MDCG 2021-5 Rev. 1

Guidance on standardisation for medical devices

Revision 1 – July 2024

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MDCG 2021-5 revision 1 main changes	
Pages 4, 8 and 10	Removal of references to the Directives and integration into those to the Regulations
Pages 4-8, 10-24	Update of footnotes and links
Pages 6-7	Addition of references: Communications, Guidelines, “Task Force”
Pages 8-9	Addition of considerations on the references to EN ISO 15189 and ISO 14155:2011
Page 12	Addition of references to the MDR/IVDR standardisation request and its amendments
Page 13	Updates on the HAS consultants
Page 14	Addition of considerations on information and clarification by CEN and CENELEC and their Technical Committees
Page 15	Updates on the IMDRF
Pages 16-18	Updates on the “state of the art”
Pages 18-21	Addition of point 3.6 on rulings of the European Court of Justice
Page 21-22	Addition of point 3.7 on European Pharmacopoeia
Pages 22-23	Addition of point 3.8 on common specifications
Page 24	Updates on SFHS (former ABHS)
Pages 25-27	Additions and updates of references and links

Guidance on standardisation for medical devices

Introduction: scope and contents

This document aims to provide guidance on different aspects related to standards in the medical devices sector in support of the requirements laid down in the applicable EU legislation, taking into account its specificities.

The contents of this document:

are not intended to be exhaustive, and must be read and used within the legal and guidance framework on EU harmonisation legislation for health, safety and performance of products in the internal market, in particular for European standardisation.

Wider information on such legal and guidance framework is available from the references and sources of information indicated in the footnotes and at the end of this document.

1. EU legislation on medical devices within the "New Approach" and the "New Legislative Framework"

The **EU legislative framework on medical devices** currently consists of two Regulations[1], adopted and entered into force in 2017:

- **Regulation (EU) 2017/745 on medical devices**[2] (MDR), applicable from 26 May 2021, replacing the previous Directives 90/385/EEC on active implantable medical devices[3] (AIMDD) and 93/42/EEC on medical devices[4] (MDD), through specific transition provisions, as amended;

- **Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices**[5] (IVDR), applicable from 26 May 2022, replacing the previous Directive 98/79/EC on *in vitro* diagnostic medical devices[6] (IVDD), through specific transition provisions, as amended.

These legislative acts are part of the EU harmonisation legislation on health, safety and performance of products in the internal market, based on the principles of the "**New Approach**" and the "**New Legislative Framework**"[7] policies. In this kind of legislation, the role of the **harmonised European standards** (hENs) is key: actually, for product characteristics, the content of legislation is limited to establishing essential requirements that products intended to be placed on the EU market must meet. The technical details and solutions supporting those essential requirements are laid down in harmonised European standards specifically developed

[1] New Regulations: https://health.ec.europa.eu/medical-devices-sector/new-regulations_en.

[2] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117 5.5.2017, p. 1). Current consolidated version: https://eur-lex.europa.eu/eli/reg/2017/745/2023-03-20.

[3] Council Directive of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (90/385/EEC) (OJ L 189, 20.7.1990, p. 17). Consolidated version: https://eur-lex.europa.eu/eli/dir/1990/385/2007-10-11.

[4] Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ L 169, 12.7.1993, p. 1). Consolidated version: https://eur-lex.europa.eu/eli/dir/1993/42/2007-10-11.

[5] Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117 5.5.2017, p. 176). Current consolidated version: https://eur-lex.europa.eu/eli/reg/2017/746/2023-03-20.

[6] Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices (OJ L 331, 7.12.1998, p. 1). Consolidated version: https://eur-lex.europa.eu/eli/dir/1998/79/2012-01-11.

[7] Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 (OJ L 218, 13.8.2008, p. 30), and Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC (OJ L 218, 13.8.2008, p. 82). See "New legislative framework": https://single-market-economy.ec.europa.eu/single-market/goods/new-legislative-framework_en.

by designated European standardisation organisations on the basis of specific standardisation requests (formerly known as "mandates") issued by the Commission.

The term "harmonised standard" is defined in Articles 2(70) MDR and 2(73) IVDR as "a European standard as defined in point (1)(c) of Article 2 of Regulation (EU) No 1025/2012", i.e. "a European standard adopted on the basis of a request made by the Commission for the application of Union harmonisation legislation". However, Articles 8 MDR and IVDR state that "References in this Regulation to harmonised standards shall be understood as meaning harmonised standards the references of which have been published in the *Official Journal of the European Union*". This guidance uses the term "harmonised standard" as defined in Regulation (EU) No 1025/2012 and whenever needed adds the clause "the references of which is published in the OJEU" (see also point 3.1).

Products designed and manufactured according to applicable harmonised European standards the references of which are published in the *Official Journal of the European Union* (OJEU) benefit from a **presumption of conformity** with the relevant legal requirements. In other words, the use of hENs cited in the OJEU confers presumption of conformity of the product with the legal requirements the standard aims to cover. This particular legal status of hENs cited in the OJEU generally allows manufacturers and the other sectorial actors (including notified bodies and national competent authorities) to make easier, quicker and less burdensome the processes related to conformity assessment procedures, affixing of the CE marking and placing on the market, market surveillance, etc.[8]. However, as a general principle, the use of such harmonised standards is voluntary (see point 2.2.).

