



PRESS RELEASE

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CEN AND CENELEC MAKE EUROPEAN STANDARDS AVAILABLE TO HELP ADDRESS COVID-19

In response to the coronavirus outbreak, CEN, the European Committee for Standardization, and CENELEC, the European Committee for Electrotechnical Standardization, agreed, in collaboration with all their Members and after the urgent request from the European Commission, to make freely available a series of European standards (ENs) for medical devices and personal protective equipment used in the context of the COVID-19 pandemic.

This exceptional decision is motivated by the need to tackle the severe shortage of protective masks and medical equipment experienced all around Europe due to the exponential growth of the COVID-19 emergency. The standards will enable a quicker and smoother access to market of new fundamental medical and protection equipment.

Providing free access to the national adoptions of this set of European standards facilitates the work of the many companies within the European Economic Area which are reconvertng their production lines to deliver tangible results quickly and ensure that healthcare professionals and patients have access to the equipment they urgently need.

The 11 standards developed by CEN and potentially 3 additional ones developed jointly with ISO made available cover common filtering masks, medical gloves and protective clothing. They are the fruit of a collective European effort. These European standards were developed and adopted by different Technical Bodies, taking into account the contributions of hundreds of experts and stakeholders in the personal protective equipment and medical field all around Europe.

The standards are available for free download from the [websites of CEN national members](#).

Thierry Breton, European Commissioner for the Internal Market, saluted the initiative: "In our battle against the coronavirus we need to act with urgency, solidarity and in a coordinated manner. We need audacity and innovative ways of producing the equipment we need. I am encouraging manufacturers to evaluate the possibilities of increasing and diversifying 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, today CEN and CENELEC agreed to make freely available the standards needed for such companies to be able to produce masks and other protective equipment. This agreement has immediate effect."

Vincent Laflèche, CEN President, commented: "Due to the coronavirus pandemic, we are living unprecedented circumstances which require exceptional measures. By making a set of standards available for free, the European standardization community is committed to help the European Commission in its effort to build the first common European reserve of emergency medical equipment (RescEU)".

Dany Sturtewagen, CENELEC President, added: "European standards play a crucial role in ensuring the availability of key medical devices and personal protective equipment. This extraordinary step is in line with the key drivers of our European standardization work: inclusiveness and unity. I salute the reaction of solidarity and commitment from our Members to support the global fight against COVID-19".

The list of the standards follows:

- [EN 149:2001 + A1:2009 Respiratory protective devices – Filtering half masks to protect against particles - Requirements, testing, marking \(commonly referred to as 'FFP masks'\)](#)
- [EN 14683:2019 Medical face masks - Requirements and test methods](#)
- [EN 166:2001 Personal eye-protection – Specifications](#)
- [EN 14126:2003 + AC 2004 Protective clothing - Performance requirements and tests methods for protective clothing against infective agents](#)
- [EN 14605:2009 + A1:2009 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 \(MDD\)](#)
- [EN 455-3:2015 Medical gloves for single use - Part 3: Requirements and testing for biological evaluation \(MDD\)](#)
- [EN 455-4:2009 Medical gloves for single use - Part 4: Requirements and testing for shelf life determination \(MDD\)](#)

In addition, upon CEN's request the following EN ISO standards are made available as read-only:

- [EN ISO 374-5:2016 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 + AC 2010 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process](#)

Furthermore, ISO decided to include the following standards, in read-only access:

- [EN ISO 22301:2019 Security and resilience — Business continuity management systems — Requirements](#)
- [ISO 22395:2018 Security and resilience — Community resilience — Guidelines for supporting vulnerable persons in an emergency](#)
- [ISO 22320:2018 Security and resilience — Emergency management — Guidelines for incident management](#)
- [ISO 22316:2017 Security and resilience — Organizational resilience — Principles and attributes](#)
- [ISO 31000:2018 Risk management — Guidelines](#)

CEN and CENELEC

CEN (European Committee for Standardization) and CENELEC (European Committee for Electrotechnical Standardization) are recognized by the European Union (EU) and the European Free Trade Association (EFTA) as European Standardization Organizations responsible for developing standards at European level. These standards set out specifications and procedures in relation to a wide range of materials, processes, products and services.

The members of CEN and CENELEC are the National Standardization Bodies and National Electrotechnical Committees of 34 European countries. European Standards (ENs) and other standardization deliverables adopted by CEN and CENELEC, are accepted and recognized in all of these countries.

European Standards (ENs) contribute to enhancing safety, improving quality, facilitating cross-border trade and strengthening the European Single Market. They are developed through a process of collaboration among experts nominated by business and industry, research institutes, consumer and environmental organizations, trade unions and other stakeholders. CEN and CENELEC work to promote the international alignment of standards in the framework of technical cooperation agreements with ISO (International Organization for Standardization) and the IEC (International Electrotechnical Commission).

CEN website: www.cen.eu

CENELEC website: www.cenelec.eu

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