



Position paper, Medical Device VS Personal Protective Equipment

The case of surgical face masks

EUCOMED is a European industry association with a membership comprising companies with European operations together with national and pan-European organizations in the medical technology sector.

Currently, EUCOMED represents more than 2,500 companies employing approximately 300,000 EU citizens that provide tens of thousands of different types of healthcare products within the EU and globally.

EDANA (European Disposables and Nonwovens Association), one of the European member associations of EUCOMED, specifically represents (among other sectors), the interests of the overwhelming majority of European manufacturers of surgical masks and single-use operation room clothing and drapes.

EXECUTIVE SUMMARY

EUCOMED and EDANA recognize and welcome the initiative by the EU to clarify the demarcation in relation to PPE and MDD for devices such as surgical masks.

The European medical device industry stresses the importance of the reference to the “principal intended purpose” of a device when determining the regulatory environment which applies to a particular product. The manufacturer clearly instructs the user in the clinical use of his products by communicating for which purpose the device has been designed and is intended.

The European medical device industry recognizes that when protection of the wearer is claimed by the manufacturer as the principal intended purpose, then the requirements of the PPE Directive apply.

The European medical device industry recognizes the obligation to positively state whether a particular product is a Medical Device or a PPE, or both to label it accordingly.



Surgical wound infections are frequent and serious complications after surgical operations and often jeopardize the desired outcome. They also cause severe strain on health care resources and suffering for the patient. It has been demonstrated that microorganisms can be spread on particles from the mouth and nose to the surgical wound. Surgical masks are routinely used during operations to prevent this spread.

As the sole purpose for the use of surgical masks is infection prevention, these products comply with the 93/42/EEC definition of a Medical Device. The definition of a Medical Device, in 93/42/EEC includes devices that are used to prevent disease such as infection and as a consequence surgical masks should be regarded as Medical Devices.

The EU Medical Devices Directive 93/42/EEC (“MDD”) also has as one of its Essential Requirements (Annex 1) that the use of Medical Devices must not result in risk of infection :

“The devices (...) must be designed in such a way as to eliminate or reduce as far as possible the risk of infection to the patient, user and third parties”

As a consequence of the above, manufacturers of surgical masks within the European Union claim third party infection control towards the patient, to be the principal intended purpose of these devices. The manufacturer is responsible for quality, safety, performance, risk analysis and conformity assessment. Compliance with the 93/42/EEC results in affixing the CE marking to the device. The European medical device industry recognizes that when protection of the wearer is claimed by the manufacturer as the principal intended purpose, then the requirement of the Personal Protective Equipment (PPE) Directive apply.

The European medical device industry recognizes the obligation to positively state whether a particular product is a Medical Device or a PPE, or both, and to label it accordingly.

Surgical masks are sold only to healthcare organizations in the European Union. The users are medical professionals well educated in infection control, both from and to themselves.

Based on the above, EUCOMED and EDANA urge the European Commission :

- **to clarify** the first indent of Art 1(4) of Council Directive 89/686/EEC (PPED) as well as Art 1(6) of Council Directive 93/42/EEC (MDD), for example by substituting to both of these the following or a similar wording to the same effect :

*“The principal intended purpose of a product shall be taken into particular account by the manufacturer when deciding whether a product falls under this Directive **and/or** another Directive designed to achieve the same objectives with regard to placing on the market, free movement of goods and safety”*

- **to inform** the relevant Member States authorities and interested parties accordingly, that the provisions of the circular of the Enterprise Directorate General (ref. D/1-BV inc n°455) of 17-12-1999 - 60973, in so far as they are covering medical devices, are **cancelled**.

