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General Secretariat

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LIMITE

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	POLCOM	**CODEC**

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WORKING DOCUMENT

From:	General Secretariat of the Council
To:	Antici Group (Simplification)
Subject:	Omnibus IV - Digitalisation and Common Specifications - Commission presentation

Delegations will find attached a presentation on the Omnibus IV - Digitalisation and Common Specifications prepared by the Commission for the meeting of the Antici Group (Simplification) of 16 June 2025.

IV Omnibus on digitalisaiton and Common Specifications

DG GROW – Internal Entrepreneurship and SMEs

European Commission

European Commission

COM(2025) 503 final, 2025/0133(COD), Proposal for a DIRECTIVE amending Directives 2000/14/EC, 2011/65/EU, 2013/53/EU, 2014/29/EU, 2014/30/EU, 2014/31/EU, 2014/32/EU, 2014/33/EU, 2014/34/EU, 2014/35/EU, 2014/53/EU, 2014/68/EU and 2014/90/EU as regards digitalisation and common specifications

COM(2025) 504 final, 2025/0134(COD), Proposal for a REGULATION amending Regulations (EU) No 765/2008, (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, (EU) 2023/1230, (EU) 2023/1542 and (EU) 2024/1781 as regards digitalisation and common specifications

Proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

amending Directives 2000/14/EC, 2011/65/EU, 2013/53/EU, 2014/29/EU, 2014/30/EU, 2014/31/EU, 2014/32/EU, 2014/33/EU, 2014/34/EU, 2014/35/EU, 2014/53/EU, 2014/68/EU and 2014/90/EU of the European Parliament and of the Council as regards digitalisation and common specifications

ANNEXES
to the

Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

amending Directives 2000/14/EC, 2011/65/EU, 2013/53/EU, 2014/29/EU, 2014/30/EU, 2014/31/EU, 2014/32/EU, 2014/33/EU, 2014/34/EU, 2014/35/EU, 2014/53/EU, 2014/68/EU and 2014/90/EU of the European Parliament and of the Council as regards digitalisation and common specifications

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

amending Regulations (EU) No 765/2008, (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, (EU) 2023/1230, (EU) 2023/1542 and (EU) 2024/1781 as regards digitalisation and common specifications

ANNEXES
to the

Proposal for a
REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

amending Regulations (EU) No 765/2008, (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, (EU) 2023/1230, (EU) 2023/1542 and (EU) 2024/1781 as regards digitalisation and common specifications

Digitalisation – 13 directives

- Directive 2011/65/EU - restriction of the use of certain hazardous substances in electrical and electronic equipment (ROHS)
- Directive 2014/29/EU - simple pressure vessels
- Directive 2014/30/EU - electromagnetic compatibility (EMC)
- Directive 2014/31/EU - non-automatic weighing instruments
- Directive 2014/32/EU - measuring instruments
- Directive 2014/33/EU - lifts
- Directive 2014/34/EU - equipment and protective systems intended for use in potentially explosive atmospheres (ATEX)
- Directive 2014/35/EU – low voltage
- Directive 2014/53/EU - radio equipment
- Directive 2013/53/EU - recreational craft and personal watercraft
- Directive 2014/68/EU - pressure equipment
- Directive 2014/90/EU - marine equipment
- Directive 2000/14/EC - noise emission in the environment by equipment for use outdoors

Digitalisation – 6 regulations

- Regulation (EU) 2016/424 - cableway installations
- Regulation (EU) 2016/425 - personal protective equipment
- Regulation (EU) 2016/426 - burning gaseous fuels (GAR)
- Regulation (EU) 2023/1230 – machinery
- Regulation (EU) 2023/1542 - batteries and waste batteries
- Regulation (EU) 2024/1781 - ecodesign requirements for sustainable products (ESPR)

Questions on the scope of the omnibus

BG, SL, LT: Most legislation aligned with the NLF is included within the scope of the omnibus. However, some, like the Pyrotechnics Directive and CIVEX Directive, are excluded. What might be the reason for including certain NLF legislation while omitting others?

We excluded specific pieces of NLF legislation that diverge from the NLF model due to the nature and risks of the products in their scope, to the extent that including the horizontal modifications would not be transferable one to one. For instance, with pyrotechnics and civil explosives, the risks associated with these products necessitate that instructions are part of the labelling on the packaging and there is an ongoing evaluation for both pieces of legislation.

There is one piece of legislation within the scope of this omnibus that does not align with the NLF: the Outdoor Noise Directive (2000/14/EC). Despite this, the directive often applies to products alongside other directives or regulations, such as the Machinery Regulation. To prevent manufacturers from having to comply with varying obligations when their products are covered by multiple directives, we decided to include this directive in the omnibus scope to ensure coherence and consistency.

