEs AND MDs

TABLE OF CONTENTS: 5.1 Marketing strategies in crisis – 5.2 Market surveillance and penalty system – 5.3 The counterfeiting problem – 5.4 The return to pre-pandemic procedures

5.1 Marketing strategies in crisis

In the first outbreak of the COVID-19 pandemic, the marketing strategies of FFP2 and FFP3 (PPEs) and surgical masks (MDs) also changed a lot in Italy and Europe. As the demand for this equipment skyrocketed due to the health crisis, companies had to re-evaluate their approaches to address the needs of the market[128]. Even then, the global usage of surgical masks rose from 89 million per month before the COVID-19 outbreak to 129 billion per month in 2020[129].

Manufacturing companies had to increase their production capacity very quickly. As outlined in the previous chapter, in Italy (and elsewhere) many textile and manufacturing companies shifted their operations to produce masks. This transition needed to be communicated to the public so that they knew that new products were available. Marketing strategies were based on the reliability and quality of the devices and met the required safety standards and regulations[130].

---

[128] H. JIANG, D. LUO, L. WANG, Y. ZHANG, H. WANG, C. WANG, *A review of disposable facemasks during the COVID-19 pandemic: a focus on microplastics release*, in *Chemosphere*, 2023, 312, p. 137178

[129] J.C. PRATA, A. PAÇO, V. REIS, J.P. DA COSTA, A.J.S. FERNANDES, F.M. DA COSTA, ... T. ROCHA-SANTOS, *Identification of microplastics in white wines capped with polyethylene stoppers using micro-Raman spectroscopy*, in *Food Chem.*, 2020, 331, p. 127323

[130] A.A. SANTOKI, M.H. PAREKH, *Marketing strategies during COVID-19*, in *J. Crit. Rev.*, 2020, 7(11), pp. 4040-4045

Companies used messages that were geared towards social responsibility and emphasized their role in helping to fight the pandemic. This approach enhanced the brand image and build trust with the consumers. Transparency became a key element in marketing communications – this includes details of certifications obtained, technical specifications of products[131].

Distribution also proved to be a major problem. Due to the restrictions on air and many shop closures, companies had to find new ways of reaching consumers. E-commerce and digital platforms were perfect to help with this. Companies also increased their online presence and improved their websites for direct sales and worked with marketplaces like Amazon and eBay. Targeted social media advertising campaigns and using influencers to increase product visibility were also part of the digital marketing strategies[132].

The measures that were derogatory, for example, the "Cura Italia" decree in Italy have greatly affected marketing and distribution strategies. Its simplifications enabled companies to accelerate the launch of products on the market by informing the consumers about the availability of masks at an early stage. At the European level, institutions called for cooperation between Member States to guarantee the availability of masks. Companies adopted pan-European marketing strategies to prove that they are able to supply products across different countries and to demonstrate their commitment towards the entire European society. The standardisation of

[131] *Ibidem*

[132] WEBINTERPRET BLOG, *Coronavirus eCommerce Checklist for eBay and Amazon: 10 Tips to Help You Sell During the COVID-19 Pandemic.* Available at: https://www.webinterpret.com/uk/blog/coronavirus-ecommerce-checklist-ebay-amazon (last access: 21.09.2024)

marketing communications helped to ensure that the information provided to consumers was consistent and credible[133].

E-commerce was clearly on the rise due to the social distancing measures that were to be put in place. Digital platforms helped companies to manage large order volumes and to reach customers across different geospatial areas. Marketing strategies were enhanced by the analytical capabilities of the online platforms to understand consumer needs and offer specific solutions for them. Promotion through discounts for buying several items at once, free delivery, and loyalty programs was used to increase sales. This is of course general for consumer goods, but it is also valid for masks[134].

However, this has also resulted in challenges such as counterfeit or substandard products. Some genuine companies had to go the extra mile in their marketing to be distinguished from the fraudsters. This entailed the use of guaranteed marks, the availability of visible certifications on packaging and, where appropriate, educational campaigns to assist consumers in identifying authentic and safe products[135].

Logistics was an important factor in the distribution strategies. Companies also experienced supply chain disruptions and delays in international transportation. In order to address these challenges, some companies formed partnership with local suppliers or some of the companies were able to internalize some stages of the production process. Marketing communications included information on product availability and delivery

---

[133] THE CONVERSATION (S. PARK), *The global effort to tackle the coronavirus face mask shortage*, 17.03.2020. Available at: https://theconversation.com/the-global-effort-to-tackle-the-coronavirus-face-mask-shortage-133656 (last access: 21.09.2024)

[134] V. ALI TAHA, T. PENCARELLI, V. ŠKERHÁKOVÁ, D. FEDORKO, L. KOŠÍKOVÁ, *The use of social media and its impact on shopping behavior of Slovak and Italian consumers during COVID-19 pandemic*, in *Sustainability*, 2021, 13(4), p. 1710

[135] S.C. LAM, L.K.P. SUEN, T.C.C. CHEUNG, *Global risk to the community and clinical setting: flocking of fake masks and protective gears during the COVID-19 pandemic*, in *Am. J. Infect. Control*, 2020, 48(8), pp. 964-965

time, while trying to control customers' expectations in the time of the crisis[136].

Companies also innovated in materials and mask design to differentiate themselves in the market. Facemasks with more comfortable fabrics, ergonomic designs and additional features such as interchangeable filters were developed. These innovations were the part of marketing plans, and advertisements were developed around the advantages and differences of these innovations compared to other brands' offerings[137].

Marketing also included educational components that provided knowledge on the correct usage of masks and the need for their usage in the overall health of the public. This approach helped to further establish the companies as dependable partners who are concerned with the health of the nation. The information such as video tutorials, infographics and guides were shared on digital platforms to increase the coverage of the information[138].

In Italy, for instance, positive image was the result of measures like the free distribution of masks by local authorities and companies. The actions were also public relations campaigns to communicate these actions and helped to consolidate corporate reputation.

The pricing strategies had to be reasonable to the increased production and distribution costs without being too expensive for the consumer. Some companies followed ethical pricing policies, that is they did not increase prices too much though there was high demand for the products. This

---

136 V. VECCHI, N. CUSUMANO, E.J. BOYER, *Medical supply acquisition in Italy and the United States in the era of COVID-19: The case for strategic procurement and public–private partnerships*, in *Am. Rev. Public Adm.*, 2020, 50(6-7), pp. 642-649

137 A.W. DING, S. LI, *National response strategies and marketing innovations during the COVID-19 pandemic*, in *Bus. Horiz.*, 2021, 64(2), pp. 295-306

138 S. JOAG, *Impact of COVID-19 Pandemic on Marketing of Education*, in *J. Glob. Awareness*, 2023, 4(2), pp. 1-14

behaviour was also reflected in the marketing communications to enhance consumer confidence[139].

Another element of the marketing strategies during the first wave was the collaboration of companies. The integration of manufacturers, distributors and retailers made it possible to combine resources and increase the coverage of the marketing programs. In some cases, competing companies joined efforts to guarantee the supply of PPE in the market, with all the companies involved convinced that they had to contribute their best effort towards the solution of the health crisis. The collaboration of Negri Bossi and Complastic Srl is a good example of collaboration during the first wave. From April 9, Negri Bossi offered injection molding machines for masks and face shields, with the Lombard Civil Protection's help. Complastic Srl, a thermoplastic molding company, changed its production to make PPE and met the glasses and shields EN166:2004 standard. The initiative was also co-financed by Invitalia within the framework of the Cura Italia decree and involved ADM (mold supplier), Moretto SpA (machine ancillaries), and AT & Service Srl (raw materials)[140].

Digital platforms enabled these collaborations by offering platforms on which to share information and coordinate marketing activities. Webinars, online conferences, and forums were employed in the exchange of best practices and the development of common strategies[141]. In Europe, there were regulatory differences between countries which meant that marketing

---

[139] M. BERGEN, S. DUTTA, *The N95 Mask for Pricing: Making Pricing Safer for Customers, Companies and Society*, Carlson School of Management, University of Minnesota. 2020 Jun 24. Available at: https://carlsonschool.umn.edu/news/n95-mask-pricing-making-pricing-safer-customers-companies-and-society (last access: 28.01.2025)

[140] NEGRI BOSSI, *Producing COVID-19 Masks*, in *Negri Bossi Official Website*. 2020. Available at: https://www.negribossi.com/producing-covid-19-masks/ (last access: 28.01.2025)

[141] UNIDO, *Webinar on Personal Protective Equipment (PPE): Bridging the Standardisation Gap*, in *UNIDO Official Website*. 2020. Available at: https://hub.unido.org/event/webinar-personal-protective-equipment-ppe-bridging-standardisation-gap (last access: 28.01.2025)

strategies had to be changed. "B2B" (business to business)[142] marketing messages had to be adapted to meet the legal requirements of each country which meant that there was more of an emphasis on accurate translations and marketing campaigns took more note of cultural sensitivity[143].

5.2 Market surveillance and penalty system

As explained in Chapter II, at European level, the main regulation governing PPE (including FFP2 and FFP3 masks) was Regulation (EU) 2016/425, which classified masks as Category III PPE, i.e. intended to protect against serious risks (see Table XI). Compliant products had to bear the CE marking, which attested that they met European safety standards and allowed free movement within the single European market. For surgical masks, the main regulatory reference was the Medical Devices Directive 93/42/EEC, later replaced by Regulation (EU) 2017/745. FFP2 and FFP3 masks had to comply with the harmonised standard EN 149:2001+A1:2009, which specified performance and safety requirements. Surgical masks, on the other hand, had to adhere to EN 14683:2019+AC:2019, which covered fluid resistance, filtration capacity and breathability.

Market surveillance authorities, both in Italy and in other EU countries, had the task of constantly monitoring products placed on the market. In Italy, Accredia, the national accreditation body, was instrumental in making sure that the PPE that is spread complied with standards[144]. The

[142] B2B (Business-to-Business) is a term that indicates commercial transactions between companies, i.e. when one company sells products or services to another company, rather than to end consumers (B2C - Business-to-Consumer)

[143] THE FUTURE OF COMMERCE, *Lessons learned: How B2B industries tackled COVID challenges and won*. Available at: https://www.the-future-of-commerce.com/2021/09/02/how-b2b-industries-tackled-covid-challenges/ (last access: 11.02.2025)

[144] Accredia is the body that in Italy is responsible for the accreditation of bodies that certify PPE. Accreditation by Accredia ensures that certification bodies have the necessary expertise to assess the conformity of products to the standards set by Regulation (EU) 2016/425. During the pandemic, the CE

custom authorities, in particular, stepped up checks on all imports of masks, especially those from non-European Union nations like China. It should be recalled how the sanctions provided for masks produced not in compliance with the rules set out in EU Regulation 2016/425 were contained in Legislative Decree no. 17 of 19 February 2019[145], which was substantially derogated (or at least "paused") as a result of the already discussed provisions of Article 15 of the "Cura Italia" decree.