2. The general framework for harmonised European standards

2.1. Main references

The principles of the "New Approach" and the "New Legislative Framework" concerning standardisation are implemented through a specific **legal and guidance framework for European standardisation and harmonised European standards** in support of EU harmonisation legislation. The main references are:

- **Regulation (EU) No 1025/2012 on European standardisation**[9] ("the Standardisation Regulation"), directly applicable in all Member States from 1 January 2013. It lays down

[8] For more details on the "New approach" and the "New legislative framework" and its regulatory features, see "The 'Blue Guide' on the implementation of EU product rules 2022": https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv%3AOJ.C_.2022.247.01.0001.01.ENG, and the Commission's website on CE marking: https://single-market-economy.ec.europa.eu/single-market/ce-marking_en.

[9] Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council (OJ L 316 14.11.2012, p. 12). Current consolidated version: https://eur-lex.europa.eu/eli/reg/2012/1025/2023-07-09.

the legally binding provisions on European standardisation, among others on definitions (Article 2), standardisation organisations and bodies, standardisation requests (Article 10), formal objections (Article 11) and the Committee on Standards (Article 22);

- **Rulings of the Court of Justice of the European Union** issued in specific cases relevant for the whole EU standardisation system – see point 3.6.;

- **Vademecum on European standardisation**[10], compiling key documents and providing guidance on European standardisation policy and related practice, including standardisation requests, the role and use of harmonised standards, and other related resources;

- **Communications from the Commission**:

  - An EU Strategy on Standardisation: Setting global standards in support of a resilient, green and digital EU single market[11];

  - Harmonised standards: Enhancing transparency and legal certainty for a fully functioning Single Market[12];

  - A strategic vision for European standards: Moving forward to enhance and accelerate the sustainable growth of the European economy by 2020[13];

- **General Guidelines** for the Cooperation between CEN, Cenelec and ETSI and the European Commission and the European Free Trade Association[14];

- **Guidelines** on the applicability of Article 101 of the Treaty on the Functioning of the European Union to horizontal co-operation agreements[15].

For the practical implementation of the abovementioned references, there is a set of specific documents, all of them in principle publicly available through the direct cooperation between the Commission and the European standardisation organisations:

[10] https://single-market-economy.ec.europa.eu/single-market/european-standards/vademecum-european-standardisation_en.

[11] COM/2022/31: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52022DC0031.

[12] COM(2018)764: https://ec.europa.eu/docsroom/documents/32615.

[13] COM(2011)311: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52011DC0311.

[14] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52003XC0416%2803%29.

[15] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A52011XC0114%2804%29.

- **Procedures and guidance for the CEN-CENELEC Management Centre** (CCMC)[16] and their relevant Technical Committees developing standards (through the "Business Operation Support System"[17]);

- **Procedures and guidance for the HAS consultants** supporting the Commission ("Checklist - Verification of conditions for the publication of references of harmonised standards in the Official Journal", templates and instructions to fill in the assessment reports of harmonised standards, and other ad-hoc horizontal and sectorial guidance provided by the Commission). These guidance documents have also been made available by the Commission to the European standardisation organisations, with the invitation to circulate them among their Technical Committees.

- **Procedures and guidance** as agreed in the Task Force between the Commission, EFTA, CEN, CENELEC and ETSI "Timely European Standards for a Green and Digital, Single and Global Market"[18].

2.2. Voluntary use of standards

As for the generality of the EU harmonisation legislation on products in the internal market based on the principles of the "New Approach" and the "New Legislative Framework" policies, the use of standards (either harmonised European standards the reference of which is published in the *Official Journal of European Union* or any other standard) in the medical devices sector is and remains **voluntary**. This is clearly stated in the Standardisation Regulation (EU) 1025/2012 ruling the whole system, starting with the Recitals which explain the background, and then in the enacting part (Articles) of the act:

- Recital (1): "*The primary objective of standardisation is the definition of voluntary technical or quality specifications with which current or future products, production processes or services may comply.*"

- Recital (2): "*European standardisation is organised by and for the stakeholders concerned based on national representation (the European Committee for Standardisation (CEN) and the European Committee for Electrotechnical Standardisation (Cenelec)) and direct participation (the European Telecommunications Standards Institute (ETSI)), and is founded on the principles recognised by the World Trade Organisation (WTO) in the field of standardisation, namely coherence, transparency, openness, consensus, voluntary*

[16] https://www.cencenelec.eu/.

[17] https://boss.cen.eu/.

[18] See https://www.cencenelec.eu/news-and-events/news/2022/brief-news/2022-12-20-tf-action-plan/ and the Stakeholder Workshop held on 3 October 2023 https://www.cencenelec.eu/news-and-events/events/2023/2023-10-03-ec-esos-task-force-workshop/.

application, independence from special interests and efficiency ('the founding principles')."