Digitalisation

The changes will be presented by the four main areas:

- The **digitalisation of the EU declaration** of conformity and the **communication** between economic operators and market surveillance authorities – to avoid any unnecessary accompanying paper documentation;

- The introduction of a **digital contact to facilitate** communication between economic operators and national authorities or end-users;

- The **possibility to provide instructions for use in an electronic form**;

- The introduction of an obligation **to provide the information contained in the EU declaration of conformity and instructions on the digital product passport** when the product is subject to another Union legislation that requires the use of such a digital product passport, to avoid a double administrative burden.

Declaration of conformity

Example: Regulation (EU) No 2016/425 on personal protective equipment (Art. R2 Annex I, Decision No 768/2008/EC)

Article 8

Obligations of manufacturers

1. When placing PPE on the market, manufacturers shall ensure that it has been designed and manufactured in accordance with the applicable essential health and safety requirements set out in Annex II.

2. Manufacturers shall draw up the technical documentation referred to in Annex III ('technical documentation') and carry out the applicable conformity assessment procedure referred to in Article 19 or have it carried out.

Where compliance of PPE with the applicable essential health and safety requirements has been demonstrated by the appropriate procedure, manufacturers shall draw up the EU declaration of conformity referred to in **Article 15 and affix the CE marking** referred to in Article 16.

Omnibus amendment:

(2) Article 8 is amended as follows:

(a) in paragraph 2, the second subparagraph is replaced by the following:

'Where compliance of PPE with the applicable essential health and safety requirements has been demonstrated by the appropriate procedure, manufacturers shall draw up the EU declaration of conformity referred to in Article 15, **in electronic form,** and affix the CE marking referred to in Article 16.';

Declaration of conformity

Example: Regulation (EU) No 2016/425 on personal protective equipment (Art. R2 Annex I, Decision No 768/2008/EC)

Article 8

Obligations of manufacturers

1. When placing PPE on the market, manufacturers shall ensure that it has been designed and manufactured in accordance with the applicable essential health and safety requirements set out in Annex II.

2. Manufacturers shall draw up the technical documentation referred to in Annex III ('technical documentation') and carry out the applicable conformity assessment procedure referred to in Article 19 or have it carried out.

'Where compliance of PPE with the applicable essential health and safety requirements has been demonstrated by the appropriate procedure, manufacturers shall draw up the EU declaration of conformity referred to in Article 15, **in electronic form,** and affix the CE marking referred to in Article 16.';

Declaration of conformity

General rule: the declaration of conformity must be made available to the authorities upon request

The 2022 Blue Guide:

4.4. EU declaration of conformity

— *The manufacturer or the authorised representative established within the Union must draw up and sign an EU Declaration of Conformity as part of the conformity assessment procedure provided for in the Union harmonisation legislation.*

The manufacturer, authorised representative and the importer must:

— Keep a copy of the EU Declaration of Conformity for 10 years after the product has been placed on the market ([142]) or for the period specified in the relevant Union harmonisation act.

The distributor must:

The distributor must be able to identify the manufacturer, his authorised representative, the importer or the person who has provided him with the product in order to assist the market surveillance authority in its efforts to obtain the EU Declaration of Conformity and the necessary parts of the technical documentation. Market surveillance authorities have the possibility to address their request for the technical documentation directly to the distributor. The latter is however not expected to be in possession of the relevant documentation.

Declaration of conformity

Example: Regulation (EU) No 2016/425 on personal protective equipment

Article 8

Obligations of manufacturers

10. Manufacturers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation, **in paper or electronic form,** necessary to demonstrate the conformity of the PPE with this Regulation, in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by PPE which they have placed on the market.

Omnibus amendment:

(e) in paragraph 10, the first sentence is replaced by the following:

'Manufacturers shall, further to a reasoned request from a competent national authority, provide it, **in electronic form,** with all the information and documentation necessary to demonstrate the conformity of the PPE with this Regulation, in a language which can be easily understood by that authority.';

Declaration of conformity

Example: Regulation (EU) No 2016/425 on personal protective equipment

Article 8

Obligations of manufacturers

'Manufacturers shall, further to a reasoned request from a competent national authority, provide it, **in electronic form,** with all the information and documentation necessary to demonstrate the conformity of the PPE with this Regulation, in a language which can be easily understood by that authority.';

This obligation has changed in a same way by the omnibus for authorised representatives, importers and distributors (Article R3, R4 and R5 of Decision No 768/2008/EC)

This means the following:

- When the market surveillance authorities request the DoC from the manufacturer, authorised representative or the importer, they should provide it in electronic form (e.g. send it by email to the authorities).

- Distributors do not necessarily have a copy of the DoC (as we saw on the slide citing the Blue Guide) –they should provide the information that they have, to assist the market surveillance authorities.

