Protective Equipment in the context of COVID-19

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MedTech Europe
from diagnosis to cure

Contents

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Background

Protective equipment such as personal protective equipment (PPE) or consumable medical devices includes a variety of garments, such as masks, respirators, gloves, and gowns that protect the user and/or the patient against health and safety risks. In relation to COVID-19, protective equipment offers protection against the transmission of the virus. The level of protection will vary, depending on the characteristics of the product and its use.

Based on the available evidence, the World Health Organisation (WHO) indicates that the primary transmission route of the COVID-19 virus is through respiratory droplets (droplet transmission) and close contact between people. Other transmission routes include indirect contact with surfaces in the immediate environment of the infected person, or objects used on that person (e.g. thermometer, stethoscope), or airborne transmission in settings where aerosols are generated[1]. For example, where aerosol generating procedures are performed, including intubation, disconnecting the patient from the ventilator, cardiopulmonary resuscitation, general dentistry procedures and, in particular, invasive dental surgery etc.

Understanding the nature of the virus and how it spreads is very important to determine what type of protective equipment should be used to protect against the transmission and help manage the supplies as surging global demand, panic buying, trade restrictions, misinformation and other factors contribute to disruptions in the global supply of protective equipment.

This document provides an overview of the different types of protective equipment available to protect against the transmission of COVID-19. Furthermore, it outlines some of the major issues affecting the supply chains and delivery of these products that are critical in managing this pandemic. The main focus of this document is protective equipment used in healthcare settings however, recognising the need to address the question of the level of protection offered by non-certified/self-made face masks, this document is also going to provide some comments with respect to non-certified masks that are increasingly being adopted for use by the general public.

To clarify the use of terminology, for the purpose of this document, the term ‘protective equipment’ is used to describe products that are either PPE or medical devices that are used as protective solutions in managing the pandemic.

[1] WHO, Modes of transmission of virus causing COVID-19: implications for IPC precaution recommendations.

Protective equipment against COVID-19 transmission

WHO, the European Centre for Disease Prevention and Control (ECDC), and several national competent authorities issue and update on a regular basis guidance on protection against infection and control measures[2].

Drawing on the existing guidance, depending on the type of exposure of healthcare workers, the prescribed set of protective equipment to protect against the transmission of COVID-19 includes the following products:

Type of protection	**Suggested technology**
Mouth and nose protection	FFP2 or FFP3 respirator (as respiratory protection), medical masks (as means of source control)
Eye protection	Goggles or face shield
Body protection	Long-sleeved infective agents resistant gown
Hand protection	Gloves

Wearing protective equipment alone does not guarantee protection against COVID-19, it needs to go in pair with correct dressing (donning) and undressing (doffing) as well as thorough disinfection[3].

Recognising that protective equipment represents a wide variety of products for which demand has increased tremendously as the COVID-19 pandemic spreads, it is important to clarify the level of protection offered by different types of products.

[2] E.g.: ECDC, technical report, Personal protective equipment (PPE) needs in healthcare setting for the care of patients with suspected or confirmed novel coronavirus (2019-nCoV).
[3] E.g. ECDC, technical report, Guidance for wearing and removing personal protective equipment in healthcare settings for the care of patients with suspected or confirmed COVID-19.

Regulatory complexity

Without going into the details of regulatory requirements, it is important to point out the complexity of the regulatory framework for protective equipment in Europe.

In general, a differentiation can be made between products certified under the medical device legislation – Medical Devices Directive 93/42/EEC (MDD) or Medical Devices Regulation 2017/745 (MDR), and Personal Protective Equipment Regulation – Regulation 2016/425 (PPER). The intended purpose of the product and its manufacturer's claim will trigger the applicable certification requirements and respective testing methods.

For example, surgical masks intended to be worn by healthcare workers during surgery, and designed to create a physical barrier to isolate bacteria and aerosols released from the wearer's mouth and nose to protect the patient, are considered medical devices. On the other hand, when protection equipment is designed and intended to protect the user, for example respirators such as FFP, they are considered personal protective equipment.
It is possible for a product to be both a medical device and PPE if both claims are made.

After compliance is ensured with the applicable legislation (i.e., the MDD/MDR and/or PPER), the CE marking may be affixed to the product or its packaging prior to its placement on the EU market. The medical device legislation and PPER lay down different requirements that need to be fulfilled to be able to claim that a product is a medical device (MD)[4] or a personal protective equipment (PPE)[5].