- Article 2(1): "*'standard' means a technical specification, adopted by a recognised standardisation body, for repeated or continuous application, with which compliance is not compulsory, and which is one of the following: (a) 'international standard' means a standard adopted by an international standardisation body; (b) 'European standard' means a standard adopted by a European standardisation organisation; (c) 'harmonised standard' means a European standard adopted on the basis of a request made by the Commission for the application of Union harmonisation legislation; (d) 'national standard' means a standard adopted by a national standardisation body*".

These provisions are fully applicable also to the EU legislation on medical devices, which contains direct and indirect references to the voluntary use of standards, both in their recitals and enacting terms[19]. At the same time, it is worth noting that for medical devices there are "exceptions that proves the rule" when standards can be regarded as mandatory: it is the case for symbols and identification colours that "*shall conform to the harmonised standards*"[20] when harmonised standards the reference of which is published in the OJEU containing indications on symbols or colour coding are available[21].

On the other hand, Article 5(5)(c) IVDR contains a reference to standard EN ISO 15189[22] which has a different role. It defines a condition which needs to be met by health institutions when making use of exceptions, i.e. "*the laboratory of the health institution is compliant with standard EN ISO 15189 or where applicable national provisions, including national provisions regarding accreditation*". In the absence of national provisions, the health institution needs to be compliant with this standard to fall under the exception rule; here the standard is related to the scope and applicability of IVDR requirements under specified conditions, but not to any presumption of conformity.

In the case of the references to "*the international standard ISO 14155:2011 on good clinical practice for clinical investigations of medical devices for human subjects*" included in Recital 64 MDR and to "*the international standard ISO 20916 on clinical performance studies using*

[19] Recitals and Articles 8(1) MDR and IVDR.

[20] MDR, Annex I, point 23.1 h); IVDR, Annex I, point 20.1 h).

[21] For instance, the harmonised European standards EN ISO 15223-1:2021 *Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements (ISO 15223-1:2021)*, currently cited in the OJEU under the MDR and the IVDR, and EN ISO 5359:2014+A1:2017 *Anaesthetic and respiratory equipment - Low-pressure hose assemblies for use with medical gases*, listed in the current standardisation request as existing harmonised standard to be revised under the MDR.

[22] The standard EN ISO 15189:2022 *Medical laboratories - Requirements for quality and competence (ISO 15189:2022)* with its amendment A11:2023 is currently harmonised and cited in the OJEU under the horizontal Regulation (EC) No 765/2008 on accreditation.

specimens from human subjects" in Recital 66 IVDR, they must be considered as non-binding examples only.

The voluntary character of the use of standards means in practice that the manufacturer may always choose to apply the technical solutions provided by harmonised European standards whether the reference to is cited or not cited in the OJEU, or by non-harmonised European standards, or by any other international or national standards, or even to develop its own technical solutions, provided that it is able to demonstrate that these different or alternative non-harmonised means are adequate to comply with the legal requirements applicable to the product. Such a demonstration can be given by the manufacturer through a more in-depth risk assessment, gap analysis, etc., to be reflected in the related technical documents and reports within the prescribed conformity assessment procedures on the product. Only in case of harmonised standards the references of which have been published in the OJEU, presumption of conformity can be claimed for the requirements of the Regulations which are listed as "covered" in the respective informative Annexes Z of such standards (see point 2.3).

Therefore, also in the medical devices field in the EU, **choosing to use a standard or not belongs to the manufacturer**, within its overall and ultimate responsibility on compliance. With the possible exceptions referred to above, it is not possible to impose the use of any specific standard, on the basis for instance of its status of harmonised European standard whether referenced in the OJEU or not, or of "state-of-the-art" standard, neither by national authorities in their market surveillance or vigilance activities, nor by notified bodies in the conformity assessment procedures they participate in. However, notified bodies performing conformity assessment activities must check whether the concerned device complies with the requirements of the Regulations on medical devices, and in this sense they must "*where relevant, take into consideration available CS, guidance and best practice documents and harmonised standards, even if the manufacturer does not claim to be in compliance*" (Sections 4.5.1 of Annexes VII to the MDR and the IVDR) (see also point 3.5), being necessary to understand "harmonised standard" when used in the MDR and IVDR as "harmonised standard the reference of which has been published in the OJEU" (see point 1).

Actually, to be lawfully placed on the EU market, medical devices must comply with the health, safety and performance requirements of the applicable legislation, and not necessarily with the clauses of a standard. Conversely, compliance of a device must be assessed against the legal requirements that apply to it, and this may be made through compliance with the clauses of a standard (regardless of whether the standard is a harmonised standard cited in the OJEU or not), but not necessarily, unless the manufacturer would claim compliance with the legal requirements by using a harmonised European standard cited in the OJEU thus conferring presumption of conformity.

2.3. The relationship between harmonised European standards and EU legislation: the "Annex Z"

The relationship between the clauses of a harmonised European standard drafted on the basis of a Commission's mandate or a standardisation request in support of specific EU legislation, and the requirements of such EU legislation that the standard aims to cover, is made explicit in the foreword of that standard and especially in a **separate informative annex, called "Annex Z"**. When a harmonised standard intends to cover more than one EU legislative act, it must include several Annexes Z (usually designated as "ZA", "ZB"… "ZZ"), each of them indicating the relevant legal requirements aimed to be covered by the normative contents of the standard before any reference of it may be published in the OJEU.