Declaration of conformity

Although the general rule is that the declaration of conformity must be made available to the authorities upon request,

However, there are 10 acts that require that a copy of the declaration of conformity accompanies the product:

- Directive 2014/32/EU – measuring instruments
- Directive 2014/33/EU – lifts
- Directive 2014/34/EU – equipment and protective systems intended for use in potentially explosive atmospheres (ATEX)
- Directive 2014/53/EU – radio equipment
- Directive 2013/53/EU – recreational craft and personal watercraft
- Directive 2000/14/EC – noise emission in the environment by equipment for use outdoors
- Regulation (EU) 2016/425 – personal protective equipment
- Regulation (EU) 2016/426 – burning gaseous fuels (GAR)
- Regulation (EU) 2016/424 – cableway installations
- Regulation (EU) 2023/1230 – machinery

Declaration of conformity

Example: Directive 2014/33/EU on lifts and safety components for lifts

Article 8

Obligations of manufacturers

1. When placing their safety components for lifts on the market, manufacturers shall ensure that they have been designed and manufactured in accordance with Article 5(2).

2. Manufacturers shall draw up the required technical documentation and carry out the relevant conformity assessment procedure referred to in Article 15 or have it carried out

Where compliance of a safety component for lifts with the applicable essential health and safety requirements has been demonstrated by that procedure, manufacturers shall draw up an **EU declaration of conformity, ensure that it accompanies the safety component for lifts** and affix the CE marking.

Omnibus amendment:

(3) Article 8 is amended as follows:

(a) in paragraph 2, the second subparagraph is replaced by the following:

'Where compliance of a safety component for lifts with the applicable essential health and safety requirements has been demonstrated by that procedure, manufacturers shall draw up an EU declaration of conformity, **in electronic form, ensure that the safety component for lifts is accompanied by the internet address or machine-readable code through which the EU declaration of conformity** can be accessed, and affix the CE marking.';

Declaration of conformity

Example: Directive 2014/33/EU on lifts and safety components for lifts

Article 8

Obligations of manufacturers

1. When placing their safety components for lifts on the market, manufacturers shall ensure that they have been designed and manufactured in accordance with Article 5(2).

2. Manufacturers shall draw up the required technical documentation and carry out the relevant conformity assessment procedure referred to in Article 15 or have it carried out

'Where compliance of a safety component for lifts with the applicable essential health and safety requirements has been demonstrated by that procedure, manufacturers shall draw up an EU declaration of conformity, **in electronic form, ensure that the safety component for lifts is accompanied by the internet address or machine-readable code through which the EU declaration of conformity** can be accessed, and affix the CE marking.';

Digital contact

Example: Directive 2014/34/EU relating to equipment and protective systems intended for use in potentially explosive atmospheres (ATEX)

Article 2

Definitions

(16) 'economic operators' means the manufacturer, the authorised representative, the importer and the distributor;

(17) 'technical specification' means a document that prescribes technical requirements to be fulfilled by a product;

Omnibus amendment:

(1) Article 2 is amended as follows:

(a) the following point (16a) is inserted:

'(16a) 'digital contact' means any up-to-date and accessible online communication channel through which economic operators can be reached or engaged without the need to register or to download an application;';

Digital contact

Example: Directive 2014/34/EU relating to equipment and protective systems intended for use in potentially explosive atmospheres (ATEX)

Article 2

Definitions

(16) 'economic operators' means the manufacturer, the authorised representative, the importer and the distributor;

'(16a) 'digital contact' means any up-to-date and accessible online communication channel through which economic operators can be reached or engaged without the need to register or to download an application;';

17) 'technical specification' means a document that prescribes technical requirements to be fulfilled by a product;

Digital contact

Example: Directive 2014/34/EU relating to equipment and protective systems intended for use in potentially explosive atmospheres (ATEX)

Article 6

Obligations of manufacturers

7. Manufacturers shall indicate, on the product, their name, registered trade name or registered trade mark **and the postal address at which they can be contacted** or, where that is not possible, on its packaging or in a document accompanying the product. The address shall indicate a single point at which the manufacturer can be contacted. The contact details shall be in a language easily understood by end-users and market surveillance authorities.

Omnibus amendment:

(2) Article 6 is amended as follows:

(c) in paragraph 7, the first and second sentences are replaced by the following:

'Manufacturers shall indicate, on the product, their name, registered trade name or registered trademark **as well as their postal address and digital contact** or, where that is not possible, on its packaging or in a document accompanying the product. The postal address and digital contact shall indicate a single point through which the manufacturer can be reached.';

Digital contact

Example: Directive 2014/34/EU relating to equipment and protective systems intended for use in potentially explosive atmospheres (ATEX)

Article 6

Obligations of manufacturers

7. 'Manufacturers shall indicate, on the product, their name, registered trade name or registered trademark **as well as their postal address and digital contact** or, where that is not possible, on its packaging or in a document accompanying the product. The postal address and digital contact shall indicate a single point through which the manufacturer can be reached.';

This obligation has changed in a same way by the omnibus for importers (Article R4 of Decision No 768/2008/EC)

- Market surveillance authorities may reach out to the manufacturer and importer by email, requesting information and documentation;

Questions

Declaration of conformity

? BG, LT, HR: The declaration of conformity must be provided in electronic form. What exactly constitutes a 'copy' of the DoC in this context? Is it necessary for the document to be electronically signed with a qualified signature?

