European Standardization Organizations

Online Workshop

We start at 09:30 CEST

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

Your webinar moderator

Els Somers

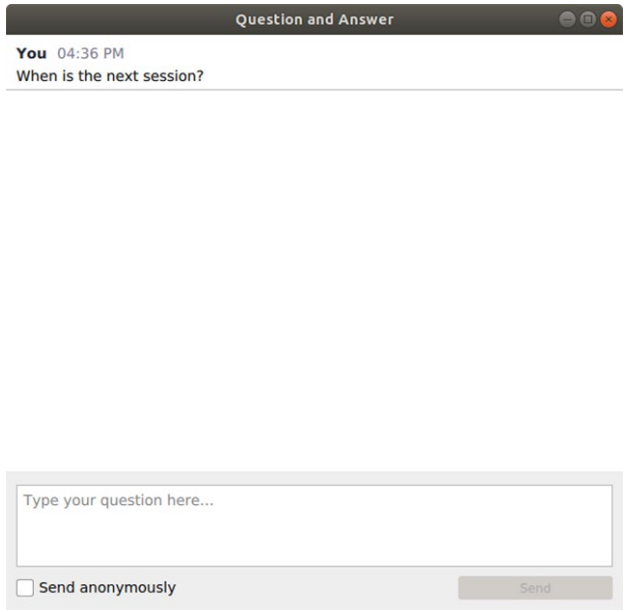
Project Manager

Policy & Partnerships

esomers@cencenelec.eu

Get the most out of the webinar today

- Use the Q&A panel to submit your questions



- Talk about us on Twitter #training4standards @Standards4EU

Agenda

- **Introduction and context**

  Henk Vanhoutte, European Safety Federation,
  CEN-CENELEC PPE sector forum

- **Introduction to the Legislative Framework**

  Mario Gabrielli-Cossellu, European Commission

- **Existing developments and key requirements for PPE products**

  Giovanna Longo, CEN/TC 159 - Hearing protectors

Agenda

- **Existing developments and key requirements for MD products**

  Sven Schöppe, CEN/TC 205 – Non-active medical devices

  (gloves, gowns, masks)

- **Statements participants**

- **Discussion / Q&A**

- **Wrap-up**

Setting the scene

Mr Henk Vanhoutte

European Safety Federation

CEN-CENELEC PPE sector forum

Poll

▶Which type of product are you familiar with?

- Personal protective equipment (PPE)
- Medical devices (MD)
- Combination products (PPE & MD)
- Other

The legislative framework

Mr Mario Gabrielli-Cossellu
European Commission

Introduction to the Legislative Framework

- Common EU policy: the "**New Legislative Framework**"
- Personal protective equipment (PPE): **Regulation (EU) 2016/425**
- Medical devices: **Regulation (EU) 2017/745**

The “New Legislative Framework” (1)

- Regulatory techniques for the development of EU harmonisation legislation on health, safety and performance of industrial and consumer products in the internal market, adopted in 1985 – the “New Approach” – and 2008 – the “New Legislative Framework”
- The “New Legislative Framework” policy consists of:
  - Regulation (EC) No 765/2008 on accreditation
  - Decision No 768/2008/EC on a common framework for the marketing of products
  - Regulation (EU) 2019/1020 on market surveillance and compliance of products
- Horizontal guidance: “The ‘Blue Guide’ on the implementation of EU product rules 2022”

The “New Legislative Framework” (2)

- Main common characteristics of EU legislation (Regulations and Directives) based on these policies:
  - scope and exclusions, general and specific definitions
  - placing/making available on the market and putting into service
  - roles and obligations of economic operators
  - essential requirements established in the law, technical specifications laid down in harmonised standards
  - categorisation/classification of products and related conformity assessment procedures, with third-party (“notified body”) intervention for medium and high-risk products
  - CE marking, EU declaration of conformity, technical documentation, certificates, accreditation, market surveillance…

Regulation (EU) 2016/425 on personal protective equipment (PPER)

- adopted in 2016, fully applicable from 2018; PPE Regulation Guidelines available
- defines PPE as "*equipment designed and manufactured to be worn or held by a person for protection against one or more risks to that person's health or safety*"
- lays down three "*categories of risks against which PPE is intended to protect users*": I (minimal risks), II (risks other than I and III) and III (very serious risks)
- sets out "*essential health and safety requirements*":
  - general requirements applicable to all PPE
  - additional requirements common to several types of PPE
  - additional requirements specific to particular risks
- provides for up to five conformity assessment procedures according to categorisation of PPE

Harmonised standards in support of the PPER

- Publications in the *Official Journal of the European Union* (OJEU) of references of harmonised standards in support of Regulation (EU) 2016/425, to confer presumption of conformity with the requirements the standards aim to cover
- Some examples of harmonised standards for potentially dual-use PPE products:
  - EN 149:2001+A1:2009 *Respiratory protective devices - Filtering half masks to protect against particles - Requirements, testing, marking*
  - EN 420:2003+A1:2009 *Protective gloves - General requirements and test methods*
  - EN ISO 13688:2013 *Protective clothing - General requirements (ISO 13688:2013)*

Regulation (EU) 2017/745 on medical devices (MDR)

- adopted in 2017, fully applicable from 2021; guidance documents and publications/factsheets available
- defines MD as "*any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for […] specific medical purposes*"
- establishes four "*risk classes… taking into account the intended purpose of the devices and their inherent risks*": I (lower risks), IIa, IIb and III (higher risks)
- sets out "*general safety and performance requirements*":
  - general requirements
  - requirements regarding design and manufacture
  - requirements regarding the information supplied with the device
- provides for up to three conformity assessment procedures according to classification of MD

Harmonised standards in support of the MDR

- Publications in the *Official Journal of the European Union* (OJEU) of references of harmonised standards in support of Regulation (EU) 2017/745, to confer presumption of conformity with the requirements the standards aim to cover
- Some examples of standards to be harmonised for potentially dual-use MD products (from the MDR standardisation request):
  - EN 455 (series) *Medical gloves for single use*
  - EN 13795 (series) *Surgical clothing and drapes - Requirements and test methods*
  - EN 14683 *Medical face masks - Requirements and test methods*