The format of the Annex Z is determined by specific agreements between the Commission and the European standardisation organisations, to ensure that clear, precise and accurate information is provided to the users of harmonised European standards the references of which have been published in the OJEU. It includes one or more tables listing the clauses of the standards, their correspondence with the legal requirements, and any other indications and comments necessary for the correct use of the standard (for instance, if some legal requirements are not covered or partially covered by the standard). In this sense, the role of Annexes Z is especially important for the purpose of legal clarity and certainty, being the necessary tool addressed to users of harmonised European standards the references of which have been published in the OJEU to clearly **identify the contents of the standard that are appropriate to cover the requirements of the EU legislation and to confer the presumption of conformity with them**, when the reference of the standard is cited in the OJEU. Annex Z also refers to legal requirements not covered or partially covered, allowing the manufacturer to identify them and to implement additional action in order to comply with these legal requirements. Without an adequate Annex Z, a harmonised standard lacks the necessary element of legal clarity and cannot be referenced in the OJEU, therefore its voluntary use cannot confer any presumption of conformity[23].

3. Harmonised European standards in support of the EU legislation on medical devices

3.1. Legal references, European standardisation organisations and standardisation mandates or requests

EU legislation on medical devices contains specific provisions on **harmonised standards** and the **presumption of conformity** conferred by its voluntary use when their references are

[23] It is important to remind that the requisite of having an Annex Z is not a new one for harmonised standards. In fact, CEN and CENELEC's Technical Committees formally decided in 1994 to introduce an informative Annex Z for harmonised standards, following extensive discussions with the Commission and with the Member States on how to ensure transparency on the correspondence between the clauses of harmonised standards and the legislative requirements covered.

published in the OJEU: they can be found in the respective Articles 8(1) of the current Regulations MDR and IVDR. It is worth noting that these Regulations define the term "harmonised standard" making reference to point (1)(c) of Article 2 of the Standardisation Regulation (EU) 1025/2012, as "*a European standard adopted on the basis of a request made by the Commission for the application of Union harmonisation legislation*", while at the same time, the abovementioned Articles 8(1) specify that "*References in this Regulation to harmonised standards shall be understood as meaning harmonised standards the references of which have been published in the* Official Journal of the European Union", thus including the direct link to the presumption of conformity conferred by harmonised European standards cited in the OJEU. For the sake of clarity, this guidance uses these terms as Regulation (EU) No 1025/2012 (see point 1).

Harmonised European standards in the field of healthcare engineering, including medical devices, are developed by the two relevant European standardisation organisations (ESOs): the **European Committee for Standardization (CEN)** for most of the types of medical devices, and the **European Committee for Electrotechnical Standardization (CENELEC)**[24] especially for medical electrical equipment.

According to Article 10 of the Standardisation Regulation (EU) 1025/2012, the Commission may request one or several European standardisation organisations to draft European standards or European standardisation deliverables according to specific requirements. This is the necessary legal basis for the development of harmonised European standards in support of the requirements of EU legislation, and to allow the publication in the OJEU of references to such standards to confer presumption of conformity. The essential legal relationship between harmonised European standards the references of which have been published in the OJEU and the standardisation requests (mandates) on which they are based has been confirmed by the jurisprudence of the Court of Justice of the European Union[25].

For the previous Directives AIMDD, MDD and IVDD, such requests had the format of **standardisation mandates**, as letters addressed by the Commission to CEN and CENELEC. Several mandates have been issued between 1989 and 2010, some of them covering the whole scope of the Directives, and some others specific aspects only. The validity of those old standardisation mandates expired in parallel to the Directives themselves, as explicitly indicated in the standardisation request in support of the Regulations (see below).

For the current Regulations MDR and IVDR, a **standardisation request** has the improved format of a Commission Implementing Decision (pursuant to the entry into force of the Standardisation Regulation), structured in recitals (reasons, objectives and contents of the act), articles (requested activities, requirements and timelines) and annexes (lists of existing standards to be revised and of new standards to be developed under the MDR and the IVDR,

[24] CEN-CENELEC: https://www.cencenelec.eu/.

[25] See point 3.6.

and specific requirements). Before adopting the standardisation request, the Commission must seek the opinion of the Committee set up by Article 22 of the Standardisation Regulation (EU) 1025/2012.

Once adopted in the three working languages of European standardisation (English, French and German), a "*Commission Implementing Decision on a standardisation request to the European Committee for Standardization and the European Committee for Electrotechnical Standardization as regards medical devices in support of Regulation (EU) 2017/745 of the European Parliament and of the Council and in vitro diagnostic medical devices in support of Regulation (EU) 2017/746 of the European Parliament and of the Council*" is published in the Commission's database on standardisation requests[26] and addressed to CEN and CENELEC. When accepted, it becomes applicable for the development of harmonised European standards in the field of medical devices and, later on, for the publication in the OJEU of their references to confer presumption of conformity with the legal requirements the standards aim to cover.