Market surveillance authorities had extensive powers to ensure product compliance, including the possibility of:

- Carrying out unannounced inspections at production or distribution sites
- Taking samples of products anonymously for testing
- Requesting detailed information on the supply chain and production processes
- Imposing a recall or recall of non-compliant products
- Banning the sale of unsafe masks

The flexibility introduced by Recommendation (EU) 2020/403 on 13 March 2020 facilitated the market introduction of rapidly produced masks, but inevitably also exposed the market to risks of fraud or non-compliant products. In order to avoid abuses, control measures were increased and very strict conditions were introduced for the provisional approval of such products. In exemptions, there were certain restrictions on the use of the exemptions such as the traceability of the products and the restriction of their distribution to health sectors and frontline workers only.

mark was a key element in identifying compliant products, and Accredia ensured that accredited bodies carried out the necessary tests on prototypes and mass-produced products. In the event of conformity, manufacturers could affix the CE mark to their products, allowing them to be placed on the market

[145] Legislative Decree no. 17 of 19 February 2019, "Adaptation of national legislation to the provisions of Regulation (EU) No 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC" (Gazzetta Ufficiale no. 59, 11 March 2019)

In the case of violations, severe sanctions could be applied by surveillance authorities to economic operators who are involved in production or distribution of non-compliant products. Sanctions included the following:

- Administrative fines proportionate to the gravity of the violation due to the effects of Law 689/1981[146]
- The immediate withdrawal of non-compliant products from the market due to the European and Italian legislation mentioned in the previous chapters
- The recall of products already distributed, also due to the European and Italian legislation mentioned in the previous chapters
- Legal actions in the most serious cases: there are indeed various criminal offences incurred by those who market and distribute counterfeit masks, including commercial fraud (art. 515 of the penal code), sale of industrial products with false markings (art. 517 of the penal code), counterfeiting of brands or patents (art. 473 of the penal code), introduction into the country and sale of products with false markings (art. 474 of the penal code)

The authorities also had the power to oblige manufacturers to cover the costs of surveillance operations and the recall of unsafe products. Sanctions were not limited to manufacturers, but could also be applied to distributors and importers who failed to meet standards or who placed counterfeit products on the market.

The surveillance system has been quite successful in identifying and preventing the use of a large portion of non-compliant masks. For instance, Italian customs have made several arrests of firms trying to import masks

[146] Law no. 689 of 24 November 1981, "Amendments to the penal system" (Gazzetta Ufficiale, no. 329, 30 November 1981)

that were not certified or had fake certifications[147]. Nevertheless, a lot of non-compliant products were still able to get through the controls and pose a risk to the consumer and health care worker.

This showed that while surveillance can be an effective tool in regulating the market and ensuring product standards, its efficacy is limited by factors such as fraud, lack of resources, and the complexity of global supply chains, and there is therefore a need for combined approaches that incorporate surveillance with other measures such as product testing, consumer education, and industry self-regulation to effectively address these issues and ensure the quality and safety of masks in the market.

5.3 The counterfeiting problem

During the first wave of the pandemic, the trade in counterfeit face masks emerged as a critical global issue. It is clear that the high demand for face masks created a tempting opportunity for criminal networks to bring fake or low-quality products onto the market and profit unfairly[148].

The counterfeit masks seized during this period were often not so much characterized by the absence of the CE marking – as certain emergency regulations, such as Article 15, paragraph 1, of the 'Cura Italia' decree, temporarily permitted the distribution of masks without the CE label to meet overwhelming demand (as extensively discussed in previous chapters) –, while non-compliance was largely due to the improper or falsified use of the

[147] IL SOLE 24 ORE (P. MACIOCCHI), *Frode in commercio per le mascherine FFP2 con falso marchio CE e prive di requisiti*, 12.02.2021. Available at https://www.ilsole24ore.com/art/frode-commercio-le-mascherine-ffp2-falso-marchio-ce-e-prive-requisiti-AD8chbJB (last access: 12.02.2025)
[148] OECD PUBLISHING, *Illicit Trade in a Time of Crisis. Chair's Summary Note*, 23.04.2020. Available at: https://one.oecd.org/document/GOV/PGC/HLRF/TFCIT(2020)3/En/pdf (last access: 29.01.2025)

CE marking, along with the absence of the requisite documentation to certify the product's legitimacy as a MD or PPE[149,150].

Why were fake masks a public health risk? A significant issue related to the quality of the materials: fake masks could not ensure the required filtering capability to counteract viral particles, which was especially true for FFP2 or FFP3 masks that were commonly used to protect frontline health professionals. The manufacturing of such products makes use of materials of lesser quality than that required for PPEs and MDs, rendering them ineffective, or worse, harmful to public health[151].

Counterfeit masks were mainly distributed through online sales channels and e-commerce platforms such as Amazon, eBay and various poorly controlled websites, where consumers, driven by urgency, purchased protective devices without being able to verify their authenticity. Digital platforms represented a privileged channel for criminals to quickly disseminate these products to a wide audience. Some of these platforms were slow to react and remove counterfeit products from their catalogues[152,153].

The placing of counterfeit face masks on the market had a direct impact on public health, because many of the seized masks didn't meet the necessary filtration requirements to effectively protect against the virus. In particular, surgical masks, which should have filtered out at least 95% of the

---

149 A. BELFORD, S. CERNIAUSKAS, M. CIVILLINI, O. WESTERBERG, *Questionable Paperwork Lets Fake and Faulty Masks Flood Europe*, in *Organized Crime and Corruption Reporting Project*. Available at: https://www.occrp.org/en/project/crime-corruption-and-coronavirus/questionable-paperwork-lets-fake-and-faulty-masks-flood-europe (last access: 28.01.2025)

150 BBC NEWS (P. KEMP), *Covid: One million masks for NHS fail high-grade safety tests*, 28.07.2021. Available at: https://www.bbc.com/news/uk-57999162 (last access: 28.01.2025)

151 M. IPPOLITO, C. GREGORETTI, A. CORTEGIANI, P. IOZZO, *Counterfeit filtering facepiece respirators are posing an additional risk to health care workers during COVID-19 pandemic*, in *Am. J. Infect. Control*, 2020, 48(7), p. 853

152 E. PROFFITT, *The dangers of fake PPE*, in *Bdj Team*, 2020, 7(8), pp. 20-21

153 F. LAZZERI, *Speculazioni nella vendita di mascherine: ristretti i confini dell'art. 501-bis c.p., interpretato dalla Cassazione come reato di pericolo concreto, si apre la strada alle sanzioni AGCM*, in *Sistema Penale*. Available at: https://www.sistemapenale.it/it/scheda/lazzeri-nota-cassazione-36929-2020-speculazioni-mascherine-501-bis-sanzioni-agcm (last access: 12.02.2025)

particles, often offered less protection. It is quite clear that this exposed both ordinary citizens and healthcare workers to an increased risk of infection[154].

The mask fraud was not limited to civil use: many healthcare facilities, especially in the early stages of the pandemic, found themselves receiving supplies of non-compliant masks, sometimes without being aware of the danger, and for health workers, who obviously depended on these devices to protect themselves, this resulted in a high risk of contagion[155].

The response of European authorities was swift. Entities such as the Guardia di Finanza in Italy and other police forces in Europe were involved in numerous seizure operations. In parallel, the European Anti-Fraud Office (OLAF) launched numerous investigations, focusing on illegal IPR (intellectual property rights). OLAF, in cooperation with Europol and Interpol, conducted large-scale operations to identify suspicious operators and stop supplies of counterfeit masks. In addition to seizures, stricter monitoring policies were implemented for digital sales channels[156].

The authorities pointed out that many of these masks came from China and Hong Kong, which became the main production and distribution centres for these illegal products during the pandemic. The disruption of supply chains and global travel restrictions created additional difficulties in monitoring the flow of goods, facilitating the spread of counterfeit products. Criminal groups demonstrated a great capacity to adapt. In fact, in contrast to the pre-pandemic period, in which counterfeiters mainly focused on consumer goods such as clothing and electronics, the pandemic prompted criminals to turn to health-related products. These included fake test kits and

---

154 E. PROFFITT, *op. cit.*

155 LA REPUBBLICA (R. CAPPELLI) *COVID, false mascherine in ospedale: "Non proteggono, riportatele"*, in *La Repubblica*, 10.04.2021. Available at: https://roma.repubblica.it/cronaca/2021/04/10/news/roma_covid_false_mascherine_in_ospedale_non_proteggono_riportatele_-295762133/ (last access: 12.02.2025)

156 EUCRIM (T. WAHL), *OLAF Investigation into Fake COVID-19 Related Products*, 01.04.2020. Available at: https://eucrim.eu/news/olaf-investigation-fake-covid-19-related-products/ (last access: 28.01.2025)

counterfeit drugs, as well as masks: these products not only violated intellectual property rights, but also seriously endangered public health[157].

International cooperation was crucial to hinder the phenomenon of counterfeit face masks. Police and customs authorities from various countries worked together to identify distribution channels and seize millions of dangerous face masks. However, despite many successes, the very nature of online trade and the high demand made it difficult to stop all illegal supplies[158].

5.4 The return to pre-pandemic procedures

The validation of PPE by INAIL (FFP2/FFP3 masks) and ISS (surgical masks) of extraordinary duration was valid until the decree-law no. 52 of April 22, 2021, was enacted[159]. This decree was called "Urgent measures for the gradual resumption of economic and social activities compatible with the need to contain the COVID-19 epidemic spread" and was converted into law with modifications by Law no. 87 of June 17, 2021, which was published in the Official Gazette of the Italian Republic on June 21, 2021 (no. 146)[160].