Ms Giovanna Longo

CEN/TC 159 – Hearing protectors

Content

- Respiratory protection

- Hearing protection
- Eye protection
- Clothing

The pandemic

The mask

The confusion

FFP Respirators

- Reduces wearer exposure to particles
- Filters at least 95% of large & small airborne particles
- Minimal leakage when properly donned

EN 149

VS

Surgical Masks

- Keeps wearer's respiratory emissions from patients
- Does not protect against smaller airborne particles
- Leakage around edge of mask when inhaling

EN 14683

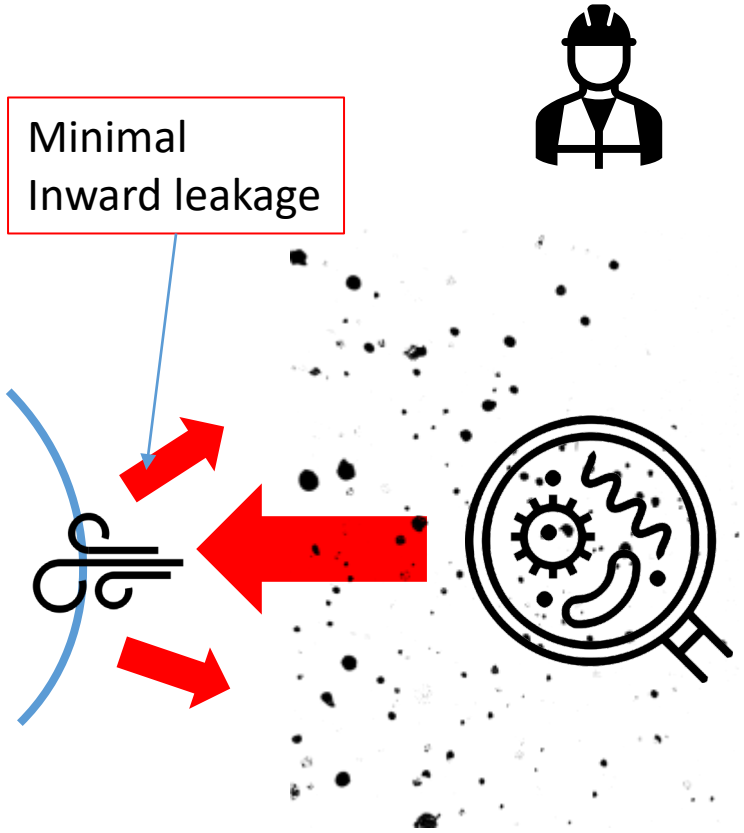
Respirators and masks