Specifically, the MDR/IVDR standardisation request was adopted by the Commission on 14 April 2021 (labelled as M/575[27]) and, after having been accepted by CEN and CENELEC, became applicable in May 2021. It is intended to be regularly revised and updated when deemed necessary, in particular with respect to the lists of standards in the Annexes, to ensure its continuous adaptation to the evolution of the standardisation work at European and international level, as well as innovation in the field of medical devices. To date, a first amendment to the MDR/IVDR standardisation request, to add and to remove some items in its Annexes I and II, was adopted by the Commission on 31 January 2023 (labelled as M/575 Amd 1[28]) and accepted by CEN and CENELEC on 28 February 2023. A second amendment, to extend the validity of the MDR/IVDR standardisation request and the deadlines for the adoption of certain standards, as well as to add and remove some items in Annexes I and II and to clarify some requirements in Annex III, was adopted by the Commission on 27 May 2024 (labelled as M/575 Amd 2[29]) and accepted by CEN and CENELEC on 25 June 2024.

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[26] https://ec.europa.eu/growth/tools-databases/enorm/.

[27] C(2021) 2406: Commission Implementing Decision of 14.4.2021 on a standardisation request to the European Committee for Standardization and the European Committee for Electrotechnical Standardization as regards medical devices in support of Regulation (EU) 2017/745 of the European Parliament and of the Council and in vitro diagnostic medical devices in support of Regulation (EU) 2017/746 of the European Parliament and of the Council: https://ec.europa.eu/growth/tools-databases/enorm/mandate/575_en.

[28] C(2023) 694: Commission Implementing Decision of 31.1.2023 amending Implementing Decision C(2021) 2406 on a standardisation request to the European Committee for Standardization and the European Committee for Electrotechnical Standardization as regards medical devices in support of Regulation (EU) 2017/745 of the European Parliament and of the Council and in vitro diagnostic medical devices in support of Regulation (EU) 2017/746 of the European Parliament and of the Council: https://ec.europa.eu/growth/tools-databases/enorm/mandate/575Amd1_en.

[29] C(2024)3371: Commission Implementing Decision of 27.5.2024 amending Implementing Decision C(2021) 2406 on a standardisation request to the European Committee for Standardization and the European Committee for Electrotechnical Standardization as regards medical devices in support of Regulation (EU) 2017/745 of the European Parliament and of the Council and in vitro diagnostic medical devices in support of Regulation (EU) 2017/746 of the European Parliament and of the Council, as regards the scope and validity

3.2. Development of harmonised European standards for medical devices and assessment by the HAS consultants

On the basis of the relevant MDR/IVDR standardisation request, **CEN and CENELEC develop harmonised European standards** in the field of medical devices through their specific Technical Committees (TCs). The process includes several phases, following the internal rules of the European standardisation organisations, aimed to ensure the highest quality of the standards produced, with the adequate participation of national and international experts, stakeholders and interested parties[30].

During the standardisation process, specific assessment of the draft harmonised standards under development is carried out by the "**Harmonised Standards (HAS) consultants**", as technical experts supporting the Commission services, to ensure the compliance of the draft harmonised standards with the relevant EU legislative framework and with the relevant MDR/IVDR standardisation request. This assessment of draft harmonised standards is an obligation that the Commission, together with the European Standardisation organisations, has pursuant to Article 10(5) of the Standardisation Regulation, and the HAS consultants complement the Commission's expertise and resources needed for this task. Their activities are based on the rules on European standardisation and on specific procedures, guidance documents and templates, to carry out the necessary technical and legal assessments and to provide reports to the Commission at three specific phases of the standardisation development process (the so-called milestones: First Committee Draft, Enquiry and Formal Vote). As such, the HAS consultants work under the instructions of the Commission, managed by an independent contractor, and must keep their full independence from the European standardisation organisations and their TCs. The smooth management, coordination and follow up of such activities include periodical initiatives by the Commission for exchange of information and feedback at horizontal and vertical level (training sessions, webinars, alignment and sectorial meetings, etc.) to guarantee a common approach and the effectiveness of the work.

In the field of "Healthcare Engineering", there are currently up to seven HAS consultants for harmonised standards in support of the EU legislation on medical devices, administratively managed by an external entity according to a specific contract stipulated with the Commission for a number of sectors[31].

of the request and the deadlines for the joint final report and for the adoption of certain harmonised standards, certain general requirements and the requirements for certain specific standards: https://ec.europa.eu/growth/tools-databases/enorm/mandate/575Amd2_en.

[30] More information on the development of European standards in the field of medical devices is available on the websites of the relevant European standardisation organisations, CEN and CENELEC and their Management Centre: https://www.cencenelec.eu/.

[31] More information: https://www.ey.com/en_be/consulting/harmonised-standards-consultant.

