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DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health systems, medical products and innovation
Medical Devices

Guidance on regulatory requirements for medical face masks

Options for supporting production and/or placing on the market of medical face masks in the context of COVID-19 pandemic

1. INTRODUCTION

The World Health Organization (WHO) declared the COVID-19 outbreak a pandemic on March the 12th 2020.

The COVID-19 virus is transmitted mainly via small airborne droplets emitted by infected people, especially when sneezing, coughing or talking. Therefore, a wide array of protective products designed to ensure protection against airborne particles or small droplets are used, such as: face masks, gloves, coveralls, etc.

A medical face mask (also known as surgical or procedure mask) is a medical device covering the mouth, nose and chin ensuring a barrier that limits the transition of an infective agent between the hospital staff and the patient. They are used by healthcare workers to prevent large respiratory droplets and splashes from reaching the mouth and the nose of the wearer and help reduce and/or control at the source the spread of large respiratory droplets from the person wearing the face mask[1].

Medical face masks are recommended, as well, as a means of source control for persons who are symptomatic in order to prevent the spread of respiratory droplets produced by coughing or sneezing. The application of medical masks as source control has been shown to decrease the release of respiratory droplets carrying respiratory viruses[1].

The European Centre for Disease Control (ECDC) have outlined recommendations on the preferential supply of medical face masks to healthcare professionals and symptomatic patients based on need and the emerging evidence[1].

Other products such as face covers (also known as 'community'/'artisanal'/'textile'/ 'domestic'/'non-medical' face masks) include various forms of self-made or commercial masks or face covers made of cloth, other textiles or other materials such as paper. They are not intended for use in healthcare settings or by healthcare professionals.

Manufacturers of medical face masks and face covers may include technological adaptation in the design of these products (with a transparent window), in order to allow lip reading for hearing impaired people (including healthcare professionals).

Under the current COVID-19 context, the demand for different types of face masks has rapidly increased. Therefore, this document intends to outline the regulatory options for the placing of medical face masks on the EU market indicating their feasibility to allow short-term supply.

In addition to the use of masks and face covers, other public health measures must be promoted, such us respiratory etiquette (i.e. covering of the mouth and nose with a tissue when coughing) to limit the spread of infection from an infected individual[1].

[1] See also the ECDC Technical report "Using face masks in the community": https://www.ecdc.europa.eu/en/publications-data/using-face-masks-community-reducing-covid-19-transmission

2. LEGAL BACKGROUND

Most of these masks are among the so-called 'harmonised products' for which there is specific EU product legislation in place.

Medical face masks or surgical face masks are products falling within the scope of the EU legal framework on medical devices – Directive 93/42/EEC (MDD), to be replaced by Regulation (EU) 2017/745 (MDR) as from 26 May 2021.

Some products used in the COVID-19 context, such as filtering face-piece respirators (also called protective face masks or respirators), are considered as personal protective equipment (PPE) and hence fall under the scope of Regulation (EU) 2016/425 (PPER).

A face covering is another type of mask, for which the EU regulatory framework has not established specific legal requirements. Therefore, the General Product Safety Directive (GPSD) 2001/95/EC would apply. In addition, some Member States, standardisation bodies or other entities may provide guidance on the specifications and use of these face covers.

3. DEFINITION OF MEDICAL FACE MASKS AND INTENDED USE OF OTHER TYPES OF FACE MASKS

Medical Face Mask: medical device covering the mouth and nose providing a barrier to minimize the direct transmission of infective agents between staff and patient.

A medical face mask must fulfil the definition as a medical device and therefore have a medical purpose as intended by the manufacturer.

This intended purpose is normally to limit the transmission of infective agents from staff to patients during surgical procedures and other medical settings with similar requirements. A medical face mask with an appropriate microbial barrier should also be effective in reducing the emission of infective agents from the nose and mouth of an asymptomatic carrier or a patient with clinical symptoms.

Medical face masks should be distinguished from protective face masks or respirators (PPE), which are intended only to be worn by a person for protection against one or more risks to that person's health or safety, without a medical purpose, and do not fall under the definition of medical device. For further advice on the conformity assessment of these type of masks and other types of protective equipment, a questions and answers document has been published on the Commission web site: https://ec.europa.eu/docsroom/documents/40521

Face covers do not meet the legal definitions of a PPE and neither they meet the legal definition of a medical device, as there is no intended medical or personal protection purpose made by the manufacturer. However, some Member States, standardisation bodies or other entities may provide guidance on the specifications and use of these face covers.

4. CLASSIFICATION

4.1 Classification according to Medical Devices Directive 93/42/EEC and Medical Devices Regulation (EU) 2017/745

Medical Face Masks are classified according to Rule 1 for non-invasive devices, as devices that either do not touch the patient or contact intact skin only (see guidance[2]). There are two possible classifications:

- Class I: non-sterile medical face masks. For them, the manufacturer is entitled to carry out a self-assessment conformity procedure, without the intervention of a notified body.

- Class Is: sterile medical face masks. For them, the intervention of a notified body is required in the assessment of the sterility process and validation of documentation.