Need to protect the wearer

EN 149

PPE

Respirators and masks

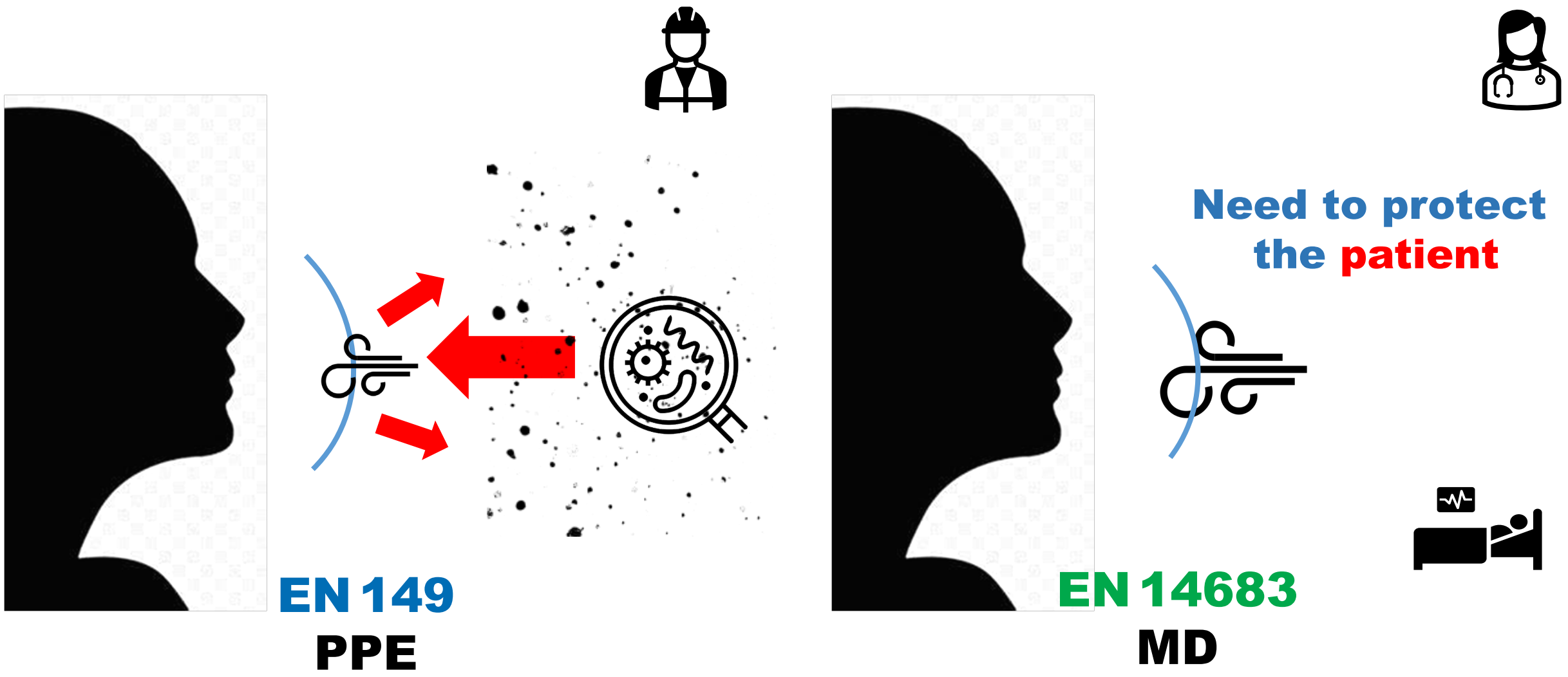


EN 149

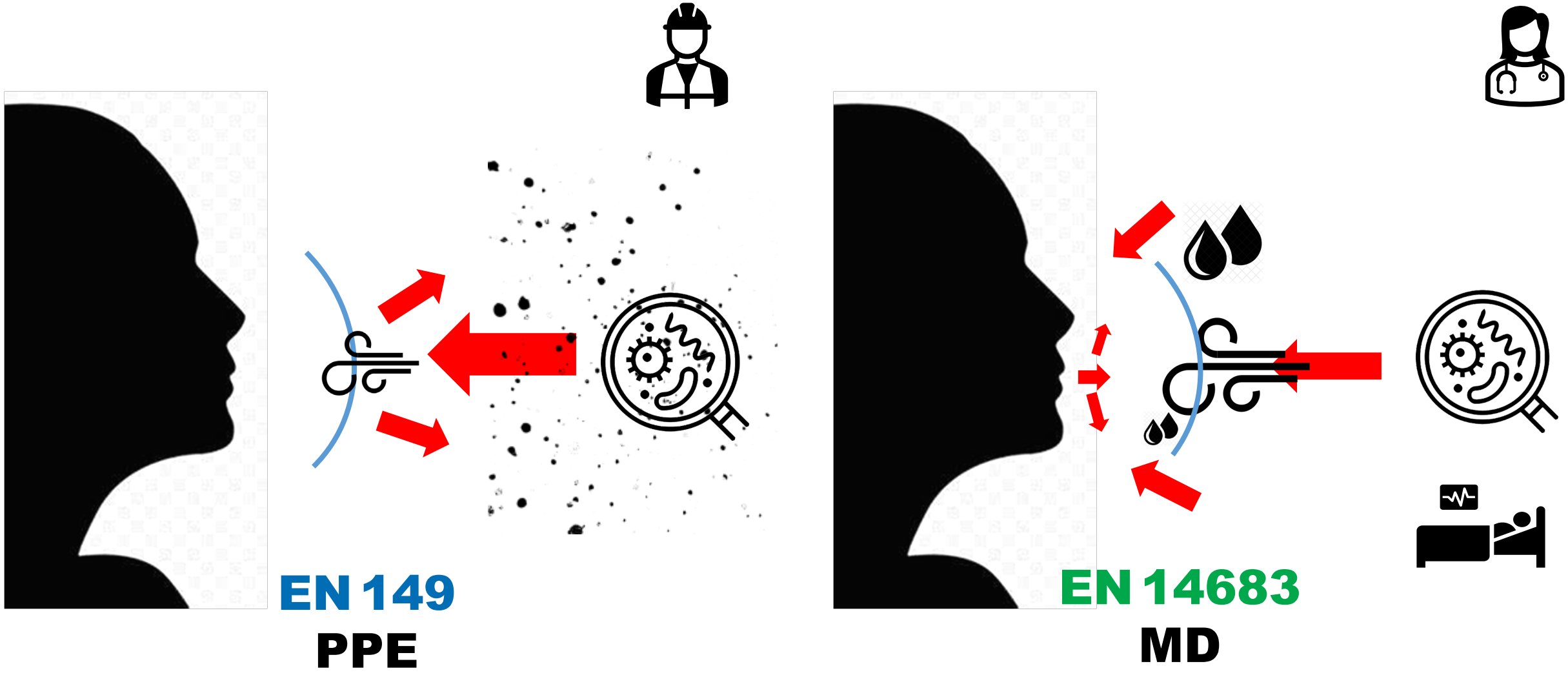
PPE

- Inward leakage is an important parameter
- A respirator protect the user as long as the fit is ensured on the user himself

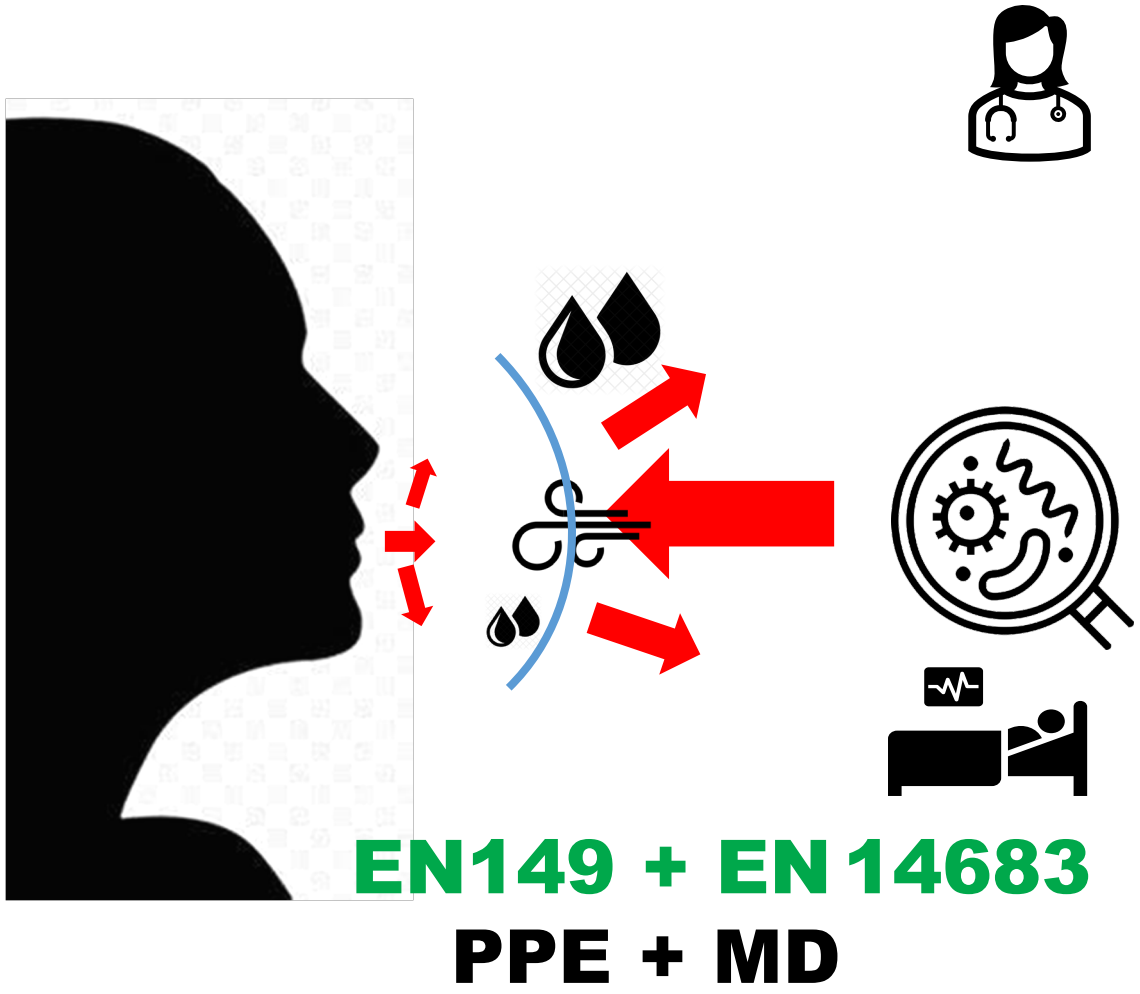
Respirator and mask



Respirator and mask



Double certification



- EN 149 + EN 14683
- Differential pressure: breathability according to respiratory standards if for specific medical use
- Challenges (ISO 13485, registration, post market surveillance…)