In cases where the product is intended to protect both the user/wearer and the patient, it is qualified both as a PPE and as a medical device and thus would need to comply with both legal acts (MDD/MDR and PPER). Examples of products pursuing a double purpose include masks used by healthcare workers during operation that are also designed with a function to protect the user against body liquids or infective agents such as COVID-19 and to protect the patient, or gloves with a medical purpose (e.g. examination gloves) to protect both the user and the patient from cross contamination. Under European law, such products would bear one CE mark, but as already explained, they would need to meet the requirements of both the medical devices legislation (MDD/MDR) and the PPE legislation (PPER).

In order to mitigate supply shortage during the COVID-19 pandemic, the European Commission has issued a recommendation to Member States to allow, temporarily and under certain conditions, exceptions to the conformity assessment rules for protective equipment[6]. Based on this recommendation it is possible for non-CE marked products to enter the market, however, their placing on the market needs to be approved by the respective national authority. For products falling under the definition of medical device, the amendment to the MDR of 23 April 2020, which is of immediate application, envisages the possibility for EU-wide derogation to be given to critically needed devices[7].

[4] European Commission webpage, Medical Devices.
[5] European Commission webpage, Personal protective equipment (PPE).
[6] Commission Recommendation (EU) 2020/403 ;Corrigendum to this Recommendation.
[7] As foreseen in MDR, Article 59(3). Regulation (EU) 2020/561.

Protective equipment overview

Mouth and nose protection

Not all products are the same. The examples below provide an overview of the main categories of masks and respirators and an explanation of the level of protection offered by these products:

Medical masks (often referred to as surgical masks)

When speaking of medical masks, the most common product type is a surgical mask, also known as procedure mask. A surgical mask is a disposable medical device covering the mouth, nose and chin of the wearer that is designed to block bacteria and infectious agents transmitted by large-particle droplets from the wearer's mouth and nose when the wearer exhales[8]. Some surgical masks can offer splash resistance against splashes of liquid, for example, patient's blood during surgery, but such masks are not designed to protect the wearer against inhaling airborne bacteria or virus particles.

Medical masks qualify as medical devices. EN 14683:2019 *Medical face masks - Requirements and test methods* is a harmonised standard setting the requirements for surgical masks in order to bear a CE-mark.

- **Type I medical face masks** – refers to the least filtering of the three masks with a bacterial filtration efficiency of at least 95%.
- **Type II medical face masks** – refers to a bacterial filtration efficiency of at least 98%.
- **Type IIR medical face masks** – refers to a bacterial filtration efficiency of at least 98%, with a splash resistance of ≥16 kPa.

Respirators

A respirator or filtering face piece (FFP) is considered as personal protective equipment as it is designed to protect the wearer against particulates such as dust particles and various viruses in the air, including COVID-19. This type of mask, unlike the surgical mask, protects the wearer from inhaling infectious agents or pollutants

[8] ECDC, technical report, Using face masks in the community.

in the form of aerosols, droplets, or small solid particles. Respirators are used by healthcare workers, mainly to protect themselves during aerosol-generating procedures[9].

To provide effective respiratory protection, a respirator must fit snugly on the user's face to ensure there are no gaps between the face and the respirator seal. Even very small gaps between the face and the edge of the respirator allow air and particles to go around the filter media.

FFP respirators are considered as a PPE[10]. In Europe, EN 149:2001+A1:2009: *Respiratory protective devices - Filtering half masks to protect against particles - Requirements, testing, marking* is a harmonised standard specifying minimum requirements for respirators.

The standard prescribes test methods to measure aerosol filtration and 'total inward leakage' of the device. Based on the test results, EN 149 differentiates between three categories of respirators:

- **FFP1** refers to the least filtering of the three respirators with an aerosol filtration of at least 80% and leakage to the inside of maximum 22%.
- **FFP2** respirators have a minimum of 94% filtration percentage and maximum 8% leakage to the inside.
- **FFP3** respirators are the most filtering respirators of the FFPs. With a minimum filtration percentage of 99% and maximum 2% leakage to the inside, they protect against very fine particles.

Based on the existing guidelines and recommendations for healthcare workers dealing with suspected or confirmed COVID-19 patients, FFP2 or FFP3 are suggested. A FFP3 respirator should be always used when performing aerosol-generating procedures[11].

Respirators are subject to various standards around the world which specify certain requirements and performance characteristic for these products, including:

- FFP2 – Europe (EN 149:2001)
- N95 – USA (NIOSH-42CFR84)
- KN95 – China (GB2626-2006)
- P2 – Australia/New Zealand (AS/NZA 1716:2012)
- Korea 1st class – Korea (KMOEL – 2017-64)
- DS – Japan (JMHLW-Notification 214, 2018)

EN 149 (Europe) and N95 (USA) are considered as the most important standards for respirators[12]. In general, N95 category is considered fit for the same purpose as FFP2[13].