4.2 Classification according to the harmonised European standard EN 14683:2019+AC:2019

Medical face masks are classified as Type I and Type II according to bacterial filtration efficiency, whereby Type II is further divided (Type II and IIR) according to whether or not the mask is splash resistant. The 'R' signifies splash resistance.

Type I medical face masks should only be used for patients and other persons to reduce the risk of spread of infections particularly in epidemic or pandemic situations. Type I masks are not intended for use by healthcare professional in an operating room or in other medical settings with similar requirements[3].

5. USE OF HARMONISED EUROPEAN STANDARDS

The use of harmonised European standards remains voluntary. Manufacturers are free to choose any other technical solution to demonstrate compliance with the mandatory legal requirements.

The medical devices regulatory framework offers the possibility for manufacturers to rely on specific technical solutions, which are detailed in harmonised European standards or parts thereof. When the references of these harmonised European standards are published in the *Official Journal of the European Union* in support of the applicable EU legislation, the voluntary use of those standards confers presumption of conformity with the legal requirements the standard aims to cover. It means that, where a manufacturer chooses to adopt the technical solutions laid down in those standards, the product is presumed to be in conformity with the applicable essential safety and performance requirements.

This is the case of the abovementioned harmonised European standard EN 14683:2019+AC:2019 for medical face masks under the MDD.

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[2] MEDDEV 2.4/1 rev.9 - Classification of medical devices

[3] See the harmonised European standard EN 14683:2019+AC:2019 *Medical face masks - Requirements and test methods*

6. REGULATORY OPTIONS FOR PLACING MEDICAL FACE MASKS ON THE EU MARKET AS MEDICAL DEVICES

Medical face masks in the scope of the MDD and the MDR[4] must comply with the applicable essential safety and performance requirements. Thus, these products must be CE-marked and accompanied by the EC or EU declaration of conformity issued by the manufacturer. The manufacturer must prepare the appropriate technical documentation and keep it available for market surveillance authorities on request.

The CE marking should be affixed to the device where practicable and should be visible on the packaging. All labelling and information requirements should be met according to Annex I.13 of MDD and Annex I.23 of MDR.

In the context of the COVID-19 outbreak, several industries have expressed their willingness to support and scale up the production of medical face masks. There are different regulatory options available for supporting production or placing in the market medical face masks. These options are presented below ordered in terms of feasibility to allow a swift supply under the current context.

6.1. Supplying semi-finished or finished face masks to medical devices manufacturers currently placing the masks on the market

When the actual manufacturer has already undergone a conformity assessment for the medical face mask, has issued the EC declaration of conformity and is lawfully placing face masks on the market under its own name, other producers (e.g. not currently working in the medical devices field) can support its production. Such producers can provide semi-finished or finished products, therefore becoming suppliers or subcontractors of the actual manufacturer.

Given that the medical devices sector is highly regulated and complex, leveraging the knowledge and responsibilities of an already established manufacturer of face masks could be the least burdensome and fastest option to scale up the production of face masks.

Manufacturers of medical devices producing face masks may provide the specifications of their face masks to another producer that becomes its subcontractor. This other producer will manufacture the face masks but the actual medical device manufacturer will keep its role of legal manufacturer according to the MDD or MDR.

The actual manufacturer of the face masks, which should have implemented and maintained a quality management system, qualifies, approves and controls the subcontractor that might need to be audited by the actual manufacturer as part of the control of subcontractors and on the basis of its criticality.

[4] See also MDCG 2019-15 – Guidance notes for manufacturers of Class I medical devices

6.2. Derogation procedure: placing on the market authorised by the competent authorities of a Member State in the interest of public health

The EU legislation on medical devices allows for specific derogations from some requirements. In fact, according to Article 11(13) of the MDD and Article 59 of the MDR, the competent authorities of the Member States may authorise, on duly justified request, the placing on the market and putting into service within the territory of the Member State concerned, of specific devices for which the relevant conformity assessment procedures have not been carried out but the use of which is in the interest of public health or patient safety or health.

By the amending Regulation of 23 April 2020[5], Article 59(1) of the MDR empowers Member States' competent authorities to adopt national derogations under both the MDD and the MDR from the date of entry into force of that amendment (24 April 2020).

The relevant competent authority of the Member State in this case authorises the placing on the market within its territory. In practice, this implies that each competent authority would need to assess whether the devices produced by the manufacture provides an adequate level of safety and performance in respect to the applicable legal requirements or applicable standards. The assessment procedures can vary among Member States and in some cases will involve the support of third parties (e.g. testing laboratories).

In the exceptional COVID-19 context, the assessment procedures will ensure a short-term supply while guaranteeing patient safety[6]. The Member State will evaluate the available technical documentation to find evidence that essential safety and performance requirements are guaranteed in the context of use. In particular, the role of healthcare teams and health facilities is essential to allow a rational use and a continuous assessment of these crisis solutions.

Once this assessment is performed, the authority has to take a decision, whether or not the respective device produced by the manufacturer may enter the national territory of the Member State. As by 24 April 2020, competent authorities have to inform the Commission and their counterparts in the other Member States of any temporary agreement they have granted to specific devices.