Two worlds under stress

The need for a new direction

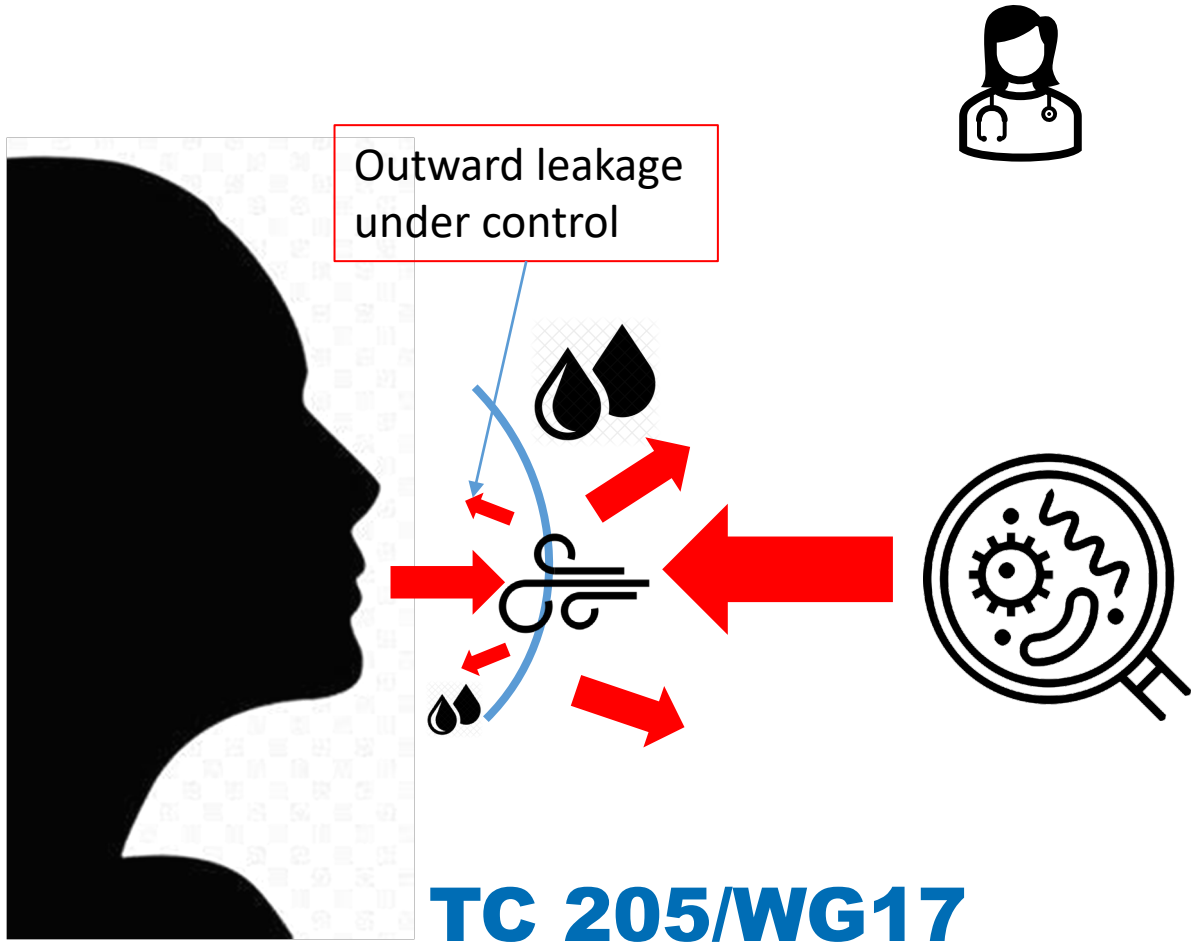
- The pandemic made clear there is the need for a different type of products
- Something that is more than the sum of two standards
- It was necessary to re-think the approach
- The work on the **infection prevention mask** started

The need for a new direction

CEN/TC 205 Subcommittees and Working Groups

Working group	Title
CEN/TC 205/WG 14	Surgical clothing and drapes, and medical face masks
CEN/TC 205/WG 15	Wound dressings
CEN/TC 205/WG 17	Infection protection masks
CEN/TC 205/WG 3	Medical gloves

The need for a new direction



- Inward leakage + outward leakage
- Wear time
- Elderly people or people with medical condition
- Children