[9] ECDC, technical report, Using face masks in the community.
[10] FFP respirators can also be registered as a medical device, particularly if splash resistance is provided. In that case, such FFP respiratory would also conform to EN 14683:2019, in addition to EN 149: 2000+A1 2009.
[11] ECDC, technical report, Guidance for wearing and removing personal protective equipment in healthcare settings for the care of patients with suspected or confirmed COVID-19.
[12] For respirators used in medical settings, EN 14683:2019 would also be applicable.
[13] Technical Bulletin created by 3M provides a clear comparison of similarities of different performance standards.

In case of non-CE marked respirators (FFP) that are labelled with references to standards recognised by other jurisdictions, it is important that procurers and users evaluate and understand the performance capability and fit of the product to ensure it is appropriate for their intended application and population.

Recognising that it might be difficult to verify the validity of test reports from different countries, certificates of compliance to the claimed standards issued by recognised conformity evaluation bodies would give additional certainty.

Community face masks (also referred to as public/home-made masks)

Community face masks, also known as non-medical face masks, include a variety of self-made or commercial face covers made of cotton cloth or other textiles.

Community face masks are not intended for use in healthcare settings[14].

National standardisation institutes in some countries have been working on defining minimum criteria for community masks for general public use, for example in France[15] and in Spain[16], however, there are no established standards that would define minimum criteria and set testing methods to verify performance of community masks.

These are not CE marked products, nor are they assessed for conformity to harmonised standards for respirators or medical masks[17].

The unprecedented raise in global demand for protective equipment due to the spread of COVID-19, and supply shortages due to various factors, have led governments to incentivise the production of community masks for general public use. It is important to note that community face masks do not offer a comparable level of protection of the wearer to respirators or means for source control as medical masks. ECDC reports that there is a limited indirect evidence showing that community face masks may decrease the release to the environment of respiratory droplets produced by coughing, but ECDC also warns that use of community face masks may convey a false sense of protection leading to less cautious approach to physical distancing, poor respiratory etiquette and hand hygiene[18].

[14] ECDC, technical report, Using face masks in the community.
[15] France, Information note.
[16] Spain, Information note.
[17] EN 149:2001+A1:2009 for FFP respirators and EN 14683:2019 for medical masks.
[18] ECDC, technical report, Using face masks in the community.

Eye protection

As COVID-19 transmission occurs via droplets deposited on mucosal surfaces, eye protection is also essential for healthcare workers. There are variety of eye protection devices available. In the context of COVID-19, goggles and face shields are the recommended eye protection devices.

Goggles

Goggles are special protective eyewear that enclose the area surrounding the eye in order to prevent particulates, water or chemicals, or potentially infectious droplets, from contact with the eyes. Goggles that protect against droplets or splashes of liquid are marked with the number "3". In the context of COVID-19, it is highly recommended to use goggles with transparent lenses.

Goggles are considered as a PPE. EN 166:2001 *Personal eye-protection – Specifications*, is a harmonised standard for eye protection equipment, including goggles.

Safety visors (face shields)

While goggles help protect the wearer's eyes from splashes, sprays, and droplets, a face shield can help reducing exposure to both the eyes and other facial areas. Face shields, whether disposable or reusable, should cover the front and sides of the face. This will help reduce the possibility of splash, sprays and droplets from going around the edges of the shield and reaching the eyes or other facial areas.
As with goggles, safety visors with clear lenses and marked with the number "3" to indicate protections against droplets or splashes of liquids may be considered suitable for use against COVID-19.

Safety visors are considered as a PPE. EN 166:2001 *Personal eye-protection – Specifications*, is a harmonised standard for eye protection equipment, including safety visors.

Body protection

Body protection provided by medical gowns and aprons or chemical (biological) protective clothing (CPC) are another form of protective equipment that is recommended to use by healthcare workers involved in the direct care of COVID-19 patients[19].

[19] WHO, Interim guidance, Rational use of personal protective equipment (PPE) for coronavirus disease (COVID-19).

The ECDC recommends wearing at least long-sleeved water-resistant clothing to prevent body contamination. This PPE item does not need to be sterile unless it is used in a sterile environment (e.g. operating room). If MD (EN 13795-2) or PPE (EN 14126) clothing are not available, a single use plastic/water resistance apron worn over the non-water-resistant gown can be used[20].