Furthermore, a specific Commission Recommendation[7] allows for some degree of flexibility in placing certain medical devices on the EU market, under certain conditions, to improve availability of such products in view of the epidemiological context as well as the exponential growth in demand. Accordingly, Member States' market surveillance authorities may authorise the making available on the EU market of some products, as national derogations, for a limited period of time and while the necessary procedures are being carried out, even though the conformity

[5] Regulation (EU) 2020/561 of the European Parliament and of the Council of 23 April 2020 amending Regulation (EU) 2017/745 on medical devices, as regards the dates of application of certain of its provisions (OJ L 130, 24.4.2020, p. 18).

[6] Some Member States have published guidance on their respective websites to support this assessment e.g. in case of implementation of innovative manufacturing processes such as 3D printing.

[7] Commission Recommendation (EU) 2020/403 of 13 March 2020 on conformity assessment and market surveillance procedures within the context of the COVID-19 threat (OJ L 79I, 16.3.2020, p. 1).

assessment procedures, including the affixing of CE marking, have not been fully finalised.

Among the products explicitly addressed in the Recommendation, there are medical face masks covered by the MDD and MDR.

The Commission issued guidance for the sound implementation of the referred derogations: Guidance on medical devices, active implantable medical devices and in vitro diagnostic medical devices in the COVID-19 context.

Timing to obtain a derogation by a competent authority will greatly depend on the quality and adequacy of the evidence provided by the manufacturer. When technical documentation and evidence of safety and performance is adequate this can be a feasible option to ensure short-term supply.

In addition, Article 59(3) of the MDR establishes the possibility for the Commission, in exceptional cases relating to public health or patient safety or health, to extend for a limited period of time the validity of an authorisation granted by a Member State to the territory of the EU and set the conditions under which the device may be placed on the market or put into service. This allows addressing potential EU-wide shortages of vitally important medical devices in an effective manner.

6.3. Manufacture of the finished face masks by a producer currently not placing face masks on the market under its own name

Producers of medical face masks who are no currently medical device manufacturers under MDD or MDR must ensure they assume all legal obligations before they place on the market products under their own name. This means that the manufacturer will need to fulfil all requirements of the MDD or the MDR (e.g. including the need to draw up the full technical documentation related to the face mask, and to establish and keep up to date a systematic procedure to review experience gained from devices in the post-production phase).

The manufacturer who places the finished CE-marked face mask on the EU market under its own name must ensure that the device complies with the legal requirements (the essential requirements established in Annex I to the MDD or the general safety and performance requirements established in Annex I to the MDR) and provide relevant evidence (EC or EU declaration of conformity, technical documentation, etc.). Only if the face mask is supplied in sterile condition, a notified body must be involved in the assessment of the sterility process and validation of documentation.

Therefore, the route for certification can vary. In particular:

1. Class I non-sterile face masks:
   - EC declaration of conformity according to Annex VII of MDD, or
   - EU declaration of conformity referred to in Article 19 after drawing up the technical documentation set out in Annexes II and III of the MDR.

2. Class I sterile face masks:
    - EC declaration of conformity according to Annex VII combined with an assessment by a notified body[8] of the quality assurance of the production applicable to the sterility aspects according to Annex II, IV, V or VI of MDD, or
    - EU declaration of conformity referred to in Article 19, after drawing up the technical documentation set out in Annexes II and III, combined with an assessment by a notified body[8] of the procedures set out in Chapters I and III of Annex IX, or in Part A of Annex XI of MDR.

If the finished CE-marked face mask is produced outside the EU and imported into the single market, the legal manufacturer must designate a single authorised representative in the EU, who must assume responsibility for placing the device on the EU market, ensuring that European and national regulatory frameworks are complied with.

Given that the medical devices sector is highly regulated and complex, the scenarios presented below will typically be the most burdensome and therefore only applicable to increase supply in the medium-long term.

6.3.1. Medical devices manufacturers' not currently producing face masks extending their product range

This option is available for medical devices manufacturers currently placing in the marked other devices and wishing to add face masks to their product range. They could seek the support from (non-medical devices) producers to act as subcontractors.

From the procedural point of view, a medical devices manufacturer may produce the finished face mask or may utilise a subcontractor (i.e. producer linked or not to the medical devices field). In the latter case, the manufacturer must retain the overall responsibility on the product and therefore qualify, approve and control the new subcontractor.

6.3.2. Medical face masks manufactured entirely by a producer that is not currently the actual manufacturer under the MDD or the MDR

Producers of medical face masks that do not currently qualify as actual manufacturers under the MDD or the MDR and decide to place face masks on the market under their own name must comply with all the legal requirements for manufactures under the MDD or the MDR. It is important to mention that some Member States could have specific requirements, for instance, to authorise the facility of the medical device manufacturer prior to start production.

[8] Information on notified bodies can be found in the Commission's NANDO information system (https://ec.europa.eu/growth/tools-databases/nando/) by searching for those designated for Code MDS 7006 (Medical devices in sterile condition) for MDD or code MDS 1005 (Devices in sterile condition) for MDR.