TC 205/WG17

PPE + MD

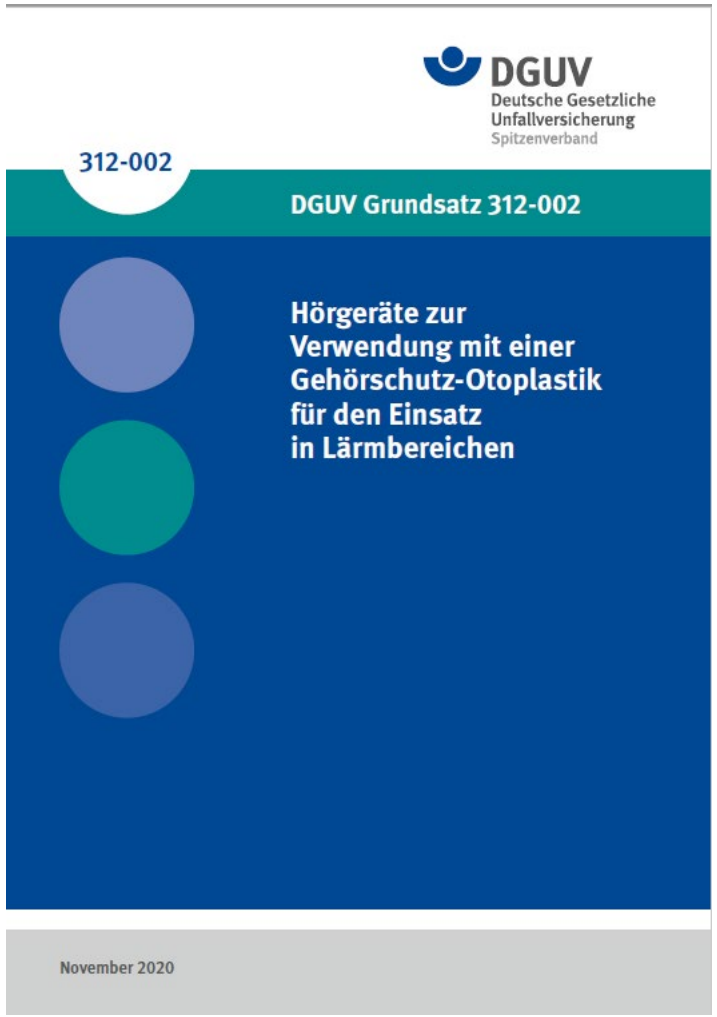
Example for hearing protection

- Situation:

A person wearing hearing aid and working in a noisy environment

Example for hearing protection

Hearing aid + **Hearing protection**



[DGUV Grundsatz 312-002 „Hörgeräte zur Verwendung mit einer Gehörschutz-Otoplastik für den Einsatz in Lärmbereichen“ | DGUV Publikationen]

Eyewear

- Protective eyewear are tested and certified according to EN 166
- What is somebody wants to replace the lenses with magnifiers glasses (to read better)
- Or even wants to exchange the lenses with corrective glasses?

Protective clothing

- New development of clothing with sensors, EN 17673
- How to deal with phisiological sensors, like the one to measure heart beats?

Existing developments and key requirements for MD products

Mr Sven Schöppe

CEN/TC 205 – Non-active medical devices (gloves, gowns, masks)

Most Wanted during COVID-19

Image Source: leo-system.net

Spot the difference!

Image sources: vandijk.nl

Easy to tell the difference!

Medical Device, Class I(s)

EU 2017/745 - MDR

(Chapter I, Article 1, (3)):

Medical and non-medical devices must comply with both the requirements for medical devices and the requirements for non-medical devices".

PPE, Category III

EU 2016/425 PPE-R

(Chapter III, Article 15, (3)):

Where a PPE is subject to more than one Union act requiring an EU declaration of conformity, a single EU declaration of conformity shall be drawn up in respect of all Union acts.

The (un)intended duality

- Since the MDR focuses on patient protection, the view on protection of the surgeons or operating teams takes a back seat.
- However, a manufacturer may also identify the HCW-protective functions separately as PPE.
- He must document these and declare them to be in conformity with the PPE-R requirements.

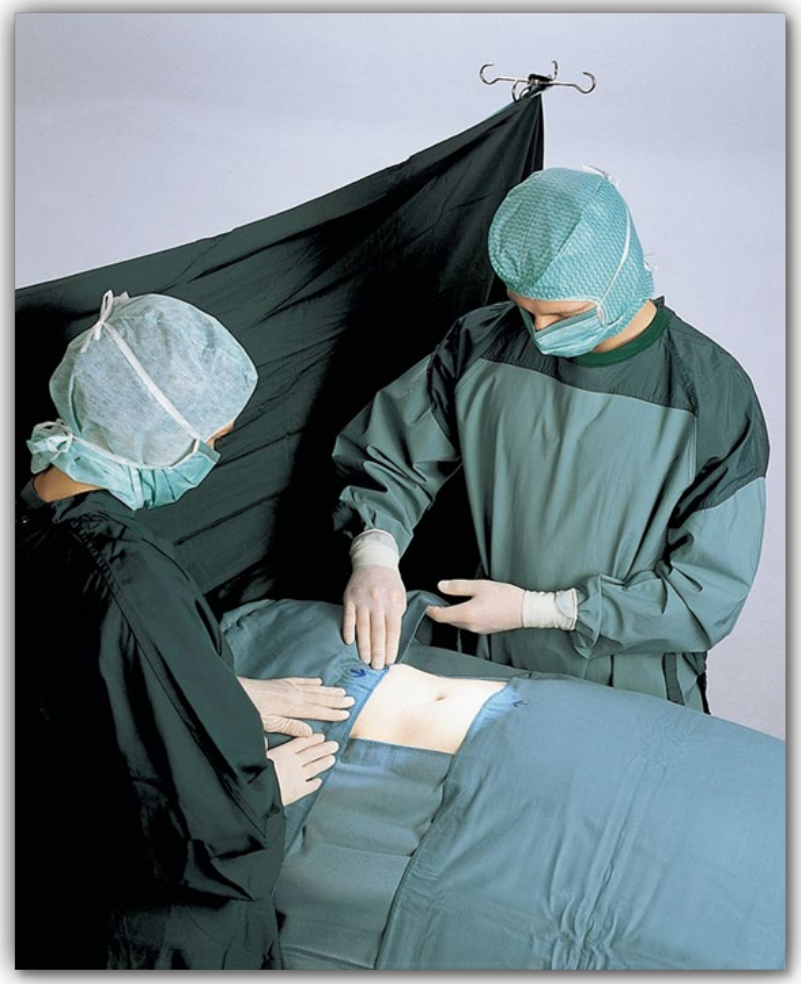


Image source: leo-system.net

Different Risk Classifications

EU 2017/745 - MDR

- According to general interpretation, a surgical gown is classified as a medical device of risk class 1 or 1s:
  - Declaration of conformity possible in own responsibility (if non-sterile),
  - Notified Body for sterilisation and (in GER)
  - reprocessing according to RKI (QMS according to EN ISO 13485)
  - if reusable in conjunction with EN 14065

EU 2016/425 PPE-R

- According to general interpretation, a surgical gown would be classified as category III PPE
- Type examination and production support:
  - Module C2 „product monitoring“ or
  - Module D „quality monitoring“
- Four-digit reference number NB