3.3. Publication in the OJEU of references to harmonised European standards to confer presumption of conformity

Once CEN and CENELEC complete their standardisation work by publishing new or revised harmonised European standards in the field of medical devices, they propose to the Commission the **publication of the references of such standards in the OJEU**, to make them conferring the presumption of conformity with the legal requirements the standards aim to cover. The Commission carry out the final assessment on compliance of these proposed standards with the requirements of the legislation as well as of the relevant MDR/IVDR standardisation request, taking into account the assessment reports by the HAS consultants (which are however not binding on the Commission), as well as additional information and clarification that may be provided by CEN and CENELEC and their relevant Technical Committees when necessary, to decide to publish, not to publish or publish with restrictions the references in the OJEU. In case of not publication or publication with restrictions, the Commission inform the European standardisation organisations accordingly.

Since December 2018, the publications in the OJEU of lists of references to harmonised European standards in support of legislation on medical devices must have the format of **Commission Implementing Decisions**[32] in the "L" series. These acts with an improved and more robust legal format replace the previous publications as Commission Communications in the "C" series and are structured in recitals, articles and annexes that contain the lists of references: those to standards conferring presumption of conformity (both already published and those published for the first time, usually presented as a consolidate list) and those to standards withdrawn for being superseded by new standards, or for becoming obsolete.

The change of publication system was announced by the Commission in its Communication on harmonised standards of 22.11.2018[33] and is a logical consequence of the jurisprudence of the Court of Justice of the European Union[34].

3.4. International aspects of standardisation

In the medical devices sector, most of the European standards are developed by CEN and CENELEC in parallel to international standardisation developed by the **International Organization for Standardization (ISO)**[35] and the **International Electrotechnical Commission (IEC)**[36], on the basis of the Vienna Agreement (1991) and the Dresden

[32] Final publication under the previous Directives on medical devices: OJ L 090I, 25.3.2020, pp. 1, 25 and 33.

[33] COM(2018) 764: https://ec.europa.eu/docsroom/documents/32615.

[34] In particular, the ruling in Case C-613/14 James Elliott Construction Limited v Irish Asphalt Limited (see also point 3.6).

[35] https://www.iso.org/.

[36] https://www.iec.ch/.

Agreement (1996) reconfirmed by the Frankfurt Agreement (2016) respectively[37]. Within such agreements, the normative texts of the respective standards are substantially the same, while harmonised European standards the references of which are intended to be published in the OJEU must also contain a "European foreword" and the Annex(es) Z necessary to link the clauses of the standard with the requirements of the EU legislation(s) the standard aims to cover. This is especially important to clearly identify in each standard which clauses are suitable to confer presumption of conformity with the legal requirements and those not, in view of the publication in the OJEU of the reference of that standard. It is the responsibility of CEN and CENELEC to prepare and add the European foreword and the Annex(es) Z to the ISO/IEC standards when they adopt them as EN ISO or EN IEC standards intended to be harmonised in support of EU legislation on medical devices.

Some useful guidance on the development of standards in support of legislation can be taken from the **International Medical Device Regulators Forum (IMDRF)**[38]. The IMDRF is a voluntary group of medical device regulators from around the world to promote international and regional regulatory harmonisation, convergence and recognition in the field of medical devices, by providing guidance on strategies, polices and operational directions. Its management committee is currently integrated by Australia, Brazil, Canada, China, European Union, Japan, Russia, Singapore, South Korea, United Kingdom and United States of America; the European Commission held the Chair and Secretariat in 2023[39].

Especially, the specific IMDRF Standards Working Group developed different initiatives and documents, such as "*IMDRF recognised standards*"[40], "*Standards Improving the quality of international medical device standards for regulatory use*"[41], "*Optimizing standards for regulatory use*"[42] and "GHTF/SG1/N044:2008 *Role of Standards in the Assessment of Medical Devices*"[43] of the Global Harmonisation Task Force (GHTF). These documents provide useful indications for the development of international standards in the field of medical devices and their recognition and implementation at regional and national level, which is especially important for harmonised European standards the references of which are intended to be published in the OJEU in support of MDR and IVDR.

[37] CEN-CENELEC international cooperation: https://www.cencenelec.eu/european-standardization/international-cooperation/.

[38] https://www.imdrf.org/.

[39] See https://health.ec.europa.eu/medical-devices-dialogue-between-interested-parties/international-cooperation_en#eu-chairs-imdrf-in-2023 and https://imdrf2023.com.

[40] https://www.imdrf.org/working-groups/imdrf-recognized-standards.

[41] https://www.imdrf.org/working-groups/standards-improving-quality-international-medical-device-standards-regulatory-use.

[42] https://www.imdrf.org/consultations/optimizing-standards-regulatory-use.

[43] https://www.imdrf.org/sites/default/files/docs/ghtf/final/sg1/procedural-docs/ghtf-sg1-n044-2008-standards-in-assessment-of-medical-devices-080305.pdf.

