

CEN and CENELEC workshop on Personal Protective Equipment (PPE) – Medical Devices (MD) dual use products

CEN and CENELEC personal protective equipment sector forum and the Advisory Board for Healthcare Standardization (ABHS) are pleased to invite you to participate in a PPE-MD dual use workshop taking place virtually on the 5th of October 2022.

The workshop will feature presentations on the key legislative requirements, existing work in technical committees and a discussion on how we could potentially generate an approach to integrate the requirements for PPE, medical products, and dual use products. Therefore, we hope to bring together stakeholders from different perspectives.

During the COVID-19 crisis there was (and still is) a lot of confusion about the legal status and the intended/claimed purpose of equipment to be used by the healthcare sector or to protect against the virus. It is not always clear for the users if a product is a PPE product, a MD product, a combination of both or none of those. The fact that in many communications 'protective equipment' is used to refer to both types of products is only contributing to the confusion. Furthermore, some of PPE that are not related to the current health crisis should be considered as dual use product, MD as well as PPE.

To create clarity and to avoid this confusion, a harmonised approach in the single market should be considered for those products. In this workshop, we would like to create a first step towards a common understanding of the opportunities and challenges to create this integrated approach.

Attendees will be invited to discuss and share their views and experiences that will enable CEN and CENELEC to make an informed decision on the possibility of standards in this area.

We invite you to participate in the important discussions and sincerely hope that you can join us on the day to contribute. Enclosed you find a schedule for the workshop.

You are welcome to provide a short statement during or in advance of the workshop, please indicate this in the <u>registration form</u>.

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5 October 2022

Dial in at 9:30am Central European Time

09:30am	Introduction and context Mr Henk Vanhoutte, European Safety Federation
09:45am	Introduction to the Legislative Framework Mr Mario Gabrielli-Cossellu, European Commission
10:10am	Existing developments and key requirements for PPE products Mrs Giovanna Longo, CEN/TC 159 - Hearing protection
10:40am	Existing developments and key requirements for MD products Mr Sven Schöppe, CEN/TC 205 – Non-active medical devices (gloves, gowns, masks)
11:10am	Coffee break
11:20am	Discussion

- 12:25pm Wrap-up
- 12:30pm Workshop close