The manufacturers' dilemma

- Despite having conducted all required assessment and quality control for a medical device
- manufacturer would have to claim conformity to PPE-R on a second path
- A second Surveillance authority comes into play (GER: ZLG/ZLS)
- Often also a second NB would be required

ZERTIFIKAT

Hiermit wird bescheinigt, dass das Unternehmen

Example Company
12345 Town
ABC Street
EU Country

ein **Qualitätsmanagementsystem** eingefü

Geltungsbereich:
Herstellung und Vertrieb von wiederverwendbarer

Durch ein Audit, dokumentiert in einem Bericht, d
wurde der Nachweis erbracht, dass das Managen
Regelwerks erfüllt:

DIN EN ISO 13485 : 2016 +
EN ISO 13485 : 2016 + AC
ISO 13485 : 2016

Zertifikat-Registrier-Nr.	531509 MP2016
Zertifikat-ID	170778315
Gültig ab	2021-10-04
Gültig bis	2023-02-16
Frankfurt am Main, den	2021-10-04

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Geschäftsführerin

August-Schanz-Straße 21, 60433 Frankfurt am Main,
Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de

IQNet

EG-ZERTIFIKAT
(Qualitätssicherung Produktion)

Hiermit wird bescheinigt, dass das Unternehmen

Example Company
12345 Town
ABC Street
EU Country

ein Qualitätssicherungssystem für die Herstellung und Endprüfung der Produkte eingeführt hat und anwendet.

Durch ein Audit, dokumentiert in einem Bericht, durchgeführt von DQS Medizinprodukte GmbH, wurde der Nachweis erbracht, dass dieses Qualitätssicherungssystem die Forderungen gemäß

Anhang V der Richtlinie 93/42/EWG des Rates über Medizinprodukte

bezüglich folgender Medizinprodukte erfüllt:

Patientenabdeckungen, OP-Mäntel, Sonstige Abdeckungen und Kombinationen (Klasse Is)

Der Hersteller unterliegt der Überwachung nach Anhang V, Abschnitt 4. Die CE Kennzeichnung mit der Kennnummer der Benannten Stelle (0297) darf an den auf dem Zertifikat gelisteten Produkten angebracht werden. Das Zertifikat beschränkt sich für Produkte der Klasse I(s) (I(s) = Produkte der Klasse I die in sterilem Zustand in Verkehr gebracht werden) ausschließlich auf die Herstellung im Zusammenhang mit der Sterilisation und der Aufrechterhaltung der Sterilität. Das Zertifikat beschränkt sich für Produkte der Klasse I(m) (I(m) = Produkte der Klasse I mit Messfunktion) ausschließlich auf die Herstellung im Zusammenhang mit der Konformität der Produkte mit den messtechnischen Anforderungen.

Zertifikat-Registrier-Nr.	531509 MR5
Zertifikat-ID	170746126
Gültig ab	2020-02-17
Gültig bis	2024-05-26
Frankfurt am Main, den	2020-02-17

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Geschäftsführerin

Dr. Thomas Feldmann
Leiter der Zertifizierungsstelle

August-Schanz-Straße 21, 60433 Frankfurt am Main,
Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de

Die DQS Medizinprodukte GmbH ist Benannte Stelle gemäß der Richtlinie 93/42/EWG des Rates über Medizinprodukte mit der Kennnummer 0297.

411.21 Version 1.0

HYGCEN AUSTRIA

EINGEGANGEN AM 22. FEB. 2021

Bischofshofen, 09.02.2022

rüfbericht / *test report* B 29062

atory:	B 29062
	217 OP-Mantel SP L / 9336217.1 / standard performance
designation:	217 OP-Mantel SP L
	9336217.1
	n/a
	2021-12-23
very:	2022-01-13
sis:	2022-01-20 bis / *to* 2022-02-08
ions:	Die Prüfung erfolgte im Anlieferungszustand. / *The test was done in the delivery state.*
	Operationskleidung und –abdecktücher – Anforderungen und Prüfverfahren – Teil 1: Operationsabdecktücher und –mäntel / *Surgical clothing and drapes – Requirements and test methods – Part 1: Surgical drapes and gowns*
	EN 13795-1:2019

Seite 1 von 14

Different NBs, small overlap

EU 2017/745 - MDR

NB 0044	TÜV NORD CERT GmbH	Germany
NB 0123	TÜV SÜD Product Service GmbH	Germany
NB 0124	DEKRA Certification GmbH	Germany
NB 0197	TÜV Rheinland LGA Products GmbH	Germany
NB 0297	DQS Medizinprodukte GmbH	Germany
NB 0482	MEDCERT ZERTIFIZIERUNGS- UND PRÜFUNGSGESELLSCHAFT FÜR DIE MEDIZIN GMBH	Germany
NB 0483	MDC MEDICAL DEVICE CERTIFICATION GMBH	Germany
NB 0633	Berlin Cert Prüf- und Zertifizierstelle für Medizinprodukte GmbH	Germany