---

[157] IL FATTO QUOTIDIANO, *Coronavirus, l'emergenza sulle mascherine diventa business: sequestri in tutta Italia. A ditta privata quelle destinate a un ospedale*, 09.04.2020. Available at: https://www.ilfattoquotidiano.it/2020/04/09/coronavirus-lemergenza-sulle-mascherine-diventa-business-sequestri-in-tutta-italia-a-ditta-privata-quelle-destinate-a-un-ospedale/5765071/ (last access: 28.01.2025)

[158] EUROPOL, *Corona crimes: multi-million face mask scam foiled by police across Europe.* Available at: https://www.europol.europa.eu/media-press/newsroom/news/corona-crimes-multi-million-face-mask-scam-foiled-police-across-europe (last access: 28.01.2025)

[159] Decree-law no. 52 of 22 April 2021, "Urgent measures for the gradual resumption of economic and social activities while respecting the need to contain the spread of the COVID-19 epidemic" (Gazzetta Ufficiale, no. 96, 22 April 2021)

[160] Law no. 87 of 17 June 2021, "Conversion into law, with modifications, of decree-law No. 52 of 22 April 2021, providing urgent measures for the gradual resumption of economic and social activities while respecting the need to contain the spread of the COVID-19 epidemic" (Gazzetta Ufficiale, no. 146, 21 June 2021)

What were the consequences of this return to normality? Essentially, the reintroduction of standard certification protocols required producers to return to pre-pandemic rigour, so most of the smaller or 'opportunistic' producers (i.e. who had converted to mask production out of a spirit of service or simply by seizing entrepreneurial opportunities) who had entered the market during the emergency period found it impossible to meet the strict regulatory requirements and were forced to cease their activities.

CHAPTER VI

ETHICAL CONSIDERATIONS, CONCLUSIONS AND FUTURE RESEARCH DIRECTIONS

TABLE OF CONTENTS: 6.1 Ethical issues in masks allocation – 6.2 Consumer protection and safety – 6.3 Transparency and trust: communication challenges during the pandemic – 6.4 The role of innovation in ensuring ethical standards for PPE – 6.5 Summary of findings of the thesis – 6.6 Policy recommendations – 6.7 Future research directions

6.1 Ethical issues in masks allocation

As widely expected, the COVID-19 pandemic raised ethical issues in the production, distribution, and management of PPE, particularly masks. In the early stages of the pandemic masks were widely used, especially in the healthcare contexts, and this led to shortages, as declared to the world with great concern by the WHO in a note of 3 March 2020[161]. The shortages were particularly threatening for the healthcare workers, as stated in the note: *"… Healthcare workers rely on personal protective equipment to protect themselves and their patients from being infected and infecting others. But shortages are leaving doctors, nurses and other frontline workers dangerously ill-equipped to care for COVID-19 patients, due to limited access to supplies such as gloves, medical masks, respirators, goggles, face shields, gowns, and aprons. Without secure supply chains, the risk to healthcare workers around the world is real. Industry and governments must act quickly to boost supply, ease export restrictions and put measures in place to stop speculation and hoarding. We can't stop*

[161] WHO, *Shortage of personal protective equipment endangering health workers worldwide*, 3 Mar 2020. Available at: https://www.who.int/news/item/03-03-2020-shortage-of-personal-protective-equipment-endangering-health-workers-worldwide (last access: 04.02.2025)

COVID-19 without protecting health workers first …". So, a fundamental ethical problem arose: to whom should the scarce PPE resources be allocated?[162].

In order to answer this question we should probably refer to the four ethical values of justice, equity, reciprocity, and duty of care, as identified by O'Sullivan et al. in their 2022 systematic review of the principles that should guide the distribution of resources in a pandemic[163]. The fact that these four principles should be the ones that we must refer to is quite logical, but it's quite hard to determine how to apply them in an appropriate way. For example, in the note by the WHO it is taken for granted that healthcare workers have priority to get PPEs, but should this evaluation be based on occupational exposure only, or should other factors like socioeconomic status, comorbidities, and geographical inequalities also be considered?[164].

The idea of prioritizing healthcare workers is in fact consistent with the reciprocity principle, since doctors and nurses were the most exposed to the virus due to their direct contact with COVID-19 patients. So, in return for the work and risks they took, it would be logical and fair for society to protect them, also because the chances of defeating the pandemic largely depended on the efficiency of the healthcare system. But, given the PPE shortage, this implied leaving a significant portion of the general population unprotected, and this not only could be considered as unfair, but also could exacerbate the diffusion of the pandemic[165]. The issue became even more complex to deal with because of the problems in production and supply

---

[162] J. VONDERSCHMITT, S. WÖHLKE, S. SCHICKTANZ, *Scarce resources, public health and professional care: the COVID-19 pandemic exacerbating bioethical conflicts – findings from global qualitative expert interviews*, in *BMC Public Health*, 2023, 23(1), p. 2492

[163] L. O'SULLIVAN, E. ALDASORO, Á. O'BRIEN, M. NOLAN, C. MCGOVERN, Á. CARROLL, *Ethical values and principles to guide the fair allocation of resources in response to a pandemic: a rapid systematic review*, in *BMC Medical Ethics*, 2022, 23(1), p. 70

[164] D.I. JEFFREY, *Relational ethical approaches to the COVID-19 pandemic*, in *J. Med. Ethics*, 2020, 46(8), pp. 495-498

[165] R.J. MCDOUGALL, L. GILLAM, D. KO, I. HOLMES, C. DELANY, *Balancing health worker well-being and duty to care: an ethical approach to staff safety in COVID-19 and beyond*, in *J. Med. Ethics*, 2021, 47(5), pp. 318-323

chain. Many countries, indeed, including Italy, the United States and the United Kingdom, were not well positioned to meet the sudden increase in demand for PPEs and MDs because they did not have enough capacity within the country, and this led to the development of the derogatory rules discussed in the previous chapters[166]. So: how to increase the availability of masks for everyone while ensuring their effectiveness?

The "relaxation" of the rules was necessary to (partially) solve the problem of the lack of materials, but at the same time it created a higher risk of reducing the quality of the masks, and this could even endanger healthcare workers and the community. So, a major ethical issue was whether these derogation measures would result in the creation of substandard, dangerous, masks capable of violating the principle of non-maleficence (the principle that states one should do no harm)[167].

Similar considerations can be made in relation to the global scenario, since bigger and wealthier countries were more likely to buy masks due to their money and existing structure, and this made them outcompete the poorer countries. The ethical principle at risk is, clearly, the equity principle, which, contrary to what one may think, is not only applicable on a small scale but also on a large scale (global inequalities)[168].

Further complicating the situation, there were panic buying and hoarding of masks by individuals and institutions, that also helped to prolong the mask shortages and widen the gaps. The governments tried to fight these behaviors, for example, adopting measures like preventing the exportation

---

166 C.Y. PARK, K. KIM, S. ROTH, S. BECK, J.W. KANG, M.C. TAYAG, *Global shortage of personal protective equipment amid COVID-19: supply chains, bottlenecks, and policy implications*, in *Future Reg. Coop. Asia Pac.*, 2020, 442

167 L.A. JANSEN, *Medical beneficence, nonmaleficence, and patients' well-being*, in *J. Clin. Ethics*, 2022, 33(1), pp. 23-28

168 S.H.P. DROUARD, T. AHMED, P. AMOR FERNANDEZ, P. BARAL, M. PETERS, P. HANSEN, G. SHAPIRA, *Availability and use of personal protective equipment in low-and middle-income countries during the COVID-19 pandemic*, in *PLOS ONE*, 2023, 18(7), p. e0288465

of the masks and setting prices on the masks, but such measures had some side effects such as decreasing the global supply of masks and increasing the black market for fake PPE[169].

Another important ethical issue concerning the use of PPE (and particularly masks) is the issue of transparency and trust. In fact, in many countries there was a huge informational chaos and ambiguity in relation to the government actions concerning mask usage, particularly at the beginning of the pandemic. For instance, some governments first advised the public not to use masks (particularly if not sick), in order to conserve masks for health care workers, only to change the positions later as more masks became available. Confusion was created also by media, since many television programs gave wrong or inaccurate information on masks usage (the case of a television journalist who made a tutorial on how to make a mask out of baking paper – which is completely unsuitable to protect against viruses – had a particular media resonance). This confused and inconsistent direction led the population to implement wrong behaviours and to develop mistrust in the efficacy of the measures taken by the authorities[170].

More, it should be considered that the ethical principle of transparency is very important in the maintenance of confidence, especially in emergency contexts. Some critics, indeed, accused policymakers of not explaining their actions properly, sinning by lack of transparency, and this left the public guessing and cynical. Perhaps, a deeper explanation of the reasons for assigning masks to certain groups of citizens on the basis of scientific and

[169] NBC NEWS (B. POPKEN), *Coronavirus mask mania spurs internet's gray markets into action*, 9.03.2020. Available at: https://www.nbcnews.com/tech/social-media/coronavirus-mask-mania-spurs-internet-s-grey-markets-action-n1153426 (last access: 29.01.2025)

[170] LINKEDIN (S. LOPATIN), *How the CDC's Mask Messaging Went Wrong*, 30.07.2021. Available at: https://www.linkedin.com/pulse/how-cdcs-mask-messaging-went-wrong-shari-lopatin (last access: 29.01.2025)

ethical criteria could have helped to reduce some of the consequences for the trust of the population[171].

The described ethical issues can be exploited in order to be better prepared for the future pandemic and the allocation of resources in the case of scarcity. In fact, one of the most important lessons learned is the need to establish clear and proper mechanisms for the fair distribution of resources in any crisis, which are based on ethical values that are capable of protecting the rights of the individual and the community at the same time. Also, on a larger scale, it is important for countries to develop their own production and supply of domestic and resilient medical supplies. This may possibly decrease the reliance on the global market, which can be unreliable during calamities, and ensure that all countries are in a position to protect their people without putting more strain on the world's inequities.

6.2 Consumer protection and safety

In the previous chapters of this thesis the author has already discussed the fact that the COVID-19 pandemic of 2020-2021 increased the global demand for personal protective equipment. Well, this unprecedented rise resulted in a shortage of the critical supplies, which was then exploited by counterfeiters to introduce substandard and false PPE into the market (see Chapter V, Section 5.3). The counterfeits of PPE had obviously an adverse effect on the consumer safety, and so posed a significant threat to the efforts being made by the public health authorities to fight the progression of the pandemic. As if this were not enough, the increase in the demand for PPE products gave a boost to the counterfeiters who started distributing fake and

[171] J. MARTIN, C. BACCARANI, *Some thoughts on Covid-19 communication transparency*. Available at: https://sites.les.univr.it/eisic/wp-content/uploads/2020/04/2_SOME_THOUGHTS_Martin_Baccarani.pdf (last access: 29.01.2025)

substandard products. The OECD (Organisation for Economic Co-operation and Development) and EUIPO (European Union Intellectual Property Office) reported that production and trade of counterfeit pharmaceutical and healthcare products followed the pandemic to markets in the European Union[172]. The above-mentioned entities also pointed out that these counterfeit products were dangerous because they did not meet the required safety standards, and therefore were ineffective and dangerous to the user (mistakenly convinced he was protected and would not spread the virus). For example, as has been mentioned before, counterfeit masks that did not have the right filtration system were unable to prevent the spread of viruses.

