European Commission - Press release

Coronavirus: European standards for medical supplies made freely available to facilitate increase of production

Brussels, 20 March 2020

In the context of the Coronavirus crisis, the Commission is working with industry and Member States to maximise the availability of masks, gloves, gowns and other medical supplies. Efforts include increasing production by existing manufacturers, facilitating imports and activating alternative ways of producing equipment.

Upon the urgent request of the Commission, the European Committee for Standardization (CEN) and the European Committee for Electrotechnical Standardization (CENELEC), in collaboration with all their members, have agreed to immediately make available a number of European standards for certain medical devices and personal protective equipment. This action will help both EU and third-country companies willing to manufacture these items to swiftly start production and place products on the internal market more easily while ensuring a high degree of safety.

Commissioner for Internal Market Thierry **Breton** said: *"We need to act collectively with urgency, solidarity, and audacity. I am encouraging manufacturers to increase and diversify production, building on positive examples such as textile and shoe manufacturers starting to produce masks and gowns. I will do everything possible to support their efforts. I am pleased to announce that following contacts with the Commission, CEN/CENELEC has agreed to make freely available the standards needed for such companies to be able to produce masks and other protective equipment."*

Today's agreement has immediate effect. The 11 standards developed by CEN and potentially 3 additional ones developed jointly with ISO that are made available cover common filtering masks, medical gloves and protective clothing.

This initiative complements the Commission Recommendation on the conformity assessment and market surveillance procedures, which provides guidance to national bodies on allowing non CE-marked personal protection equipment that comply with the necessary health and safety standards to enter the EU market within the context of the Coronavirus.

How the free access to these standards helps increasing production

Providing free access to the national adoptions of these European standards helps both EU and third-country companies which are reconverting their production lines to manufacture quickly these critical items for preventing the coronavirus pandemic. The use of the standards will enable companies that use them to access the market for such fundamental medical and protection equipment quicker and to provide those in need with such medical equipment.

Normally, standards must be purchased and used in line with the intellectual property right rules, as the copyright of the standards lies with the organisations, which have developed the standards. The derogation from this business model is a strong European response, based on a sense of social responsibility and solidarity, to address the shortage problem of protective equipment deriving from the Covid-19 epidemics.

The standards are available for free download from the websites of CEN national members.

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 consumer.

European legislation for medical devices and personal protection equipment does also rely on harmonised standards. In our common effort to face the corona virus outbreak, the Commission and the European Committee for Standardization (CEN) have agreed to make a number of harmonised

standards for important protective equipment like face masks and single-use gloves freely available to those companies that are willing to start producing these items.

For More Information

List of available standards:

- EN 149:2009 Respiratory protective devices – Filtering half masks to protect against particles - Requirements, testing, marking (commonly referred to as 'FFP masks'
- EN 14683:2019 EN Medical face masks - Requirements and test method
- EN 166:2001 Personal eye-protection – Specifications
- EN 14126:2003 Protective clothing - Performance requirements and tests methods for protective clothing against infective agents
- EN 14605:2009 Protective clothing against liquid chemicals - performance requirements for clothing with liquid-tight (Type 3) or spray-tight (Type 4) connections, including items providing protection to parts of the body only
- EN 13795-1:2019 Surgical clothing and drapes - Requirements and test methods - Part 1: Surgical drapes and gowns
- 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
- EN 455-1:2000 Medical gloves for single use - Part 1: Requirements and testing for freedom from holes (MDD)
- EN 455-2:2015 Medical gloves for single use - Part 2: Requirements and testing for physical properties (MMD)
- EN 455-3:2015 Medical gloves for single use - Part 3: Requirements and testing for biological evaluation (MDD)
- EN 455-4:2009 EN Medical gloves for single use - Part 4: Requirements and testing for shelf life determination (MDD)

In addition, possibly:

- EN ISO 374-5:2017 Protective gloves against dangerous chemicals and micro-organisms - Part 5: Terminology and performance requirements for micro-organisms risks
- EN ISO 13688:2013 Protective clothing - General requirements
- EN ISO 10993-1:2009 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

European Standards

European Committee for Standardisation

European Committee for Electrotechnical Standardisation

IP/20/502

Press contacts:

Sonya GOSPODINOVA (+32 2 296 69 53)
Federica MICCOLI (+32 2 295 83 00)

General public inquiries: Europe Direct by phone 00 800 67 89 10 11 or by email