Image sources: NANDO MD/PPE, retrieved 24.06.2022

EU 2016/425 PPE-R

NB 2004	Bureau Veritas Consumer Products Services Germany GmbH	Germany
NB 0158	DEKRA Testing and Certification GmbH	Germany
NB 0340	DGUV Test Prüf- und Zertifizierungsstelle Elektrotechnik Fachbereich Energie Textil Elektro Medienerzeugnisse der Deutschen Gesetzlichen Unfallversicherung e.V. (DGUV)	Germany
NB 0299	DGUV Test Prüf- und Zertifizierungsstelle Fachbereich Persönliche Schutzausrüstungen der Deutschen Gesetzlichen Unfallversicherung e.V. (DGUV)	Germany
NB 0418	DGUV Test Prüf- und Zertifizierungsstelle Fachbereich Rohstoffe und chemische Industrie der Deutschen Gesetzlichen Unfallversicherung e.V. (DGUV)	Germany
NB 0556	DGUV Test Prüf- und Zertifizierungsstelle Nahrungsmittel und Verpackung Fachbereich Nahrungsmittel der Deutschen Gesetzlichen Unfallversicherung e.V. (DGUV)	Germany
NB 0196	DIN CERTCO GESELLSCHAFT FÜR KONFORMITÄTSBEWERTUNG MBH	Germany
NB 0098	DNV GL SE	Germany
NB 0297	DQS Medizinprodukte GmbH	Germany
NB 0515	Deutsche Gesetzliche Unfallversicherung e.V. DGUV Test Prüf- und Zertifizierungsstelle Fachbereich Bauwesen c/o BG BAU - Prävention	Germany
NB 0363	Deutsche Prüf- und Zertifizierungsstelle für Land- und Forsttechnik	Germany
NB 1883	ECS European Certification Service GmbH	Germany
NB 0555	HOHENSTEIN LABORATORIES GmbH & Co. KG	Germany
NB 0121	Institut für Arbeitsschutz der Deutschen Gesetzlichen Unfallversicherung (IFA) Prüf- und Zertifizierungsstelle im DGUV Test	Germany
NB 0102	Konformitätsbewertungsstelle der Physikalisch-Technischen Bundesanstalt (PTB)	Germany
NB 1080	MATERIALPRÜFUNGSANSTALT UNIVERSITÄT STUTTGART	Germany
NB 0432	Materialprüfungsamt Nordrhein-Westfalen (MPA NRW)	Germany
NB 0193	PFI - PRÜF-UND FORSCHUNGSINSTITUT PIRMASENS E.V.	Germany
NB 1974	PZT GmbH	Germany
NB 0516	Sächsisches Textilforschungsinstitut e. V. - An-Institut der Technischen Universität Chemnitz	Germany
NB 0125	TÜV Rheinland LGA Products GMBH **14/02/2012 (Expired/Withdrawn)**	Germany
NB 0197	TÜV Rheinland LGA Products GmbH	Germany
NB 0123	TÜV SÜD Product Service GmbH	Germany
NB 1771	UNIVERSITÄT STUTTGART INSTITUT FÜR FÖRDERTECHNIK UND LOGISTIK	Germany
NB 0366	VDE Prüf- und Zertifizierungsinstitut GmbH	Germany
NB 0414	ZERTIFIZIERUNGSSTELLE FÜR ATEMSCHUTZGERÄTE UND AUTONOME LEICHTTAUCHGERÄTE DER BERGBAU-BERUFSGENOSSENSCHAFT	Germany

Different Product assessments

EU 2017/745 - MDR

- MD risk class 1 / 1s
- hEN: EN 13795-1:2019
- Standard/High-Performance
- Specific test methods, performance values
- Material certifications, testing institutes / notified bodies?
- Technical documentation?

EU 2016/425 PPE-R

- PPE category 3
- hEN 14126:2003/AC:2004
- 5 or 6-class gradation
- Specific test methods, performance values
- Material certifications, testing institutes / notified bodies?
- Technical documentation?

Dual Use covered in EN 14126

Protection against chemical agents

Image sources: ksta.de

Protection against biological/infective agents

Protective clothing - Performance requirements and test methods for protective clothing against infective agents

ISO acts now, CEN/EU need to catch up

- EN 14126 is currently under revision, ISO 22615 as the successor is under construction
- In Lists of harmonised standards for MD and PPE one does not find cross-referencing of EN 13795 (MD) / EN 14126 (PPE)
- ISO/TC 94/SC 13/WG 6 has noticed the need for a European perspective integrated into a world-wide standard application
- ISO/TC 94/SC 13/WG 6 has acknowledged that giving space to manufacturers for claiming conformity to certain “agent groups” could be key for acceptance and for using this standard for choosing appropriate protection
- A proposal / guideline on vice-versa acceptance for successfully conducted conformity assessments MD/PPE could be very helpful

Slippery Grounds for Dual Use Products

- In the course of the COVID-19 pandemic response:
  - the demand for protective gowns grew rapidly and was also to be met with surgical gowns, conformity to the intended „PPE"-use was not always apparent or approved
  - medical masks according to EN 14683 (MD Class 1) and FFP protective masks according to EN 149 (PPE Category 3) with different protection targets were used in mixed settings
- But even in times not impacted by pandemics
  - could gloves, for example, become subject to different documentation and conformity requirements when in contact with food instead of with patients?

Tackling the obstacles

- The existing hurdles in the mutual or vice-versa recognition of existing accreditations, certifications and performance assessments of the two sectors must be removed
- This must be done in cooperation with relevant standardization bodies, DG GROW (PPE) and DG SANTE (MD) in the form of guidelines
- It must become easier to develop products with combined functionality and to go through combined conformity assessment procedures
- Today, double documentation and certification costs halve market opportunities for dual use products

Coffee break

Poll

▶What would your preferred outcome be for European standardization?

- Integrated standards which can be used to meet both MD and PPE requirements
- Keep PPE and MD standards separate
- It would depend on the dual use product

Statements

- Omar Dhaher
- Pawel Gorski
- Alexis Percival
- Aikaterini Poustourli (with slides)
- Anna Ruhala (with slides)

CEN and CENELEC workshop on Personal Protective Equipment (PPE) – Medical Devices (MD) dual use products, 5th October 2022

POLICY/DECISION MAKING

EUROPEAN COMMISSION DG SANTE, OTHER POLICY DGs (GROW, ECHO, HOME, DEFIS, CNECT)
EMA, HERA, ECDC, ECHA, EFSA and EU-OSHA ,JRC, EIT, ERC
International Medical Device Regulators Forum (IMDRF)

WHO, UNICEF, UNECE WP.6 Forum, ISO, IEC, …

TASK FORCES

Advisory Board for Healthcare Standardization (ABHS)
Unique Device Identifiers (UDI)
European Medical Device Nomenclature (EMDN)
Medical Device Coordination Group (MDCG) and its 13 subgroups
MSs Joint Assessment Teams
MSSG, MDSSG, MDSG, ETF, CHMP, TF AAM EMA/HMA
PPE committee working group

LEGISLATION

EU NEW DIRECTIVES and REGULATIONS

NEW Medical Devices Regulation (EU) 2017/745 (MDR)
NEW in Vitro Diagnostic Medical Devices Regulation (EU) 2017/746 (IVDR) and amendments to the MDR and the IVDR
M/553, M/295, M/252, M/467
MPD DIRECTIVE 2001/83/EC
REGULATIONS 2022/123, 2021/522, 2017/746, 2004/726, 2016/425, Recommendation (EU) 2020/403
GDPR; Regulation 428/2009 Dual-Use .