The main principle is that the changes should not result in an increased burden on economic operators. Therefore, a 'copy' indeed refers to a straightforward electronic version of the document. This could include a manually signed document that is scanned and sent via email.

Questions

Declaration of conformity

BG: The modules still use the term 'written.' Does 'written' imply that the form must be paper-based?

'Written' signifies that the information should be conveyed in a **text-based format**, but it does not specify the physical material or medium used, such as paper, screen, or stone. Emails, websites, PDFs, and legal documents stored in databases are all considered 'written,' even if they are never printed.

Questions

Declaration of conformity

SK: Some SMEs, particularly small local businesses, might not even have an email address. For them, digitalisation can present a significant burden.

The requirement for manufacturers to draft a declaration of conformity is not a new obligation. This has been in place alongside the need to prepare technical documentation, including a risk assessment for the product, carrying out the relevant conformity assessment procedures, and affixing the CE marking on the product. Considering all these requirements, it is difficult to imagine that any manufacturer could comply with these obligations today without utilising digital tools, even if the manufacturer is a small business. **Small businesses, corner shops could be distributors, who do not have an obligation to provide the declaration of conformity.** They are expected to identify the manufacturer, its authorised representative and the importer who has provided them with the product, in order to assist the market surveillance authority in its efforts to obtain the declaration of conformity.

Digital instruction

Example: Directive 2014/32/EU on measuring instruments

Article 8

Obligations of manufacturers

7. Manufacturers shall ensure that the measuring instrument which they have placed on the market is accompanied by **a copy of the EU Declaration of conformity and by instructions and information** in accordance with point 9.3 of Annex I, in a language which can be easily understood by end-users, as determined by the Member State concerned. Such instructions and information, as well as any labelling, shall be clear, understandable and intelligible.

Besides the instructions, the DoC was to be provided with each product, on paper

Omnibus amendment:

(d) in paragraph 7, the first sentence is replaced by the following:

'7. Manufacturers shall ensure that the measuring instrument which they have placed on the market is accompanied by **the internet address or machine-readable code through which the EU declaration of conformity can be accessed, and by instructions and information** in accordance with point 9.3 of Annex I in a language which can be easily understood by end-users, as determined by the Member State concerned. **The instructions and information may be provided in electronic form.** Such instructions and information, as well as any labelling, shall be clear, understandable and intelligible.

The manufacturer shall take into account **the intended use and the foreseeable end-user** of the product when deciding the specific format for the instructions and information in accordance with point 9.3 of Annex I.

In the case of measuring instrument **intended for consumers or that can, under reasonably foreseeable conditions, be used by consumers, even if not intended for them**, the manufacturer shall provide, in paper format, or mark on the product, the information in accordance with point 9.3 of Annex I. Such information shall be easily visible and legible for consumers.

When drafting the instructions and information in accordance with point 9.3 of Annex I, the manufacturers shall take account of **the intended use and foreseeable misuse by the end-user**, as well as the role which the instructions and information play for ensuring safety.

This article continues on the next slide....

Regulation (EU) 2019/1020 on market surveillance: **'end user'** means any natural or legal person residing or established in the Union, to whom a product has been made available either as a **consumer** outside of any trade, business, craft **or** profession **or as a professional end user** in the course of its industrial or professional activities.

Digital instruction

Example: Directive 2014/32/EU on measuring instruments

Article 8

Obligations of manufacturers

Omnibus amendment:

When the **instructions**, referred to in the first subparagraph, are provided **in electronic form,** the manufacturer shall:

(a) mark on the measuring instrument, or, where that is not possible, on its packaging or in an accompanying document, **how to access them and how to request them in paper format;**

(b) present them in a format that **makes it possible for the end-user to print and download the instructions and save** them on an electronic device so that the end-user can access them at all times, in particular during a breakdown of the measuring instrument; this requirement also applies where the instructions are embedded in the software of the measuring instrument;

(c) make them accessible online during the expected lifetime of the measuring instrument and for at least 10 years after the placing on the market of the measuring instrument.

However, the end-user may, **at time of the purchase of the measuring instrument, or up to six months after that** purchase, request the instructions and information in accordance with point 9.3 of Annex I in paper format. Where the end-user requests those instructions information in accordance with point 9.3 of Annex I, **the manufacturer shall provide them to the end-user, free of charge, within one month of receiving the request**.';

Questions

Instruction of use and safety information

HU: Paper-based instructions can be very useful, especially when consumers need to look up information, such as details related to the maintenance of a product.