3.5. The concept of "state of the art", European standardisation and conformity assessment for medical devices

As in other sectors based on the principles of the "**New Approach**" and the "**New Legislative Framework**"[44] policies, the EU legislation on medical devices contains a number of references to the need to "***take into account the generally acknowledged state of the art***"[45] to comply with the health, safety and performance requirements. However, it is important to underline that "taking into account" is different from "compliance", due to the fact that "state of the art" is not a legally defined concept and it involves several dynamic and complex aspects, difficult to be expressed in a single and clear definition. Actually, there are different sources providing **references, definitions and practical examples on the "state of the art"**, all of them non-legally binding but still useful to consider. It is the case of horizontal and vertical guidance documents, agreements of working parties, European and international standards, sectorial papers etc., as the following ones, among others:

- "*The concept of essential requirements is based on the assumption that the harmonised standards reflect generally acknowledgeable state of the art and the ESO review standards regularly in accordance with the relevant standardisation request*" ("The 'Blue Guide' on the implementation of EU product rules 2022"[46], section 4.1.2.4., p. 53).

- "*The most recent editions of standards published by the standardisers should be considered as reflecting state-of-the-art, regardless of the OJ referencing*" (COM statement, Minutes of the meeting of the MDCG Subgroup on Standards held on 20 May 2019[47], item 3, p. 1).

- "*The current knowledge/ state of the art in the corresponding medical field, such as applicable standards and guidance documents, information relating to the medical condition managed with the device and its natural course, benchmark devices, other devices and medical alternatives available to the target population*" (MEDDEV 2.7/1 revision 4 - Clinical evaluation: a guide for manufacturers and notified bodies under Directives 93/42/EEC and 90/385/EEC[48], section 7., p. 16).

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[44] Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 (OJ L 218, 13.8.2008, p. 30), and Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC (OJ L 218, 13.8.2008, p. 82). See "New legislative framework": https://single-market-economy.ec.europa.eu/single-market/goods/new-legislative-framework_en.

[45] Among others, in particular in the MDR and IVDR in their respective Annexes I "General safety and performance requirements".

[46] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv%3AOJ.C_.2022.247.01.0001.01.ENG.

[47] https://ec.europa.eu/transparency/expert-groups-register/screen/meetings/consult?lang=en&meetingId=17334.

[48] https://ec.europa.eu/docsroom/documents/17522/attachments/1/translations/.

- "*State of the Art: Developed stage of technical capability at a given time as regards products, processes and services, based on the relevant consolidated findings of science, technology and experience. NOTE 1: The state of the art embodies what is currently and generally accepted as good practice in technology and medicine. The state of the art does not necessarily imply the most technologically advanced solution. The state of the art described here is sometimes referred to as the 'generally acknowledged state of the art'. (Modified from ISO/IEC Guide 2:2004)*" (IMDRF/GRRP WG/N47 FINAL:2018 Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices[49], 3.43, p. 11).

- "*'State of the art': IMDRF/GRRP WG/N47 provides the following definition: Developed stage of current technical capability and/or accepted clinical practice in regard to products, processes and patient management, based on the relevant consolidated findings of science, technology and experience. Note: The state-of-the-art embodies what is currently and generally accepted as good practice in technology and medicine. The state-of-the-art does not necessarily imply the most technologically advanced solution. The state-of-the-art described here is sometimes referred to as the 'generally acknowledged state-of-the-art'*" (MDCG 2020-6 - Regulation (EU) 2017/745: Clinical evidence needed for medical devices previously CE marked under Directives 93/42/EEC or 90/385/EEC. A guide for manufacturers and notified bodies[50], section 1.2., pp. 5-6).

- "*State of the art: developed stage of technical capability at a given time as regards products, processes and services, based on the relevant consolidated findings of science, technology and experience. Note: The state of the art embodies what is currently and generally accepted as good practice in technology and medicine. The state of the art does not necessarily imply the most technologically advanced solution. The state of the art described here is sometimes referred to as the 'generally acknowledged state of the art' [Source: ISO/IEC Guide 63:2019, 3.18]*" (EN ISO 14971:2019 *Medical devices - Application of risk management to medical devices (ISO 14971:2019)*[51], section 3.28, p. 6).

In order to have a clear reference especially with respect to the practical implementation of the concept, it is commonly considered that **the most recent versions of standards with the technical solutions they contain reflect the "state of the art"**. However, **the mere compliance with the most recent version of a standard the reference of which has not been published in the OJEU does not automatically imply compliance with the requirements of the applicable EU legislation**, if no further evidences are provided in the technical

[49] http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-181031-grrp-essential-principles-n47.pdf.

[50] https://health.ec.europa.eu/document/download/a6d29444-b5d5-4afb-8024-10be85256aa7_en?filename=md_mdcg_2020_6_guidance_sufficient_clinical_evidence_en.pdf.

[51] https://standards.cencenelec.eu/dyn/www/f?p=CEN:110:0::::FSP_PROJECT,FSP_ORG_ID:63920,581003&cs=1E49E5771CD516EE42AB5934FFE88807A.

documentation of the product. Actually, "state-of-the-art" standards as such do not confer any presumption of conformity if their references are not cited in the OJEU, as harmonised European standards developed by the ESOs on the basis of a standardisation mandate or request issued by the Commission.