STANDARDS

EU NEW STANDARDISATION STRATEGY

Harmonised Standards Official Journal of the European Union (EN)
CEN CENELEC HEALTH CARE BT, TCs, WGs
CEN CENELEC OCCUPATIONAL HEALTH & SAFETY
CEN CENELEC DEFENCE & SECURITY BT, TCs, WGs (TC 391 WG1,2,3)
CE-marked products
EN, TS, other CEN CENELEC Standardisation Deliverables

PLATFROMS – INTEROPERABILITY

ESMP, EUDAMED new European database on medical devices
GALILEO, COPERNICUS

R&I

Horizon Europe Pillars I, II, III. Clusters 1: Health; 3: Civil Security for Society; 4: Digital, Industry & Space; 6: Food, Bioeconomy, Agriculture
HERA Incubators
SMART PPE , SMART MD
Emerging and disruptive healthcare technologies with dual-use potential (AI, QC, Metaverse (AR/VR/XR), ML, 3D pronting, Health wearables etc.)

RISKS

PRODUCTS (ITEMS, SUPPLY CHAIN, DISTRIBUTION CHANNELS etc))
STAKEHOLDERS (MANUFACTURERS, NOTIFIED BODIES, PHARMACEUTICAL COMPANIES, NATIONAL AUTHORITIES, HOSPITALS, EXPORTERS/IPORTERS, CUSTOMS,
Healthcare workers and other first-line responders.
COVID-19, Monkeypox, Zika, Embola
PANDEMICS CRISES, Emergencies, Disasters

INTERDEPENDENCIES

DUAL- USE (from the security point of view. CBRN , PPE. Biosafety, biosecurity.
EDA (EDSTAR),; NATO (NASTAG)
IFAFRI (firefighters, first responders SaR crews);
IDMP |
Hybrid products, …..

Finnish Institute of
Occupational Health

Solution proposal: Need of isolation gowns in healthcare

Erja Mäkelä

Correspondence: Erja.Makela@ttl.fi

Need of isolation gowns and aprons with sleeves for healthcare

- Occupational safety legislation requires that PPE needs to be used for protection, when other risk management methods are not enough.
- Avian and swain influenza and COVID-19 learning:
  - Healthcare safety personnel and purchasers do not know about requirements, classes, types, or protection properties of clothing against biological risks, EN 14126
    - Just EN 14126 clothing asked and anything applies starting from class 6-B with very low level protection.
  - EN 14126 is so complicated that specialists have difficulties to explain the standard: https://oshwiki.eu/wiki/Protective_clothing_against_chemical_and_biological_hazards
  - **Important in crisis situation:** Potential manufacturers of the clothing do not understand the EN 14126 and PPE Regulation 426/2016 or the needs of clothing properties.

Problem solution proposal: New part in EN 14126 - Isolation gowns and aprons

- The possibilities for choosing between different properties are minimized for isolation gowns and aprons.
- Models:
  - Gown to be opened from backside, tied from backside, not possible to tie from frontside, the backside hems need to overlap for protection from the back
  - Apron with sleeves, the same properties, but the hems do not overlap

- Next page, some proposed testing requirements taken from standards of surgical gowns and from protective clothing against infecting agents.

Testing proposal

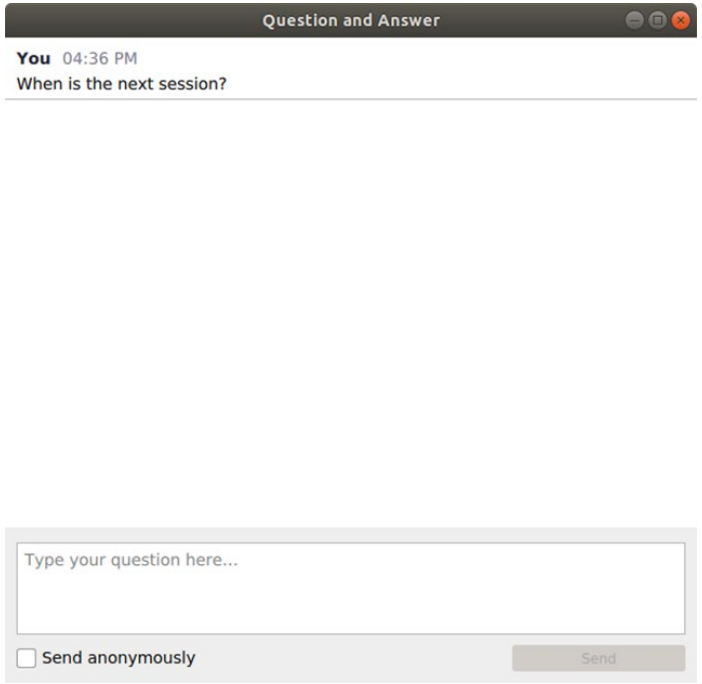
Property	Test standard	Requirement
Liquid penetration EN 13795-1:2019	EN ISO 811	>= 20 cmH2O
Pull (traction) strength, dry, EN 13795-1:2019 / EN 14126:2003/AC:2004	EN 29073-3	>= 20 N
Pull (traction) strength, wet, EN 13795-1:2019	EN 29073-3	>= 20 N
Crack strength of the seams, EN 14126:2003/AC:2004	ISO 13935-2:2014, maximum grap strength with grap method	Minimum 20 N, but at least the same as of the material
Blood and viral penetration	ISO 16603 and EN 16604	>= class 4

Disposable and reusable models possible

- If not disposable,
- washing in accordance with EN 14065:2016; If reapplication of surface modifiers are needed, the method needs to be explained. Maximum washing cycles to be informed.
- OR
- EN ISO 6330:2012, 90 °C. Maximum washing cycles to be informed.

Question time

- Use the Q&A panel to submit your questions



Discussion

- Do we need integration of standards, or is it preferred to have separate standard and in which case?
- Would it make sense for manufacturer to combine?
- Separate approach needed for two groups of products with different criteria?
- International or European outlook, are there existing examples internationally?
- Any other input or experience and that are missing from today's conversation?
- …

Wrap-up

Open poll

- Please share your thoughts in a few words (e.g. what challenges do we need to overcome, which dual use products should be the focus, what kind of criteria should we review as an outcome of the webinar?)

European Standardization Organizations

Thank you for your participation!

Next webinars/events

2022-11-25 - Webinar 'Hearing for life – How can hearing protection support?’

2022-12-12 – Training for newly CEN & CENELEC Technical Committees