



Coronavirus: harmonised standards for medical devices to respond to urgent needs

Brussels, 25 March 2020

Yesterday, the Commission adopted decisions on harmonised standards which will allow manufacturers to place on the market high performing devices to protect patients, health care professionals and citizens in general. The standards will facilitate a faster and less expensive conformity assessment procedure. The revised harmonised standards play a pivotal role in the current coronavirus pandemic because they relate to critical devices* such as:

- medical face masks
- surgical drapes, gowns and suits
- washer-disinfectors
- sterilisation

Stella **Kyriakides**, Commissioner for Health said: *"We must not waste a second in our fight against the coronavirus. With the measures we adopt today, we speed up the entry of safe, essential medical equipment and devices such as masks, gowns and suits in the EU market. This equipment is fundamental for our health professionals – the brave and resilient women and men at the front line - to keep saving lives"*.

Once implemented, the use of these standards will allow manufacturers of medical devices and other concerned economic operators, to comply with the health and safety requirements of the EU legislation, taking into account the most updated technical solutions. These standards, once referenced in the Official Journal of the European Union, grant conformity of devices with the requirements of the three Directives on medical devices.

The decision to adopt these harmonised standards for medical devices represents an additional measure taken by the Commission to respond to the coronavirus outbreak. Also upon the urgent request of the Commission, the European Committee for Standardization (CEN) and the European Committee for Electrotechnical Standardization (CENELEC), in cooperation with their members made available a number of [European standards for certain medical devices and personal protective equipment](#).

Background

European standards are an essential pillar of a fully functioning internal market. They reduce costs, promote innovation, ensure interoperability between different devices and services, and help companies to access markets.

To support EU product legislation, the Commission can request the development of European harmonised standards to facilitate compliance by manufacturers of the relevant requirements. Once agreed and referenced in the Official Journal of the European Union, these harmonised standards become part of EU law and allow companies an easy and direct access to the internal market for their products, while ensuring a high degree of safety for users and consumers.

European legislation for medical devices also relies on harmonised standards. In particular, under the three current directives on medical devices, there are about 300 harmonised standards conferring presumption of conformity with the legal essential requirements. The Commission and the concerned European standardisation organisations (CEN and CENELEC) continuously work together to update and improve the set of harmonised standards available to economic operators in the EU. In such a common effort to face the coronavirus pandemic, the Commission, CEN and CENELEC have agreed to make a number of harmonised standards for important medical protective equipment like face masks and single-use gloves freely available to those companies that are willing to start producing these items.

Useful links

[Dedicated Commission webpage on the EU's response to the COVID-19 outbreak](#)

[Medical devices](#)

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- Medical face masks (EN 14683:2019)
- Surgical drapes, gowns and suits (EN 13795:2019 parts 1 and 2)
- Washer-disinfectors (EN ISO 15883:2018 part 4)
- Sterilisation (EN ISO 13408:2018 and EN ISO 25424:2019)

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