This is why end users, not just consumers, may request paper-based instructions. Manufacturers are obliged to provide a paper copy of the instructions within one month of the request. Additionally, the instructions must be available in a format that is both downloadable and printable.

Digital product passport

Example: Directive 2014/53/EU - radio equipment

Article 18

EU declaration of conformity

4. By drawing up the EU declaration of conformity, the manufacturer shall assume responsibility for the compliance of the radio equipment with the requirements laid down in this Directive.

Omnibus amendment:

(8) Article 18 is amended as follows:

(b) the following paragraph 5 is added:

'5. Where other Union legislation applicable to radio equipment requires the economic operator to include the information that the product complies with the requirements set out in that legislation in a digital product passport or to upload the EU declaration of conformity or instructions in a digital product passport, the information required in Annex IV to be included in the EU declaration of conformity and the instructions referred to in Article 10(8) shall be provided only in that digital product passport.';

Digital product passport

Example: Directive 2014/53/EU - radio equipment

Article 18

EU declaration of conformity

4. By drawing up the EU declaration of conformity, the manufacturer shall assume responsibility for the compliance of the radio equipment with the requirements laid down in this Directive.

'5. Where **other Union legislation applicable to radio equipment requires** the economic operator to include the information that the product complies with the requirements set out in that legislation in a digital product passport or to upload the EU declaration of conformity or instructions in a digital product passport, the information required in Annex IV to be included in the EU declaration of conformity and the instructions referred to in Article 10(8) shall be provided only in that digital product passport.';

Common Specifications

Simplifying Compliance in the Single Market

- The Omnibus package helps businesses comply with EU legal rules when harmonised standards are not available.

- **How it Works**:
  - ✓ The Commission aligns a fall-back option: *common specifications* for businesses to follow.
  - ✓ Businesses use these specs to prove they meet EU requirements.

- **Simplification brings**:
  - ✓ Legal certainty (legal effect: *presumption of conformity*)
  - ✓ Less costs for businesses
  - ✓ Alignment with existing legal framework:
    - Common specifications already exist in +10 legislative acts.
    - Proposal to align 16 additional directives/regulations.
  - ✓ Consistent rules for businesses across sectors.
  - ✓ Addressing challenges:
    - unavailability of draft harmonised standards based on ISO/IEC for 15 months
    - mandatory legal dependency on European standardisation organisations
    - dependency on ISO/IEC standards (28% of CEN, 67% of CENELEC hENs)
    - delays in standards development

Savings from common specifications

I. Overview of Benefits (total for standardisation) – Preferred Option		
Description	***Amount***	***Comments***
Direct benefits		
Compliance cost reduction resulting from the availability of common specifications	On average 4 000 EUR per product, which would have required certification in the absence of a harmonised standard.	The figure given is not an aggregated one. It represents the amount for a single conformity assessment of one individual product (placed on the market) in the absence of harmonised standards and when no alternative option exists for using the presumption of conformity (i.e. common specifications) under one of the legislative acts covered by the proposal. On top of this, the business would avoid costs related to legal uncertainty and finding alternative methods to demonstrate compliance, which cannot be quantified.

Source: SWD(2025)130 - Commission staff working document accompanying COM(2025)503 and COM(2025)504, p. 23.

Legal aspects

March 2024*:* Landmark CJEU Ruling

The Court of Justice of the European Union (Grand Chamber) ruled in case C-588/21P (*Public.Resource.Org and Right to Know v Commission and Others*) that the Commission must grant access to harmonised standards under the *Access to Documents Regulation (EC) 1049/2001*.

Consequences:

- *System Disruption:* Eligible standards are now accessible for *free* to citizens and businesses.
- *Ongoing Dispute*: The International Electrotechnical Commission (IEC) and International Organization for Standardization (ISO) have brought a case (T-631/24) against the Commission in December 2024.
- *Non-availibility:* Over 100 harmonised standards based on ISO/IEC standards have not been delivered since March 2024.
- *Legal uncertainity*: Although the relevant EU legislation is applicable, the necessary standards to support its implementation are not available.

Average length to develop hENs

Phase	Subphase	Average duration (2024)
Phase A	**Standardisation requests adopted by the European Commission**	1 year and 8 months
Phase B	**Acceptance of standard request by the ESOs**	1 month
	Drafting	3 years and 1 month
Phase C	**ESO submission time to EC after standard reference adoption**	3 months
	Citation time in the OJEU	11 months
Total		**6 years and 1 month**

Source: *Evaluation Study of the Regulation (EU) 1025/2012 on European Standardisation*

Why is the wording not alligned with the Machinery Regulation?