The analysis of the available information shows that the counterfeits of PPE had certain implications for safety of consumers because people who used PPE to protect themselves during the COVID-19 pandemic actually faced higher risks due to the use of ineffective means of protection, and this not only put the health of individuals at risk, but also made it impossible for others to follow the measures that had been put in place to fight the virus. Furthermore, the large availability of the counterfeit PPE also affected the confidence that the public had towards health organizations and the measures that were being taken to contain the pandemic. Thus, people who realized that they have been using protective equipment that was fake were more anxious and doubtful in respect to the information provided by the officials[173]. In addition, as explained above, the "relaxation" of certain regulations in the process of increasing the supply of PPE during the

[172] OECD, *Illicit Trade in a Time of Crisis. Chair's Summary Note*, 2020. Available at: https://www.oecd.org/gov/illicit- trade/oecd-webinar-illicit-trade-time-crisis-23-april.pdf (last access: 29.01.2025)

[173] PINKERTON, *Identifying and Combating Counterfeit PPE. How to identify potentially counterfeit goods, avoid PPE scammers, and protect employees and businesses.* Available at: https://pinkerton.com/our-insights/blog/identifying-and-combating-counterfeit-ppe (last access: 01.02.2025)

pandemic context also led to the development of loops which were used by counterfeits. Although these derogations were adopted to address shortages, they led also to the entry of counterfeits into the market. In fact, the OECD/EUIPO report pointed out that the COVID-19 pandemic offered new business opportunities for criminals to trade in counterfeit and substandard products, with law enforcement seizures showing that production was increasingly taking place within the EU itself[174].

The challenges that enforcement agencies faced in identifying and intercepting counterfeit PPE included the large number of products, as well as the sophisticated counterfeiting operations. These challenges highlighted the need for better and clearer regulatory frameworks and international cooperation in order to prevent the diffusion of counterfeit PPE in the event of future public health emergencies[175].

6.3 Transparency and trust: communication challenges during the pandemic

As already discussed in the previous paragraphs, the COVID-19 pandemic highlighted how communication strategies (both by the media and the authorities) play a pivotal role in the management of public health crises, and thus made it possible to understand how incorrect communication strategies can lead to important critical issues in the management of public safety.

For example, in the early stages of the pandemic, it was long said that the only masks that could guarantee some kind of protection were FFP2 and FFP3, but that they were only necessary for those who were ill, to avoid

---

[174] OECD, *op. cit.*

[175] ALLIANCE FOR INTEGRITY, *Fighting Counterfeit Medicines and PPE in Times of Covid-19*. Available at: https://www.allianceforintegrity.org/wAssets/docs/learnings/Fighting-Counterfeit-Medicines-and-PPE-in-Times-of-Covid-19.pdf (last access: 01.02.2025)

releasing droplets of saliva or mucus into the air that could infect others. For a long time it was also said that wearing the same mask for several days or placing it wrongly on the face made them useless or even harmful, and therefore the recommendation to healthy people was not to use them. The initial advice was later changed when face masks became more available and studies showed that they effectively helped prevent the spread of the virus. However, this change in the content of the message (although supported by science), generated much confusion and instilled many doubts in the population, who lost confidence in the authorities and found it hard to trust the advice coming from government agencies and scientific societies[176]. The examples of communication 'twists' are countless, both in the international and Italian context. One above all, that of the WHO, which, contrary to what was said in an initial note of 6 April 2020[177], in a subsequent one of 5 June 2020[178] affirmed the usefulness of adopting masks even by healthy individuals.

The dissemination of accurate and inaccurate information has undoubtedly been amplified by social media, which have been useful in providing information to the public, but have at the same time became channels through which erroneous or contradictory information about PPEs were spread, including myths and rumours about their use and safety. This has even led to an 'infodemic', declared by the World Health Organisation, which has made it extremely difficult for governments and health agencies to fight the problem of misinformation. There are many examples, but we may recall here the one relating to the claim that wearing a surgical mask would lead to an accumulation, in the space between the face and the mask,

[176] UNC SCHOOL OF INFORMATION AND LIBRARY SCIENCE (Z. TUFEKCI), *Why Telling People They Didn't Need Masks Backfired,* 17.03.2020. Available at: https://sils.unc.edu/news/zeynep-tufekci-why-telling-people-they-didnt-need-masks-backfired/ (last access: 04.02.2025)
[177] WHO, *Advice on the use of masks in the context of COVID-19*, Interim Guidance, 6 Apr 2020
[178] WHO, *Advice on the use of masks in the context of COVID-19*, Interim Guidance, 5 Jun 2020

of carbon dioxide (CO_2), increasing the risk of hypercapnia (a fact that has no scientific basis whatsoever)[179].

Confirming the above, transparency in the decision-making process for PPE certification and distribution has been identified as a key factor in the process of restoring public confidence in healthcare institutions and organisations. Governments and regulators that provided a clear explanation of the reasons for their decisions, including the selection of healthcare providers and the relaxation of certain requirements, were more likely to sustain public trust. For example, Italian regulators developed a strategy to share information with the public on how PPE received during the emergency was certified and safety tested[180]. Similarly, the European Commission has developed guidelines to improve the traceability and transparency of medical devices and PPE (Regulation 2017/745) in order to increase consumer confidence.

It is therefore important that in the event of future health crises, clear, non-contradictory communication plans are constructed, based on sound science and, if possible, involving the population in the process, so that they are able to understand and share the rationale behind the measures to be taken and the implications for their well-being. This is because, it should not be forgotten, trust is not simply the result of good health policy, but an essential component of the cooperation between institutions and the population that must be nurtured through transparency and accountability.

---

[179] REUTERS, *Fact check: False and misleading information in post listing 'dangers' of face masks*. Available at: https://www.reuters.com/article/world/fact-check-false-and-misleading-information-in-post-listing-dangers-of-face-m-idUSKBN24333B/ (last access: 04.02.2025)

[180] COMITATO NAZIONALE PER LA BIOETICA, *I documenti del CNB sul COVID-19*, Mag 2021. Available at: https://bioetica.governo.it/media/4231/documenti-cnb-sul-covid-19_ita.pdf?utm (last access: 04.02.2025)

6.4 The role of innovation in ensuring ethical standards for PPE

Among the many lessons learnt from the COVID-19 pandemic, one undoubtedly relates to the importance of innovation in the manufacture of personal protective equipment. The push for innovation was driven primarily by the combination of increased global demand and the fact that traditional production methods and supply chains could not keep up with the demand for PPE, necessitating the rapid development of materials, production techniques and quality assurance processes. These innovations not only made up for the immediate shortcomings, but also had the merit of bringing the principles of safety, fairness and sustainability to the forefront of PPE production and distribution.

One of the most significant technological innovations during the pandemic was the development of new materials and designs that improved the performance of PPE[181]. In addition, 3D or additive manufacturing technology was recognised as a revolutionary resource during the pandemic, as it could offer decentralized and on-demand production of PPE (an extremely advantageous circumstance). Such an approach also solved the problem of supply chain disruption and helped to quickly create the products most needed at the time (e.g. face shields and mask components). Moreover, in this way, 3D printing optimized production capacities and solved access and equity problems by making protective equipment available to underserved regions and small healthcare facilities[182,183]. The decentralized production model is an example of how innovation can contribute to the

[181] J. SHI, H. LI, F. XU, X. TAO, *Materials in advanced design of personal protective equipment: a review*, in *Mater. Today Adv.*, 2021, 12, p. 100171
[182] R. AGARWAL, *The personal protective equipment fabricated via 3D printing technology during COVID-19*, in *Ann. 3D Print. Med.*, 2022, 5, p. 100042
[183] G.R. SWENNEN, L. POTTEL, P.E. HAERS, *Custom-made 3D-printed face masks in case of pandemic crisis situations with a lack of commercially available FFP2/3 masks*, in *Int. J. Oral Maxillofac. Surg.*, 2020, 49(5), pp. 673-677

achievement of ethical standards by reducing the gaps in the distribution of PPE worldwide.

The pandemic also made it possible to use digital technologies to further improve quality assurance and regulatory compliance. The most striking example is blockchain technology[184], which has been used to optimise the traceability of PPE along the supply chain, as it has provided a way to create an immutable record of a product's origin, certification and distribution, helping to combat PPE counterfeiting (and consequently restore consumer confidence in the safety of protective equipment)[185].

Innovation, however, was not limited to the production of PPE, but also to the sustainability of PPE production and disposal processes, as the amount of single-use PPE used during the pandemic was unprecedented and led to serious environmental problems due to pollution (especially from plastic). In response, researchers and manufacturers began to investigate biodegradable materials and reusable PPE designs that could be sterilized several times without compromising the safety of the design, in keeping with the ethical principle of sustainability, which is to protect the equipment needed now, but also in the future, in the long term.

Again, collaboration between governments, industry and academia was a key driver of innovation during the pandemic, with partnerships being established that decisively accelerated the creation and distribution of high quality personal protective equipment, as many governments provided funding and regulatory support to drive innovation. The most important example is the European Union's Horizon 2020 programme, where Italy's national innovation funds have been crucial in driving innovation in PPE technology to meet required ethical and regulatory standards.

---

[184] See note 68

[185] S.S. PRIYANKA, N. LOKESWARI, K. AMARAVATHI, *Blockchain – a potential solution for COVID-19 pandemic economical crisis environment*, in *Int. J. Res. Eng. Sci. Manag.*, 2020, 3, pp. 17-21

In conclusion, through improved materials, production methods and regulatory standards, innovation has not only provided a solution to immediate public health problems, but also laid the foundation for a more ethical and sustainable approach to PPE in the future, and all these efforts demonstrate the potential of innovation as a means to address ethical imperatives and technical excellence in times of crisis[186].

6.5 Summary of findings of the thesis

The study presented in this thesis, although complex and laborious given the breadth of the topic, turned out to be prolific and worthwhile, since it allowed to understand how a given legal framework can change under pressure from the demands of society and public health. In fact, this was the aim of the thesis, which, despite dealing with medicine and health, was written at the end of a legal academic course: to study and understand the malleability of a given legal framework and the effects on its application.