Surgical gowns

Surgical gown is a classic example of protective garment worn by surgeons during operating procedure. The general product characteristics are long sleeves with cuffs, attached waists and neck ties, adjustable neckline with yellow hook-and-loop style neck binding.

If the gown is intended to provide protection to the patient, it is considered as a medical device. The relevant harmonised standards laying down the requirements for surgical garments are:
EN 13795-1:2019 *Surgical clothing and drapes - Requirements and test methods - Part 1: Surgical drapes and gowns*, and
EN 13795-2:2019 *Surgical drapes, gowns and clean air suits, used as medical devices for patients, clinical staff and equipment - Part 2: Test methods*

Many surgical gowns and aprons are also designed to protect the healthcare personnel which qualifies such products as PPE, meaning that in such case, the requirements of both regulations and standards apply.

Chemical (biological) protective clothing (personal protective equipment)

Coveralls, aprons or other chemical protective clothing garments are worn for the protection of the wearer against chemicals, but also for potentially infectious material, and for the protection of the environment against potentially infectious material spread by the wearer.

Chemical (biological) protective clothing (CPC) providing body protection to the wearer are considered as PPE.

In the context of COVID-19, the relevant harmonised standard laying down the requirements for protective clothing (PPE) is EN 14126:2003 + AC 2004 *Protective clothing - Performance requirements and tests methods for protective clothing against infective agents.* This standard uses requirements from other chemical standards to set type tests to measure the overall imperviousness to gases, liquids (jet and spray),

[20] ECDC, technical report, Personal protective equipment (PPE) needs in healthcare settings for the care of patients with suspected or confirmed novel coronavirus (2019-nCoV).

particulates and mists (Type 1 through Type 6)[21]. The most appropriate type is the Type 4 (high spray), followed by Type 6 (low spray), and by Type 5 covered respectively in EN 14605, EN 13034, EN ISO 13982 (EN 1073-2).

Hand protection

Hand protection is offered by gloves which can be considered as a medical device if they are intended to protect the patient from an infection during a surgery or treatment, or as a PPE for hands if they are intended to protect the wearer.

Medical gloves

The two most common types of medical gloves are examination gloves and surgical gloves (both medical devices). EN 455-(1-4) are harmonised standards setting the requirements and testing methods for medical gloves for single use.

Examination gloves are common disposable gloves which healthcare workers wear when visiting a patient. They are manufactured from materials including nitrile, vinyl or latex. They are available in multi-unit packaging for easy access in clinical areas and worn during patient contact where there is a risk of exposure to body fluid. They are non-sterile devices, ambidextrous and with a smaller variety size such as XS, S, M, L, XL. Generally, examination gloves are usually thin (0.09 mm at fingertip) and their length allows low covering of the wrist (around 25 cm length).

Surgical gloves are worn to prevent contamination of the patient during invasive procedures and to protect the hand from exposure to potentially infectious materials. The gloves are either latex or non-latex. Surgical gloves have more precise sizing with improved precision and sensitivity and are made to a higher standard. Surgical gloves are by definition sterile and right and left-handed. They are packed at the pair level and have a wider variety of size from 5.5 up to 9. Surgical gloves are usually thicker (around 0.13-

[21] EN 943-1:2015+A1:2019 & EN 943-2:2019 – *Protective clothing against dangerous solid, liquid and gaseous chemicals, including liquid and solid aerosols – Part 1: Performance requirements for Type 1 (gas-tight) chemical protective suits & Part 2: Performance requirements for Type 1 (gas-tight) chemical protective suits for emergency teams (ET);* EN 14605:2009 + A1:2009 – *Protective clothing against liquid chemicals – performance requirements for clothing with liquid-tight (Type 3) or spray-tight (Type 4);* EN ISO 13982-1:2004+A1:2010- *Protective clothing for use against solid particulates — Part 1: Performance requirements for chemical protective clothing providing protection to the full body against airborne solid particulates (type 5 clothing*); EN 13034:2005 +A1:2009 *Protective clothing against liquid chemicals – Performance requirements for chemical protective clothing offering limited protective performance against liquid chemicals (Type 6),* EN 1073-2:2002 – *Protective clothing against solid airborne particles*.

0.20 mm) and their length is around 29 cm to cover the wrist and be pulled up to the surgical gown that is worn by the OR staff.

The soaring demand for gloves and limitation to increase their production further at this stage leads to serious risk of supply disruption. Using surgical gloves to compensate the lack of examination gloves would not be a sustainable solution due to the volumes needed and complexity of the production process.

Gloves (personal protective equipment)

There are variety of gloves on the market which are available in different thickness, textures, materials, colours and qualities. PPE users should consider the use of different gloves depending on the exposure risk associated with the planned intervention[22]. Single use disposable of less than 0,3 mm in thickness should be considered.