- Commission Implementing **Regulation (EU) 2020/1207** regarding common specifications for the reprocessing of single-use devices
  - **Date of application:** 26 May 2021
- Commission Implementing **Regulation (EU) 2022/1107** laying down common specifications for certain class D in vitro diagnostic medical devices
  - **Date of application:** 25 July 2022
- Commission Implementing **Regulation (EU) 2023/1194** regarding transitional provisions for certain products without an intended medical purpose listed in Annex XVI to Regulation (EU) 2017/745
  - **Date of application:** 22 June 2023

Development of CSs under Medical Devices Reg.

1) Preliminary discussion in the concerned thematic subgroup of the sectoral expert group, the Medical Device Coordination Group (MDCG) – *Art. 103 of Regulation (EU) 2017/745*

- the In vitro diagnostic medical devices (IVD) Subgroup (Working Group 11)
- the "Annex XVI" products Subgroup (Working Group 13)

2) Creation of a technical group within the subgroup, *with experts from the competent authorities of the MS and sectorial stakeholders*

3) Preparation and presentation of final draft CS to Subgroup for endorsement

4) Submission of CS to the MDCG for endorsement

5) Launch of the adoption procedure: inter-service consultation, translation, adoption, publication in the *Official Journal of the European Union* (OJEU) with the appropriate transitional, entry into force and application provisions.

6) Committee on Medical Devices adopts CS – *Art. 114 Reg. (EU) 2017/745 and 2017/746*

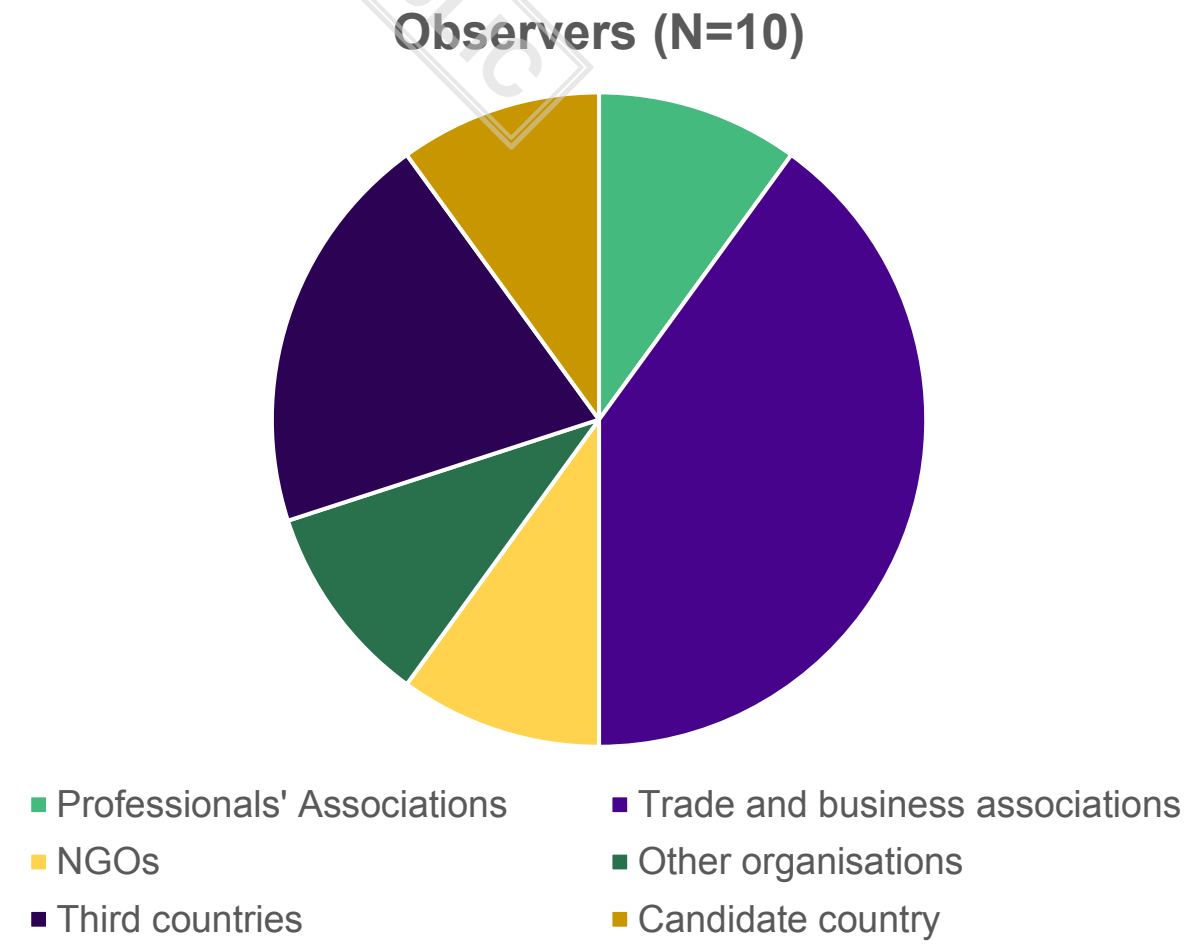
In vitro diagnostic medical devices Subgroup