The collected data showed, in fact, that regulatory frameworks are flexible, and can also be such without necessarily compromising on quality and safety, as long as high-quality standards are maintained (in the case of this study related to the effectiveness and efficiency of PPEs and MDs). According to the findings of this thesis, one of the keys to preserve these high-quality standards is to ensure that the regulatory framework's structure is more integrated and less complex. One of the examples of this integration is the one between Regulation 2016/425 and Regulation 2017/425, able to clarify the regulatory frameworks for personal protective equipment and

[186] IL POST (M. ALPOZZI), *Chi si era messo a fare mascherine in Italia ora ha un bel problema*, in *Il Post*, 23.02.2023. Available at: https://www.ilpost.it/2023/02/23/industria-italiana-mascherine-crisi/ (last access: 12.02.2025)

medical devices – albeit with some critical points that have led to confusion, but given the complexity of the discipline it was inevitable that this might happen –.

The study also showed how the changes in regulatory framework had to come to terms with the weaknesses of the global supply chain model, and in particular with the concentration of manufacturing activities in a few countries, a circumstance that gave rise, on the one hand, to the proliferation of a parallel market (of counterfeiting), and on the other hand to the development of technological innovations (such as 3D-printed PPE and PPE made of reusable materials) and the adaptability of companies (companies that converted production to the manufacture of masks).

From a juridical point of view, one of the aspects that most struck the author (positively) was the effectiveness of emergency decrees through the instrument of the decree-law, which is also of particular relevance considering the subject of the doctoral course (Civil Law and Constitutional Legality). Effectively, the decree-law – which will soon be 100 years old, having been established by Law no. 100 of 31 May 1926 – finds constitutional legitimacy in Article 77 of the Italian Constitution, and so represents a perfect example of a rule – even if in the case at issue in this thesis of public law rather than civil law – that fits in harmoniously with the constitutional rules. Finally, along the same lines, it seems legitimate for the author to argue that the experience of the pandemic has shown how necessary it is to have a flexible and, at the same time, sustainable regulatory framework, i.e. one that itself will be able to resist emergencies without losing its attention to norms of the basic law. Thus, comprehensively, it would seem appropriate for integrated reconsideration of European and national regulatory acts to be conducted to allow the derogations to be granted only for a restricted term and to return as soon as possible.

6.6 Policy recommendations

On the basis of what emerged from the study, the author believes he can identify some useful recommendations for the management of emergency situations similar to the one studied in this thesis.

First, regulatory bodies should consider streamlining frameworks to increase clarity and efficiency. This would help in the simplification of the current dual categorization of personal protective equipment and medical devices – useful and necessary, but potentially responsible of confusion and misinterpretations – in order to avoid confusion and increase the speed of response during emergencies.

Secondly, governments should probably encourage domestic production while promoting international cooperation in order to avoid reliance on centralized production hubs. In doing so, in fact, the problem of dependence on foreign states in the supply of PPE would be prevented at the root (Italy, moreover, has amply demonstrated that it can successfully meet this challenge). Also, advanced manufacturing technologies (such as 3D printing) could be incorporated into the national emergency preparedness plans, because this would enable the scaling up of PPE production during emergencies.

Third, PPE production should also consider the environmental as one of the priorities. In order to do so, policymakers should support the research and development, the promotion, and the use of biodegradable and reusable PPE (through funding, tax incentives, and partnership between the public and private sectors). Also, regulations that address the proper disposal of used single-use PPE should be put in place to minimize the impact on the environment, and public awareness campaigns should not only educate

people on how to use PPE correctly, but also on the need to share it fairly, thus fostering togetherness.

Finally, governments should include PPE strategies in their overall public health and occupational safety plans, since preventive and control interventions that combine education, training, and infrastructure development can probably result in a sustained use of safety measures.

6.7 Future research directions

In the author's opinion, future work should focus mainly on the innovation in the PPE technology to meet the new challenges posed by future (probable) pandemics. This could be done through the collaboration of engineering, material science, and healthcare professionals in order to develop a new generation of smart, technological, and "intelligent" PPE. Let's think, for example, of a mask capable of detecting viruses in the air and notifying the mobile phone. It may sound like science fiction, but a group from Tongji University in Shanghai has developed just such a mask[187]. Why is it not possible to imagine a future in which all PPEs are so technologized, perhaps even with integration with AI systems?

Another area of research should be represented by environmental impact assessments, with the purpose of designing PPE that respond effectively with the principles of the so-called "circular economy".

A third field that should be studied is constituted by the psychological and social aspects of PPE use. With the aid of social sciences, in fact, we should look into the perceptions and practices of the public with regards to the use of PPE, exploring the barriers to adherence and the possibilities for

[187] B. WANG, D. YANG, Z. CHANG, R. ZHANG, J. DAI, Y. FANG, *Wearable bioelectronic masks for wireless detection of respiratory infectious diseases by gaseous media*, in *Matter*, 2022, 5(12), pp. 4347-4362

enhancement. Such an activity could probably lead to implement effective education campaigns and interventions that could be very effective in the event of a new pandemic.

FIGURE REFERENCES

Figure 1.

Image provided by Shutterstock, entitled *"Size comparison between germ, pm 2.5 (microscopic aerosol droplet created by a cough), Coronavirus (COVID-19 virus), Streptococcus bacteria, and Bacteriophage"*. Author: Designua. The writer of this thesis holds the standard licence to reproduce the image.

Figure 2.

Image provided by Shutterstock, entitled *"The comparison of how diseases spread around the world and how it call as Endemic, Epidemic and Pandemic"*. Author: M. PATTHAWEE. The writer of this thesis holds the standard licence to reproduce the image.

Figure 3.

Image provided by Shutterstock, entitled *"Airborne disease. Virus human-to-human transmission. contamination and ways of infection with viruses: airborne, droplet, and Aerosol form. poster about Virus pandemic transfer. Infographic"*. Author: Designua. The writer of this thesis holds the standard licence to reproduce the image.

Figure 4.

Image provided by Shutterstock, entitled *"Comparison of different type face masks. Vector set of N95, surgical and fashion medical masks. Range of virus protection masks"*. Author: Topuria Design. The writer of this thesis holds the standard licence to reproduce the image.

Figure 5.

Image reproduced from *"Katre, P., Banerjee, S., Balusamy, S., & Sahu, K. C. (2021). Fluid dynamics of respiratory droplets in the context of COVID-19: Airborne and surfaceborne transmissions. Physics of Fluids, 33(8)"* with the permission of AIP Publishing.

Figure 6.

Image created by the thesis writer using the Power Point programme.

Figure 7.

Graph realised via the website "https://ourworldindata.org/covid-cases", with data source represented by WHO COVID-19 Dashboard

LEGAL AND REGULATORY REFERENCES

Article 288 (ex-Article 249 TEC), in the consolidated version of the Treaty on the Functioning of the European Union, OJ C 326, 26.10.2012, p. 171-172. Available at: http://data.europa.eu/eli/treaty/tfeu_2012/art_288/oj (last access: 10.02.2025)

CE, 28 juin 1918, Heyriès, req. n° 63412. Available at: https://www.conseil-etat.fr/fr/arianeweb/CE/decision/1918-06-28/63412 (last access: 10.02.2025)

Council Directive no. 89/686/EEC, 21 December 1989, in OJEC L 399, 30.12.1989, pp. 18-38

Decision no. 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC

Decree-law no. 9 of 2 March 2020, "Urgent measures to support families, workers, and businesses affected by the epidemiological emergency caused by COVID-19" (Gazzetta Ufficiale, No. 53, 2 March 2020)

Decree-law no. 18 of 17 March 2020, "Measures to strengthen the National Health Service and provide economic support for families, workers, and businesses related to the COVID-19 emergency" (Gazzetta Ufficiale, no. 70, 17 March 2020)

Decree-law no. 52 of 22 April 2021, "Urgent measures for the gradual resumption of economic and social activities while respecting the need to contain the spread of the COVID-19 epidemic" (Gazzetta Ufficiale, no. 96, 22 April 2021)

Directive, C. (1993). Council Directive 93/42/EEC of 14 June 1993 concerning medical devices. Official Journal L, 169(12/07), 0001-0043

Italian Ministry of Health, Circular No. 3572 of March 18, 2020

Italian Ministry of Economic Development (MISE), Circular No. 107886 of April 23, 2020

Law no. 689 of 24 November 1981, "Amendments to the penal system" (Gazzetta Ufficiale, no. 329, 30 November 1981)

Law no. 100 of 31 January 1926, "Provisions on the organization of the Government and the central administration" (Gazzetta Ufficiale, No. 26, 2 February 1926)

Law no. 87 of 17 June 2021, "Conversion into law, with modifications, of decree-law No. 52 of 22 April 2021, providing urgent measures for the gradual resumption of economic and social activities while respecting the need to contain the spread of the COVID-19 epidemic" (Gazzetta Ufficiale, No. 146, 21 June 2021)

Legislative Decree 4 December 1992, no. 475, adjusting national legislation to the provisions of Regulation (EU) no. 2016/425 of the European

Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC

Legislative Decree no. 17 of 19 February 2019, "Adaptation of national legislation to the provisions of Regulation (EU) No 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC" (Gazzetta Ufficiale no. 59, 11 March 2019)

Occupational Health and Environmental Safety Division. (1995, August). Regulation update – 42 CFR 84 (Number 18)

Recommendation, C. (2020). Commission Recommendation (EU) 2020/403 of 13 March 2020 on conformity assessment and market surveillance procedures within the context of the COVID-19 threat. Official Journal L, 77(16/03), 0001-0009

Regulation, E.U. (2008). Regulation (EC) No 765/2008 of 9 July 2008 on the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93. Official Journal L, 218(13/08), 0030-0047

Regulation, E.U. (2017). Regulation (EU) No 2017/745 of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC. Official Journal L, 117(05/05), 0001-0175

Regulation, E.U. (2020). Regulation (EU) 2020/561 of 23 April 2020 amending Regulation (EU) 2017/745 on medical devices as regards the dates of application of certain of its provisions. Official Journal L, 130(24/04), 0018-0024

United States Department of the Interior – Bureau of Mines. 30 CFR Part 14 Filter-Type Dust, Fume, and Mist, Proposed Rulemaking, Federal Register Wednesday October 7, 1964, pages 13822–13827

United States Department of the Interior – Bureau of Mines. Procedures for Testing Filter-Type Dust, Fume, Mist Respirators for Permissibility, 30 CFR PART 14 - Filter Type, Dust, Fume, and Mist Respirators, Schedule 21B, 19 June 1969

United States. (1969). Coal Mine Safety and Health Act of 1969 (Public Law 91–173, December 31, 1969)

United States. (1970). Williams-Steiger Occupational Safety and Health Act (OSH Act) of 1970. Public Law 91-596, December 29, 1970

SITOGRAPHY

Note: this section includes references for data obtained from internet pages and articles published in online newspapers.