EN ISO 374-5 is the relevant harmonised standard setting the requirements for PPE for infective agent protection and viruses. These will be labelled with the symbol with the reference to virus if the gloves meet the ISO 16604 method B.

Other PPE gloves do exist, but they should be considered for other applications.

[22] ECDC, technical document, Safe use of personal protective equipment in the treatment of infectious diseases of high consequence.

What are the main issues when it comes to making protective equipment available?[23]

The outbreak of COVID-19 has shown the importance of transparency, open and functioning global trade and supply chains, and the need for a good understanding of demand and supply.

The virus has no borders.

Protectionist measures taken by national governments create new bottlenecks in the supply chain further up or down, or in another country or continent.
Lack of coordinated approach and protectionist measures do not resolve the supply problem but rather displace it.

Protective equipment is in soaring demand all over the world. The disposable nature of many of these products creates a fundamental problem of availability to healthcare workers managing COVID-19 patients.

Most protective equipment is designed for single use. To anticipate any possible or likely supply shortages, manufacturers are considering a range of solutions. For example, where production capacity cannot be further expanded readily, to remedy the situation for examination gloves, a solution may be to develop an EU-wide emergency hygiene protocol that would facilitate extending the lifetime of gloves. However, in absence of a validated and product-type specific method from authorities, in situations where supply is limited, healthcare providers should contact the manufacturer to enquire whether any cleaning and disinfection protocol may be followed to extend the product's lifetime without jeopardising its performance.

When it comes to making available of protective equipment used to fight COVID-19, some of the main issues are:

- **Disruptions to supply chains** – a number of manufacturing sites are impacted by export controls or by COVID-19 restrictions affecting mobility of workers.

- **Production capacity** – limited ability to further expand production capacity for many product lines. Presently, this is particularly relevant to examination and surgical gloves, as well as the nonwoven materials used for most single use medical textiles including masks, gowns and drapes.

- **Access to materials** – the availability of raw materials is becoming an issue so that announced production capacity may be extremely delayed or may never be able to start.

[23] This part of the document represents the current understanding of the main issues as of the date of publication of this document. As the situation evolves, also the impact of certain measures taken in response to the pandemic can unfold over time, therefore, this section of the document might need to be updated in the future.

- **Logistics** – Products produced in Asia ship by sea freight on average taking from four to eight weeks to transport. Given the urgent need to deliver protective equipment, companies strive to resort to the use of airfreight. The cost of airfreight has skyrocketed (with prices up to four times higher compared to pre COVID-19 prices) in the past weeks due to the increased demand for airfreight.

- **Testing & certification capacity** – limited capacity of certification organisations with respect to demand for certification to harmonised standards.

- **Profiteering, supply of counterfeit or low quality products** – it is important to recognise that surging demand for the essential products to tackle the pandemic has given rise to fraudulent suppliers, counterfeit products or entities willing to exploit the current situation, charging unjustifiably high prices for critical products in light of supply shortages. Panic buying through non-established channels unintentionally encourages such practices.

The majority of the world production of protective equipment is located in Asia, in particular in China. This production has been interrupted for several weeks and is only now recovering to its pre-COVID-19 outbreak production levels. In addition, products continue to be subject to extra hurdles preventing their free circulation and disrupting the normal supply flow – 88 countries have adopted export restrictions, including an EU export authorisation regime for certain protective equipment[24].

The prolonged shutdown and the speed at which the virus spread has caused a tremendous stress on the international logistical supply chain and a fear for supply shortages. Unfortunately, the response by authorities all over the world has been rather uncoordinated. In some cases, authorities have launched calls for offers outside the normal purchase channels, bid against other purchasers, disrupted supply chains and sometimes used political intervention at a high level to have cargo re-prioritised.

The volume of protective equipment needed is much higher than the current available production levels (even at 100% capacity). The effort to increase productions levels significantly takes months if not years for several reasons, such as the need to build and install new equipment, train employees, implement quality system etc.

In most European countries, governments are slowly proceeding with relaxing or lifting the confinement measures. Their decision to mandate every citizen in Europe wearing protective equipment due to fear of a rebound of COVID-19 will continue having an important impact on the supply chain of protective equipment in general, masks and gloves in particular.

[24] Commission Implementing Regulation (EU) 2020/568.

About MedTech Europe

MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices and digital health. Our members are national, European and multinational companies as well as a network of national medical technology associations who research, develop, manufacture, distribute and supply health-related technologies, services and solutions.

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