Members	
Austria	Ireland
Belgium	Italy
Croatia	Lithuania
Cyprus	Luxembourg
Czech Republic	Netherlands
Denmark	Poland
Estonia	Portugal
Finland	Romania
France	Slovakia
Germany	Slovenia
Greece	Spain
Hungary	
Sweden	

Observers	
Biomedical Alliance in Europe (the BioMed Alliance)	Professionals' Associations
European Association Notified Bodies Medical Devices (Team-NB)	Trade and business associations
European Association of Authorised Representatives (EAAR)	Trade and business associations
European Federation of Clinical Chemistry and Laboratory Medicine (EFLM)	NGOs
European Federation of Pharmaceutical Industries and Associations (EFPIA)	Trade and business associations
MedTech Europe (MTE)	Trade and business associations
Notified Body Coordination Group - Medical Devices (NBCG-Med)	Other organisations
Directorate of Health - Norway	Third country
Icelandic Medicines Agency	Third country
Medicines and Medical Devices Agency - Turkey	Candidate country

In vitro diagnostic medical devices Subgroup

Members	
Austria	Ireland
Belgium	Italy
Croatia	Lithuania
Cyprus	Luxembourg
Czech Republic	Netherlands
Denmark	Poland
Estonia	Portugal
Finland	Romania
France	Slovakia
Germany	Slovenia
Greece	Spain
Hungary	
Sweden	



“Annex XVI” products Subgroup

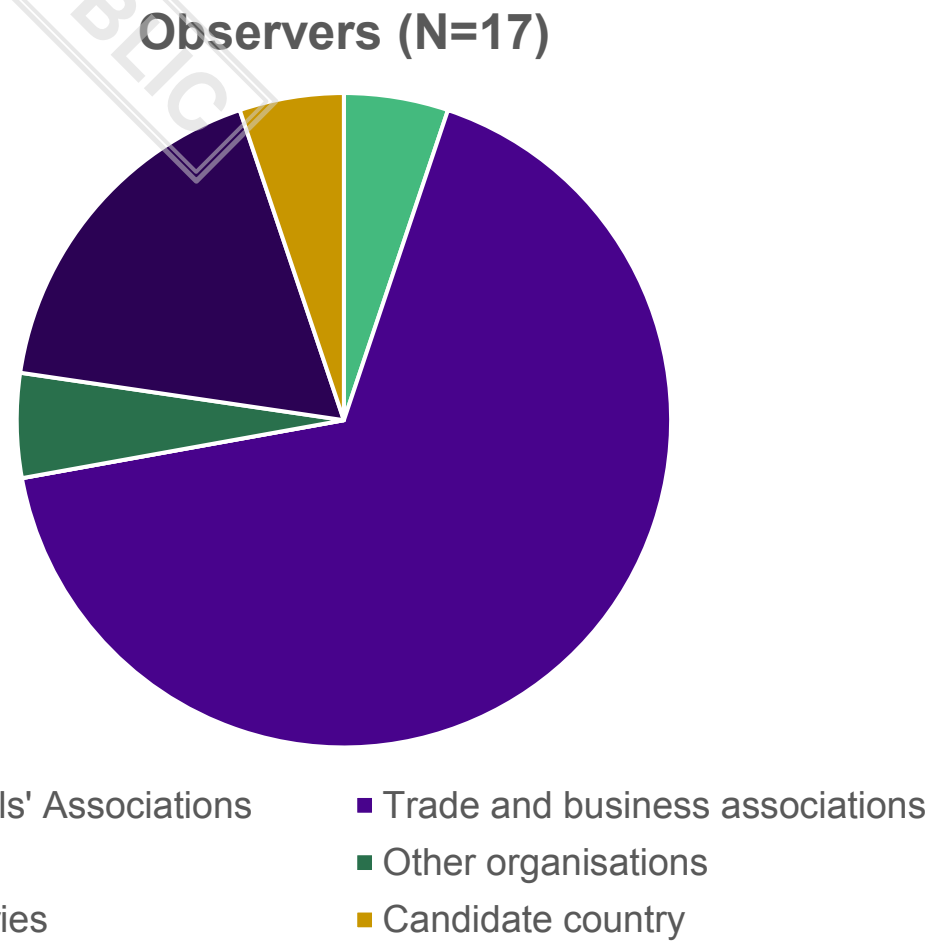
Members:
Austria
Belgium
Bulgaria
Croatia
Czech Republic
Denmark
Estonia
Finland
France
Germany
Ireland
Luxembourg
Netherlands
Poland
Portugal
Slovakia
Slovenia
Spain
Sweden