ABOUTPHARMA, *La lunga storia delle mascherine: da quelle a becco a quelle filtranti*, 16.04.2021. Available at: https://www.aboutpharma.com/scienza-ricerca/la-lunga-storia-delle-mascherine-da-quelle-a-becco-alle-filtranti/ (last access: 03.02.2025)

ALLIANCE FOR INTEGRITY, *Fighting Counterfeit Medicines and PPE in Times of Covid-19*. Available at: https://www.allianceforintegrity.org/wAssets/docs/learnings/Fighting-Counterfeit-Medicines-and-PPE-in-Times-of-Covid-19.pdf (last access: 01.02.2025)

BBC NEWS (P. KEMP), *Covid: One million masks for NHS fail high-grade safety tests*, 28.07.2021. Available at: https://www.bbc.com/news/uk-57999162 (last access: 28.01.2025)

CEN, European Committee for Standardization EN 149:2001+A1:2009, Respiratory protective devices-Filtering half masks to protect against particles-Requirements, testing, marking. [(accessed on 1 September 2022)]. European Committee for Standardization 1–44 (2009) Available at: https://standards.iteh.ai/catalog/standards/cen/f440f60a-91c1-497b-815e-4e9d46436256/en-149-2001a1-2009 (last access: 24.02.2024)

CEN, European Committee for Standardization EN 14683:2019+AC:2019, Medical face masks-requirements and test methods. [(accessed on 1 September 2022)]. European Committee for Standardization 1–23 (2019) Available at: https://standards.iteh.ai/catalog/standards/cen/4bdef56d-7660-4a66-ba96-8e287fbc7d8c/en-14683-2019ac-2019 (last access: 24.02.2024)

CENTERS FOR DISEASE CONTROL AND PREVENTION, *Milestones in Respiratory Protection*. Available at: https://www.cdc.gov/niosh/npptl/pdfs/n95-timeline-508.pdf (last access: 28.01.2025)

COMITATO NAZIONALE PER LA BIOETICA, *I documenti del CNB sul COVID-19*, Mag 2021. Available at: https://bioetica.governo.it/media/4231/documenti-cnb-sul-covid-19_ita.pdf?utm (last access: 04.02.2025)

EUCRIM (T. WAHL), *OLAF Investigation into Fake COVID-19 Related Products*, 01.04.2020. Available at: https://eucrim.eu/news/olaf-investigation-fake-covid-19-related-products/ (last access: 28.01.2025)

EUROPOL, *Corona crimes: multi-million face mask scam foiled by police across Europe*. Available at: https://www.europol.europa.eu/media-press/newsroom/news/corona-crimes-multi-million-face-mask-scam-foiled-police-across-europe (last access: 28.01.2025)

EUROSTAT NEWS, EUROPEAN UNION, *Which Country Imported the Most Face Masks?* Available at: https://ec.europa.eu/eurostat/web/products-eurostat-news/-/ddn-20201006-1 (last access: 01.02.2024)

IL FATTO QUOTIDIANO, *Coronavirus, l'emergenza sulle mascherine diventa business: sequestri in tutta Italia. A ditta privata quelle destinate a un ospedale*, 09.04.2020. Available at: https://www.ilfattoquotidiano.it/2020/04/09/coronavirus-lemergenza-sulle-mascherine-diventa-business-sequestri-in-tutta-italia-a-ditta-privata-quelle-destinate-a-un-ospedale/5765071/ (last access: 28.01.2025)

IL POST (M. ALPOZZI), *Chi si era messo a fare mascherine in Italia ora ha un bel problema*, in *Il Post*, 23.02.2023. Available at: https://www.ilpost.it/2023/02/23/industria-italiana-mascherine-crisi/ (last access: 12.02.2025)

IL SOLE 24 ORE, *Mascherine, Italia Spa: ecco tutte le aziende in pista e i volumi di produzione*, 30.03.2020. Available at: https://www.ilsole24ore.com/art/mascherine-italia-spa-ecco-tutte-aziende-pista-e-volumi-produzione-ADHvCuG (last access: 11.09.2024)

IL SOLE 24 ORE (A. CARLI), *Da Miroglio a Menarini: Fabbriche che si riconvertono contro il coronavirus*, 31.03.2020. Available at: https://www.ilsole24ore.com/art/da-miroglio-menarini-fabbriche-che-si-riconvertono-contro-coronavirus-ADLIFdD (last access: 09.09.2024)

IL SOLE 24 ORE (P. MACIOCCHI), *Frode in commercio per le mascherine FFP2 con falso marchio CE e prive di requisiti*, 12.02.2021. Available at https://www.ilsole24ore.com/art/frode-commercio-le-mascherine-ffp2-falso-marchio-ce-e-prive-requisiti-AD8chbJB (last access: 12.02.2025)

INAIL. *Report delle attività di validazione straordinaria dei dispositivi di protezione individuale*, 5 Apr. 2020. Available at: https://www.certifico.com/component/attachments/download/17308 (last access: 20.09.2024)

INAIL. *Report delle attività di validazione straordinaria dei dispositivi di protezione individuale. Report delle attività aggiornato al 4 maggio 2020*. Available at: https://www.certifico.com/component/attachments/download/17706 (last access: 20.09.2024)

ISTITUTO SUPERIORE DI SANITÀ – PREVENZIONE E CONTROLLO DELLE INFEZIONI, *Indicazioni ad interim per un utilizzo razionale delle protezioni per infezione da SARS-CoV2 nelle attività sanitarie e socio-sanitarie (assistenza a soggetti affetti da COVID-19) nell'attuale scenario emergenziale SARS-CoV2*, 14 Mar. 2020. Available at: https://www.sigg.it/wp-content/uploads/2020/03/MIN-SAL-INDICAZIONI-AD-INTERIM.pdf (last access: 09.09.2024)

ISTITUTO SUPERIORE DI SANITÀ (O. PUNZO, A. BELLA, F. RICCARDO, P. PEZZOTTI, F.P. D'ANCONA), *Tutto sulla pandemia di SARS-CoV-2*, in *Epicentro*. Available at: https://www.epicentro.iss.it/coronavirus/sars-cov-2 (last access: 28.01.2025)

LAB24, *La storia del coronavirus*, Il Sole 24 Ore. Available at: https://lab24.ilsole24ore.com/storia-coronavirus/ (last access: 28.01.2025)

LINKEDIN (S. LOPATIN), *How the CDC's Mask Messaging Went Wrong*, 30.07.2021. Available at: https://www.linkedin.com/pulse/how-cdcs-mask-messaging-went-wrong-shari-lopatin (last access: 29.01.2025)

NBC NEWS (B. POPKEN), *Coronavirus mask mania spurs internet's gray markets into action*, 9.03.2020. Available at: https://www.nbcnews.com/tech/social-media/coronavirus-mask-mania-spurs-internet-s-grey-markets-action-n1153426 (last access: 29.01.2025)

NEGRI BOSSI, *Producing COVID-19 Masks*, in *Negri Bossi Official Website*. 2020. Available at: https://www.negribossi.com/producing-covid-19-masks/ (last access: 28.01.2025)

OECD PUBLISHING, *Illicit Trade in a Time of Crisis. Chair's Summary Note*, 23.04.2020. Available at: https://one.oecd.org/document/GOV/PGC/HLRF/TFCIT(2020)3/En/pdf (last access: 29.01.2025)

OECD PUBLISHING, *Illicit trade in fakes under the COVID-19*, 04.04.2024. Available at: https://doi.org/10.1787/0c475a23-en (last access: 28.09.2024)

OSHA TECHNICAL MANUAL (OTM) – Section VIII: Chapter 2: *Respiratory Protection – Occupational Safety and Health Administration*. Available at: https://web.archive.org/web/20200328071605/https://www.osha.gov/dts/osta/otm/otm_viii/otm_viii_2.html#2 (last access: 21.01.2024)

PINKERTON, *Identifying and Combating Counterfeit PPE How to identify potentially counterfeit goods, avoid PPE scammers, and protect employees and businesses*. Available at: https://pinkerton.com/our-insights/blog/identifying-and-combating-counterfeit-ppe (last access: 01.02.2025)

LA REPUBBLICA (R. CAPPELLI) *COVID, false mascherine in ospedale: "Non proteggono, riportatele"*, 10.04.2021. Available at: https://roma.repubblica.it/cronaca/2021/04/10/news/roma_covid_false_mascherine_in_ospedale_non_proteggono_riportatele_-295762133/ (last access: 12.02.2025)

REUTERS, *Fact check: False and misleading information in post listing 'dangers' of face masks*. Available at: https://www.reuters.com/article/world/fact-check-false-and-misleading-information-in-post-listing-dangers-of-face-m-idUSKBN24333B/ (last access: 04.02.2025)

THE CONVERSATION (S. PARK), *The global effort to tackle the coronavirus face mask shortage*, 17.03.2020. Available at: https://theconversation.com/the-global-effort-to-tackle-the-coronavirus-face-mask-shortage-133656 (last access: 21.09.2024)

THE FUTURE OF COMMERCE, *Lessons learned: How B2B industries tackled COVID challenges and won*. Available at: https://www.the-future-of-commerce.com/2021/09/02/how-b2b-industries-tackled-covid-challenges/ (last access: 11.02.2025)

THE NEW YORK TIMES, *China Dominates the Market for Medical Face Masks, but Some Countries Can't Depend on It*, in *The New York Times*, 13 March 2020. Available at: https://www.nytimes.com/2020/03/13/business/masks-china-coronavirus.html (last access: 25.01.2025)

UNC SCHOOL OF INFORMATION AND LIBRARY SCIENCE (Z. TUFEKCI), *Why Telling People They Didn't Need Masks Backfired,* 17.03.2020. Available at: https://sils.unc.edu/news/zeynep-tufekci-why-telling-people-they-didnt-need-masks-backfired/ (last access: 04.02.2025)

UNIDO, *Webinar on Personal Protective Equipment (PPE): Bridging the Standardisation Gap*, in *UNIDO Official Website*. 2020. Available at: https://hub.unido.org/event/webinar-personal-protective-equipment-ppe-bridging-standardisation-gap (last access: 28.01.2025)

VOGUE ITALIA (I. PANTANO), *Mascherine antivirus e moda: Gucci, Prada e le altre maison in prima linea nella produzione*, 30.03.2020. Available at: https://www.vogue.it/moda/article/mascherine-antivirus-moda-produzione-gucci-prada (last access: 28.012025)

