Information on protective clothing / masks (corona context)

Clothing and products, such as face masks/breathing masks, for the possible prevention of infections (e.g. in the context of the current corona virus) usually have a dual intended use from a regulatory perspective: On the one hand, they are intended to protect their wearers from infections, i.e. from an emerging risk to their own health. On the other hand, they are intended to prevent the person wearing the product from transmitting his or her microbes to others, thus preventing the transmission of diseases, e.g. to patients or third parties.

In accordance with their intended use, the products fall within the scope of Regulation (EU) 2016/425 on personal protective equipment (PPE-R) and/or within the scope of Regulation (EU) 2017/745 on medical devices (MD-R), which will replace Directive 93/42/EEC on medical devices from 26 May 2020.

In case of dual use, both regulations are applicable and must be taken into account. Both regulations require the CE marking of the products and the issue of an EU Declaration of Conformity after the conformity assessment procedure has been successfully completed.

All breathing masks (products intended to protect the wearer of the mask against risks to his or her own health via the respiratory tract) must be classified in category III in accordance with the PPE-R (see also the Guide to the PPE Regulation of April 2018, No. 20 Appendix, Section 7). As part of his conformity assessment procedure, the manufacturer must have an EU type examination (Module B, in accordance with Annex V of the Regulation) carried out by a notified body.

He may then declare conformity on the basis of internal production control with supervised product testing at irregular intervals by the notified body (module C2, according to Annex VII of the Regulation). As an alternative to module C2, conformity may also be declared on the basis of quality assurance relating to the production process (module D, according to Annex VIII of the Regulation), certified by the notified body.

In any case a notified body has to be involved in the design process of the product (EU type examination) as well as in the production process (supervised product testing or production process quality assurance).

Surgical masks are medical devices in Class I, provided they have no other properties / additional functions, etc. (in this case, another product class may apply). (If such masks are also intended to protect the wearer against microbial and viral infections, etc., these masks are also category III PPE). For Class I medical devices, the manufacturer usually carries out the conformity assessment procedure on his own responsibility in accordance with Article 52 and draws up the technical documentation in accordance with Annexes II and III of the Regulation. In this context, the manufacturer must, among other things, document information on manufacturing and design, quality management, proof of conformity with the essential safety and performance requirements, benefit-risk analysis and risk management, (pre-)clinical data, biocompatibility, performance and safety, and post-market surveillance of the devices.

If the medical device manufacturer is based in a third country, he requires an authorised representative based in the EU who must perform certain tasks (see Article 11 of the Regulation).

Manufacturers must also have a person responsible for compliance with the regulatory requirements, authorised representatives shall have at their disposal such a person.

Manufacturers, authorised representatives and importers must register electronically before placing medical devices on the market. Similarly, the medical devices to be placed on the market must themselves be registered.

On 16.03.2020 the EU Commission published Recommendation (EU) 2020/403 on conformity assessment and market surveillance procedures in the context of the COVID 19 threat in the Official Journal L 79 I. In this document, the Commission recommends that all economic operators in the entire supply chain, notified bodies and market surveillance authorities take all measures at their disposal to ensure the supply of PPE and medical devices throughout the EU market. However, these measures should not and must not lead to any impairment of the general health and safety level of such products!

The recommendation contains the following proposals of the EU Commission:

Notified bodies should give priority to the conformity assessment procedure for such PPE and carry it out rapidly and, where appropriate, recognise alternative technical solutions (e.g. in accordance with proposals from the World Health Organisation (WHO)) if an equivalent level of protection is ensured. Contacts of notified bodies able to assess PPE for respiratory protection can be found in the NANDO database of the European Commission: https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=directive.notifiedbody&dir_id=155501 (Search criterion: „Products: Equipment providing respiratory system protection“)

The competent national authorities may grant an exemption (Article 59 of MD-R) or special approval (§11 of the German MPG) for medical devices upon duly justified request for the conformity assessment procedure. The Federal Institute for Drugs and Medical Devices (BfArM) is responsible for Germany on the basis of § 11 of the currently valid German Medical Devices Act (MPG). Further information can be obtained directly from the BfArM at https://www.bfarm.de/DE/Service/Presse/Themendossiers/Coronavirus/_node.html

The competent national market surveillance authorities may also grant exemptions for a limited period of time from the formal requirements for making available on the market, provided that an adequate level of health and safety is ensured. The market surveillance authority usually takes a decision in the course of customs clearance (if required by customs) on a case-by-case basis whether the products are suitable for the intended purpose and comply with the protection requirements of EU regulations. The economic operators involved are therefore recommended to keep suitable evidence (test reports, certificates, technical documents) available for inspection by the authorities in time and in sufficient detail so that the authorities can access a sufficient basis for assessment upon request.

PPE or medical devices without CE marking may also be assessed and included in the procurement process by the competent national authorities. However, it must be ensured that

these products are only available to healthcare professionals and only for the duration of the current health threat and that they do not enter the normal distribution channels and are not made available to other users!

Responsibility for exemptions and procurement procedures lies with the relevant national authorities, national market surveillance authorities and national procurement bodies. The notified bodies and testing laboratories are usually not able to help manufacturers and importers with the formalities concerning the exemptions and procurement procedures!

Important note: The details and information have been carefully researched. Nevertheless, no liability can be assumed for the completeness and correctness. In case of doubt, the client should seek professional technical and legal advice and clarify all requirements before you place your products on the market.

(The information relating to medical devices refers to the new MD-R, unless otherwise stated. For products according to the "old" Medical Device Directive, similar requirements apply in Germany, but these may differ in detail. Unfortunately I could not check the detailed national requirements in the member states except Germany).