Observers:	
APPLiA (Home Appliance Europe) (APPLiA)	Trade and business associations
Association of the European Self-Medication Industry (AESGP)	Trade and business associations
EUROM1	Trade and business associations
EUROMCONTACT	Trade and business associations
European Association Notified Bodies Medical Devices (Team-NB)	Trade and business associations
European Association of Authorised Representatives (EAAR)	Trade and business associations
European Coordination Committee of the Radiological, Electromedical and healthcare IT Industry (COCIR)	Trade and business associations
European Council of Optometry and Optics (ECOO)	Professionals' Associations
European Healthcare Distribution Association (GIRP)	Trade and business associations
MedTech Europe (MTE)	Trade and business associations
Notified Body Coordination Group - Medical Devices (NBCG-Med)	Other Organisations
SMEunited aisbl (SMEunited)	Trade and business associations
Zentralverband Elektrotechnik- und Elektronikindustrie e.V. (ZVEI)	Trade and business associations
Directorate of Health – Norway	Third country
Icelandic Medicines Agency	Third country
Medicines and Medical Devices Agency – Turkey	Candidate country
Ministry of Health – Linchenstein	Third country

“Annex XVI” products Subgroup

Members:

Austria	Ireland
Belgium	Luxembourg
Bulgaria	Netherlands
Croatia	Poland
Czech Republic	Portugal
Denmark	Slovakia
Estonia	Slovenia
Finland	Spain
France	Sweden
Germany	



What is an “urgent concern”?

Case study: Heat pumps - Delays risk market innovation and green transition

Legislation: 2006/42/EC (Machinery Directive), 2014/35/EU (Low Voltage Directive)

Standardisation Request: M/511

IEC 60335-2-40:2018 → EN IEC 60335-2-40:2023 **(5 yrs delay)**
IEC Publication: 26.01.2018 → **Available by ESO:** 05.05.2023

IEC 60335-2-40:2022 → EN IEC 60335-2-40:2024 **(2 yrs delay)**
IEC Publication: 05.09.2022 → **Available by ESO**: 08.11.2024

Machinery Regulation (EU) 2023/1230 – Art. 20

3. The Commission may adopt implementing acts establishing common specifications covering technical requirements that provide a means to comply with the essential health and safety requirements set out in Annex III for products within the scope of this Regulation.

Those implementing acts shall only be adopted where the following conditions are fulfilled:

(a) the Commission has requested, pursuant to Article 10(1) of Regulation (EU) No 1025/2012, one or more European standardisation organisations to draft a harmonised standard for the essential health and safety requirements set out in Annex III and:

  (i) the request has not been accepted; or

  (ii) the harmonised standards addressing that request are not delivered within the deadline set in accordance with Article 10(1) of Regulation (EU) No 1025/2012; or

  (iii) the harmonised standards do not comply with the request; and

(b) no reference to harmonised standards covering the relevant essential health and safety requirements set out in Annex III has been published in the *Official Journal of the European Union* in accordance with Regulation (EU) No 1025/2012 and no such reference is expected to be published within a reasonable period.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 48(3).

What is the scope of the proposals? Why is Reg. 765/2008 included?

- **List of amended legislative acts**

1. Recreational craft and personal watercraft - Directive 2013/53/EU
2. Simple Pressure Vessels - Directive 2014/29/EU
3. Electromagnetic Compatibility - Directive 2014/30/EU
4. Non-automatic Weighing Instruments - Directive 2014/31/EU
5. Measuring Instruments - Directive 2014/32/EU
6. Lifts - Directive 2014/33/EU
7. ATEX - Directive 2014/34/EU
8. Low Voltage - Directive 2014/35/EU
9. Radio equipment - Directive 2014/53/EU
10. Pressure equipment - Directive 2014/68/EU
11. Marine Equipment - Directive 2014/90/EU
12. Restriction of Hazardous Substances in Electrical and Electronic Equipment - Directive 2011/65/EU

1. Cableway installations - Regulation (EU) 2016/424
2. Gas appliances - Regulation (EU) 2016/426
3. Personal protective equipment - Regulation (EU) 2016/425
4. Requirements for accreditation and market surveillance relating to the marketing of products - Regulation (EU) 2008/765

Stakeholder views

April 2025 Industrial Forum Survey (N=96)

- Absence or delayed publication of hENs leads to higher costs and administrative burden.
- Stakeholders recommend improving legal clarity and mutual recognition of alternatives to hENs.

2024 Public consultation for *Standardisation Regulation* Evaluation (N=254)

- hENs support EU cross-border activities and trade (72% of respondents), but current standard-development process is inefficient (52%).
- For some stakeholders, technical or common specifications should be used only as a last resort.

Any Questions ?

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Thank you !