WEBINTERPRET BLOG, *Coronavirus eCommerce Checklist for eBay and Amazon: 10 Tips to Help You Sell During the COVID-19 Pandemic*. Available at: https://www.webinterpret.com/uk/blog/coronavirus-ecommerce-checklist-ebay-amazon (last access: 21.09.2024)

WHO, *Pneumonia of unknown cause – China*. Available at: https://www.who.int/emergencies/disease-outbreak-news/item/2020-DON229 (last access: 28.01.2025)

WHO, *Shortage of personal protective equipment endangering health workers worldwide*, 3 Mar 2020. Available at: https://www.who.int/news/item/03-03-2020-shortage-of-personal-protective-equipment-endangering-health-workers-worldwide (last access: 04.02.2025)

WORLD ECONOMIC FORUM, *From perfume to hand sanitiser, TVs to face masks: How companies are changing track to fight COVID-19*, in *World Economic Forum*. 24 mar 2020. Available at: https://www.weforum.org/agenda/2020/03/from-perfume-to-hand-sanitiser-tvs-to-face-masks-how-companies-are-changing-track-to-fight-covid-19/ (last access: 19.09.2024)

WORLD ECONOMIC FORUM, *Panic buying of face masks and other supplies puts healthcare workers at risk, says WHO*. 9 mar 2020. Available at: https://www.weforum.org/stories/2020/03/stop-buying-facemasks-and-other-medical-supplies-urges-who-officials/ (last access: 29.01.2025)

WORLD ECONOMIC FORUM (V. VECCHI, N. CUSUMANO), *COVID-19: lessons from Italy on public-private healthcare procurement*, in *World Economic Forum*, 12.05.2020

BIBLIOGRAPHY

AGARWAL R., *The personal protective equipment fabricated via 3D printing technology during COVID-19*, in *Ann. 3D Print. Med.*, 2022, 5, p. 100042

ALI TAHA V., PENCARELLI T., ŠKERHÁKOVÁ V., FEDORKO D., KOŠÍKOVÁ L., *The use of social media and its impact on shopping behavior of Slovak and Italian consumers during COVID-19 pandemic*, in *Sustainability*, 2021, 13(4), p. 1710

ANDREWS A.S., POWERS J.R., CICHOWICZ J.K., COFFEY C.C., FRIES M.L., YORIO P.L., D'ALESSANDRO M.M., *Respiratory protection in a time of crisis: NIOSH testing of international respiratory protective devices for emergency use*, in *Health Secur.*, 2021, 19(4), p. 379-385

ANTONELLI G., CLEMENTI M., POZZI G., ROSSOLINI G., *Principi di microbiologia medica*, quarta edizione, Casa Editrice Ambrosiana, 2022

ARPEA G., *Maschere DM, DPI e per la collettività: disciplina e deroga COVID-19*, in *Ius in itinere*, 26 marzo 2020. Available at: https://www.iusinitinere.it/maschere-dm-dpi-e-per-la-collettivita-disciplina-e-deroga-covid-19-31659 (last access: 16.09.2024)

ATHER B., MIRZA T.M., EDEMEKONG P.F., *Airborne precautions*, in StatPearls [Internet], Treasure Island (FL), StatPearls Publishing, 2025, updated to 13 March 2023

BARTKOWIAK G., BASZCZYŃSKI K., BOGDAN A., BROCHOCKA A., HRYNYK R., IRZMAŃSKA E., ... ŻERA J., *Use of personal protective equipment in the workplace*, in *Handbook of human factors and ergonomics*, 2012, p. 895 ss

BELFORD A., CERNIAUSKAS S., CIVILLINI M., WESTERBERG O., *Questionable Paperwork Lets Fake and Faulty Masks Flood Europe*, in *Organized Crime and Corruption Reporting Project*. Available at: https://www.occrp.org/en/project/crime-corruption-and-coronavirus/questionable-paperwork-lets-fake-and-faulty-masks-flood-europe (last access: 28.01.2025)

BERGEN M., DUTTA S., *The N95 Mask for Pricing: Making Pricing Safer for Customers, Companies and Society*, Carlson School of Management, University of Minnesota. 2020 Jun 24. Available at: https://carlsonschool.umn.edu/news/n95-mask-pricing-making-pricing-safer-customers-companies-and-society (last access: 28.01.2025)

BERNARDO J., *Tuberculosis: A disease of the 1990s*, in *Hosp. Pract.*, 1991, 26(10), p. 195-222

BEZZINI D., SCHIAVETTI I., MANACORDA T., FRANZONE G., BATTAGLIA M.A., *First wave of COVID-19 pandemic in Italy: data and evidence*, in *Coronavirus Therapeutics–Volume II: Clinical Management and Public Health*, Cham, Springer International Publishing, 2022, pp. 91-113

BLAKELY B., ROGERS W., JOHNSON J., GRUNDY Q., HUTCHISON K., CLAY-WILLIAMS R., ... MADDERN G., *Ethical and regulatory implications of the COVID-*

19 pandemic for the medical devices industry and its representatives, in *BMC Med. Ethics*, 2022, 23(1), p. 31

BOSA I., CASTELLI A., CASTELLI M., CIANI O., COMPAGNI A., GALIZZI M.M., VAINIERI M., *Response to COVID-19: was Italy (un)prepared?*, in *Health Economics, Policy and Law*, 2022, 17(1), pp. 1-13

BOWN C.P., *How COVID-19 medical supply shortages led to extraordinary trade and industrial policy*, in *Asian Economic Policy Review*, 2022, 17(1), pp. 114-135

CERULLO S., *Cura Italia: Italy's Covid-19 Emergency Decree*, in *PAF9181 Spring 2020 Blog. Baruch College*. Available at: https://blogs.baruch.cuny.edu/paf9181spring2020/?p=251 (last access: 19.09.2024)

CITONI G., DE MATTEIS D., GIANNONI M., *Disuguaglianze socioeconomiche in salute, equità nell'accesso e nel finanziamento dei servizi sanitari in Italia: quale evoluzione in tempi di SARS-COV-2?*, in *Sistema Salute*, 2020, 64(3), pp. 204-221

COHEN J., VAN DER MEULEN RODGERS Y., *Contributing factors to personal protective equipment shortages during the COVID-19 pandemic*, in *Preventive Medicine*, 2020, 141, p. 106263

CONTE M.P., MASTROMARINO P., *Microbiologia Medica. Batteriologia e Virologia*, Società Editrice Esculapio, 2019

COOK T.M., *Personal protective equipment during the coronavirus disease (COVID) 2019 pandemic – a narrative review*, in *Anaesthesia*, 2020, 75(7), pp. 920-927

DING A.W., LI S., *National response strategies and marketing innovations during the COVID-19 pandemic*, in *Bus. Horiz.*, 2021, 64(2), pp. 295-306

DROUARD S.H.P., AHMED T., AMOR FERNANDEZ P., BARAL P., PETERS M., HANSEN P., SHAPIRA G., *Availability and use of personal protective equipment in low- and middle-income countries during the COVID-19 pandemic*, in *PLOS ONE*, 2023, 18(7), p. e0288465

EMANUEL E.J., PERSAD G., UPSHUR R., THOME B., PARKER M., GLICKMAN A., PHILLIPS J.P., *Fair allocation of scarce medical resources in the time of Covid-19*, in *N. Engl. J. Med.*, 2020, 382(21), p. 2049-2055

FANTINI M.P., DALLOLIO L., FABBRI G., BRAVI F., *Igiene e Sanità Pubblica*, Società Editrice Esculapio, 2020

FIORAVANTI M., *Lo statuto albertino*, in *Dallo statuto albertino alla costituzione repubblicana*, in *Atti del seminario, Roma, palazzo della Consulta, 25 novembre 2011*, Giuffrè, 2012, pp. 19-38

GANDHI J.A., CHURIWALA J.J., SHINDE P.H., CHAUDHARI S.N., *Surgical Mask–the Saviour: from its Invention to the COVID-19 Era*, in *Indian J. Surg.*, 2020, 82, p. 278-279

GULLÌ B., *The sovereign exception: Notes on Schmitt's word that sovereign is he who decides on the exception*, in *Glossator: Practice & Theory of the Commentary*, 2009, 1

HABE H., SCHULTZ H., *Untersuchungen über Operationsschleier*, in *Chirurg.*, 1937, 9, p. 289-291

HOY R.F., CHAMBERS D.C., *Silica-related diseases in the modern world*, in *Allergy*, 2020, 75(11), p. 2805-2817

IPPOLITO M., GREGORETTI C., CORTEGIANI A., IOZZO P., *Counterfeit filtering facepiece respirators are posing an additional risk to health care workers during COVID-19 pandemic*, in *Am. J. Infect. Control*, 2020, 48(7), p. 853

JAIN U., *Risk of COVID-19 due to shortage of personal protective equipment*, in *Cureus*, 2020, 12(6)

JANSEN L.A., *Medical beneficence, nonmaleficence, and patients' well-being*, in *J. Clin. Ethics*, 2022, 33(1), pp. 23-28

JEFFREY D.I., *Relational ethical approaches to the COVID-19 pandemic*, in *J. Med. Ethics*, 2020, 46(8), pp. 495-498

JIANG H., LUO D., WANG L., ZHANG Y., WANG H., WANG C., *A review of disposable facemasks during the COVID-19 pandemic: a focus on microplastics release*, in *Chemosphere*, 2023, 312, p. 137178

JOAG S., *Impact of COVID-19 Pandemic on Marketing of Education*, in *J. Glob. Awareness*, 2023, 4(2), pp. 1-14

JU J.T., BOISVERT L.N., ZUO Y.Y., *Face masks against COVID-19: Standards, efficacy, testing and decontamination methods*, in *Adv. Colloid Interface Sci.*, 2021, 292, p. 102435

KARIM N., AFROJ S., LLOYD K., OATEN L.C., ANDREEVA D.V., CARR C., ... NOVOSELOV K.S., *Sustainable personal protective clothing for healthcare applications: a review*, in *ACS Nano*, 2020, 14(10), pp. 12313-12340

KATRE P., BANERJEE S., BALUSAMY S., SAHU K.C., *Fluid dynamics of respiratory droplets in the context of COVID-19: Airborne and surfaceborne transmissions*, in *Phys. Fluids*, 2021, 33(8)

KLEINSCHMIDT O., *Allgemeiner Teil*, in *Operative Chirurgie*, Berlin, Springer, 1943, p. 12-13

LAM S.C., SUEN L.K.P., CHEUNG T.C.C., *Global risk to the community and clinical setting: flocking of fake masks and protective gears during the COVID-19 pandemic*, in *Am. J. Infect. Control*, 2020, 48(8), pp. 964-965

LATINI C., *Emergenze e democrazia: alcune riflessioni in prospettiva comparata*, in *Solidarietà ed emergenze*, Editoriale Scientifica, 2022, pp. 7-16

LATINI, C. *La regola e l'eccezione. Necessità ed emergenza tra passato e presente*, in *Iurisdictio*, 2023, pp. 1-14

LAZZERI F., *Speculazioni nella vendita di mascherine: ristretti i confini dell'art. 501-bis c.p., interpretato dalla Cassazione come reato di pericolo concreto, si apre la strada alle sanzioni AGCM*, in *Sistema Penale*. Available at:

https://www.sistemapenale.it/it/scheda/lazzeri-nota-cassazione-36929-2020-speculazioni-mascherine-501-bis-sanzioni-agcm (last access: 12.02.2025)

LE A.B., SHKEMBI A., TADEE A., STURGIS A.C., GIBBS S.G., NEITZEL R.L., *Characterization of perceived biohazard exposures, personal protective equipment, and training resources among a sample of formal US solid waste workers: A pilot study*, in *J. Occup. Environ. Hyg.*, 2023, 20(3-4), pp. 129-135

LIANG M., GAO L., CHENG C., ZHOU Q., UY J.P., HEINER K., SUN C., *Efficacy of face mask in preventing respiratory virus transmission: A systematic review and meta-analysis*, in *Travel Med. Infect. Dis.*, 2020, 36, p. 101751

LYU L., BAGCHI M., MARKOGLOU N., AN C., *Innovations and development of sustainable personal protective equipment: a path to a greener future*, in *Environ. Syst. Res.*, 2024, 13(1), p. 22

MÁRQUEZ-SÁNCHEZ S., CAMPERO-JURADO I., HERRERA-SANTOS J., RODRÍGUEZ S., CORCHADO J.M., *Intelligent platform based on smart PPE for safety in workplaces*, in *Sensors*, 2021, 21(14), p. 4652

MARTIN J., BACCARANI C., *Some thoughts on Covid-19 communication transparency*. Available at: https://sites.les.univr.it/eisic/wp-content/uploads/2020/04/2_SOME_THOUGHTS_Martin_Baccarani.pdf (last access: 29.01.2025)

MATUSCHEK C., MOLL F., FANGERAU H., FISCHER J.C., ZÄNKER K., VAN GRIENSVEN M., HAUSSMANN J., *The history and value of face masks*, in *Eur. J. Med. Res.*, 2020, 25, p. 1-6

MAZAHIR F.A., AL QAMARI A.M., *Personal protective equipment (PPE) and plastic pollution during COVID-19: strategies for a sustainable environment*, in *Rev. Environ. Health*, 2022, 37(3), pp. 321-325

MCDOUGALL R.J., GILLAM L., KO D., HOLMES I., DELANY C., *Balancing health worker well-being and duty to care: an ethical approach to staff safety in COVID-19 and beyond*, in *J. Med. Ethics*, 2021, 47(5), pp. 318-323

MEHROTRA P., MALANI P., YADAV P., *Personal protective equipment shortages during COVID-19 –supply chain–related causes and mitigation strategies*, in *JAMA Health Forum*, 2020, I(5), p. e200553

MICHALEAS S.N., LAIOS K., KARAMANOU M., SIPSAS N.V., ANDROUTSOS G., *The Manchurian pandemic of pneumonic plague (1910–1911)*, in *Le Infezioni in Med.*, 2022, 30(3), p. 464

O'SULLIVAN L., ALDASORO E., O'BRIEN Á., NOLAN M., MCGOVERN C., CARROLL Á., *Ethical values and principles to guide the fair allocation of resources in response to a pandemic: a rapid systematic review*, in *BMC Medical Ethics*, 2022, 23(1), p. 70

OGBUOJI E.A., ZAKY A.M., ESCOBAR I.C., *Advanced research and development of face masks and respirators pre and post the coronavirus disease 2019 (COVID-19) pandemic: A critical review*, in *Polymers*, 2021, 13(12), p. 1998

PAJEL A., *Using PPE correctly and safely*, in *Kai Tiaki Nurs. N. Z.*, 2020, 26(9), pp. 26-28

PALMIERI V., DE MAIO F., DE SPIRITO M., PAPI M., *Face masks and nanotechnology: Keep the blue side up*, in *Nano Today*, 2021, 37, p. 101077

PARK C.Y., KIM K., ROTH S., BECK S., KANG J.W., TAYAG M.C., *Global shortage of personal protective equipment amid COVID-19: supply chains, bottlenecks, and policy implications*, in *Future Reg. Coop. Asia Pac.*, 2020, 442

PEARCE S.J., *A Discussion of the Bureau of Mines Approval Schedules for Respiratory Protective Devices*, in *Am. Ind. Hyg. Assoc. J.*, 1958, 19(2), p. 126–129

PIRET J., BOIVIN G., *Pandemics throughout history*, in *Front. Microbiol.*, 2021, 11, p. 631736

PRATA J.C., PAÇO A., REIS V., DA COSTA J.P., FERNANDES A.J.S., DA COSTA F.M., ... ROCHA-SANTOS T., *Identification of microplastics in white wines capped with polyethylene stoppers using micro-Raman spectroscopy*, in *Food Chem.*, 2020, 331, p. 127323

PRIYANKA S.S., LOKESWARI N., AMARAVATHI K., *Blockchain – a potential solution for COVID-19 pandemic economical crisis environment*, in *Int. J. Res. Eng. Sci. Manag.*, 2020, 3, pp. 17-21

PROFFITT E., *The dangers of fake PPE*, in *Bdj Team*, 2020, 7(8), pp. 20-21

RICCIARDI W., ANGELILLO I.F., BOCCIA S., BRUNO S., BRUSAFERRO S., BUCCI R. ..., VILLARI P., *Igiene, Medicina Preventiva, Sanità Pubblica*, seconda edizione, Idelson-Gnocchi, 2013, pp. 1-965

ROMANO S., *Sui decreti-legge e lo stato di assedio in occasione del terremoto di Messina e di Reggio-Calabria*, in *Rivista di diritto pubblico*, 1909

SANTERAMO F.G., TAPPI M., LAMONACA E., *On the management of COVID-19 pandemic in Italy*, in *Health Policy*, 2021, 125(8), pp. 995-1001

SANTOKI A.A., PAREKH M.H., *Marketing strategies during COVID-19*, in *J. Crit. Rev.*, 2020, 7(11), pp. 4040-4045

SHI J., LI H., XU F., TAO X., *Materials in advanced design of personal protective equipment: a review*, in *Mater. Today Adv.*, 2021, 12, p. 100171

SINGH N., TANG Y., OGUNSEITAN O.A., *Environmentally sustainable management of used personal protective equipment*, in *Environ. Sci. Technol.*, 2020, 54(14), pp. 8500-8502

SINHA M.S., BOURGEOIS F.T., SORGER P.K., *Personal protective equipment for COVID-19: distributed fabrication and additive manufacturing*, in *Am. J. Public Health*, 2020, 110(8), pp. 1162-1164

SPECCHIA M.C., *Le fonti dell'emergenza nella crisi pandemica. Riflessioni di sintesi*, in *DPCE Online*, 2021, 50(Sp). Available at: https://www.dpceonline.it/index.php/dpceonline/article/view/1554 (last access: 11.02.2025)

SPELCE D., REHAK T.R., METZLER R.W., JOHNSON J.S. *Pre-World War I firefighter respirators and the US Bureau of Mines involvement in WWI*, in *J. Int. Soc. Respir. Prot.*, 2017, 34(2), p. 128

SPELCE D., REHAK T.R., METZLER R.W., JOHNSON J.S., *History of U.S. Respirator Approval*, in *J. Int. Soc. Respir. Prot.*, 2018, 35(1), pp. 35-46

SWENNEN G.R., POTTEL L., HAERS P.E., *Custom-made 3D-printed face masks in case of pandemic crisis situations with a lack of commercially available FFP2/3 masks*, in *Int. J. Oral Maxillofac. Surg.*, 2020, 49(5), pp. 673-677

SZCZECIŃSKA K., ŁĘŻAK K., *Review of research studies of ergonomic aspects of selected personal protective equipment*, in *Int. J. Occup. Saf. Ergon.*, 2000, 6(sup1), pp. 143-151

TCHARKHTCHI A., ABBASNEZHAD N., SEYDANI M.Z., ZIRAK N., FARZANEH S., SHIRINBAYAN M., *An overview of filtration efficiency through the masks: Mechanisms of the aerosols penetration*, in *Bioact. Mater.*, 2021, 6(1), pp. 106-122

TESSAROLO F., NOLLO G., MANIGLIO D., RIGONI M., BENEDETTI L., HELFER F., PAONE N., *Testing surgical face masks in an emergency context: the experience of Italian laboratories during the COVID-19 pandemic crisis*, in *Int. J. Environ. Res. Public Health*, 2021, 18(4), p. 1462

VALDIGLESIAS V., LAFFON B., *The impact of nanotechnology in the current universal COVID-19 crisis. Let's not forget nanosafety!*, in *Nanotoxicology*, 2020, 14, pp. 1013–1016

VECCHI V., CUSUMANO N., BOYER E.J., *Medical supply acquisition in Italy and the United States in the era of COVID-19: The case for strategic procurement and public–private partnerships*, in *Am. Rev. Public Adm.*, 2020, 50(6-7), pp. 642-649

VONDERSCHMITT J., WÖHLKE S., SCHICKTANZ S., *Scarce resources, public health and professional care: the COVID-19 pandemic exacerbating bioethical conflicts – findings from global qualitative expert interviews*, in *BMC Public Health*, 2023, 23(1), p. 2492

WANG B., YANG D., CHANG Z., ZHANG R., DAI J., FANG Y., *Wearable bioelectronic masks for wireless detection of respiratory infectious diseases by gaseous media*, in *Matter*, 2022, 5(12), pp. 4347-4362

WHO, Advice on the use of masks in the context of COVID-19, Interim Guidance, 6 Apr 2020

WHO, *Advice on the use of masks in the context of COVID-19*, Interim Guidance, 5 Jun 2020

YE Y., ZHANG Q., CAO Z., CHEN F.Y., YAN H., STANLEY H.E., ZENG D.D., *Impacts of export restrictions on the global personal protective equipment trade network during COVID-19*, in *Adv. Theory Simul.*, 2022, V(4), p. 2100352

ZIMMERLING A., CHEN X., *Innovation and possible long-term impact driven by COVID-19: manufacturing, personal protective equipment and digital technologies*, in *Technol. Soc.*, 2021, 65, p. 101541