Therefore, recalling that in the EU harmonisation legislation for health and safety of products in the internal market – including also medical devices legislation – the use of standards is and remains voluntary (with the exceptions referred to in point 2.2. above), **it is not possible to impose the use of a specific standard in the conformity assessment of a product**, not even on the basis of "compliance with the state of the art": the "state of the art" expressed by standards must be taken into account but it does not mean "compliance" that must be granted with respect to the legal requirements and not to standards. In particular, for conformity assessment procedures requiring its intervention, the notified body must check whether the concerned device complies with the requirements of the Regulations on medical devices, and in this sense it must "*take into consideration available CS, guidance and best practice documents and harmonised standards, even if the manufacturer does not claim to be in compliance*" (Sections 4.5.1 of Annexes VII to the MDR and the IVDR). However, "taking into consideration" is different from making any standard "mandatory": choosing to use a standard or not, as appropriate and applicable, belongs to the manufacturer, within its overall and ultimate responsibility on the legal compliance of products intended to be placed on the EU market.

3.6. The rulings of the Court of Justice of the European Union on standardisation

The Court of Justice of the European Union[52] (European Court of Justice, ECJ) ruled on a number of cases related to specific aspects of European standardisation, with important consequences in the operation of the whole system, including for the medical devices sector.

The "James Elliott" case

On 27 October 2016, the ECJ pronounced a ground-breaking judgment with regard to standardisation, in the "James Elliott" case[53]. With this judgment, the Court clarified the role and the legal quality of voluntary harmonised European standards adopted on the basis of standardisation requests issued by the European Commission to support Union harmonisation legislation. Notably,

(i) a harmonised European standard the reference of which is published in the OJEU forms part of the EU law;

(ii) the citation of harmonised European standards, as defined in Article 2(1)(c) of Regulation (EU) No 1025/2012, in the *Official Journal of the European Union* (OJEU), has a legal

[52] https://curia.europa.eu.

[53] Case C-613/14 "James Elliott Construction Limited v Irish Asphalt Limited".

effect and, as a consequence, is subject to the Court's jurisdiction under Article 267 TFEU;

(iii) the development of standards is entrusted to organisations governed by private law;

(iv) the Commission has specific obligations and responsibilities to pursue the development process of harmonised European standards supporting European harmonisation legislation thoroughly, in particular while assessing them with regard to their compliance with the requirements set out in their respective legal acts and related standardisation requests, and the publication of their references in the OJEU.

Following the "James Elliot" case, the Commission adapted its internal procedures to improve legal certainty and transparency on harmonised European standards, and, as of December 2018, the Commission publishes their references as implementing acts in the "L series" (Legislation) of the OJEU, instead of communications in the "C series" (Information and Notices)[54].

The "Global Garden Products" case

In a judgment of 26 January 2017 on the "Global Garden Products" case[55], the General Court ruled, among others, that as long as the publication of a reference of a harmonised standard according to the old Directive 98/37/EC on machinery has not been explicitly repealed, the manufacturer of machinery conforming to this standard may continue to benefit from a presumption of conformity with the relevant essential health and safety requirements of Article 7 of the new Directive 2006/42/EC on machinery covered by this harmonised standard. This applies even if a new standard replaces the original harmonised standard.

Following the "Global Garden Products" case, the Commission systematically inserts, in the acts publishing in the OJEU references of harmonised standards in support of new EU legislation replacing old EU legislation, specific provisions on repeal of standards harmonised under that previous EU legislation.

The "Anstar Oy" case

In a judgement of 14 December 2017 on the "Anstar Oy" case[56], the General Court ruled, among others, that (i) the scope of a harmonised standard cannot be interpreted more broadly than that of the mandate [standardisation request] on which it is based; and (ii) if a harmonised standard does not indicate expressly that it is intended to replace another harmonised standard or one or more European technical assessments, those harmonised technical specifications remain in force and constitute special derogating rules.

[54] See https://style-guide.europa.eu/en/content/-/isg/topic?identifier=1-structure-of-the-official-journal.

[55] Case T-474/15 "Global Garden Products Italy SpA (GGP Italy) v European Commission".

[56] Case C-630/16 "Anstar Oy".

The "Public Resource/Right to Know" case

On 14 July 2021, in its judgement on the "Public Resource/Right to Know case"[57], the General Court confirmed the legal standing of harmonised European standards the references of which have been published in the OJEU as "part of the EU law" as recognised by the "James Elliott" judgement, but clarified that such harmonised European standards are not EU legislation as such. With respect to availability of such harmonised European standards and specific aspects of the copyright on them, the European standardisation organisations (ESOs) are private, non-profit making organisations; it has not been established that there cannot be copyright on standards. Accordingly, at the time being, the ESOs can continue to claim a fee, i.e. selling those standards.

However, on 5 March 2024, the Court of Justice, in the appeal case[58], set aside the previous judgement and considered that "the European harmonised technical standards on the safety of toys should be accessible to EU citizens", annulling the Commission's decision refusing access to those standards.

The " Stichting Rookpreventie Jeugd" case

On 22 February 2022, on the "Stichting Rookpreventie Jeugd" case[59], the ECJ concluded that a provision in EU law making an ISO standard mandatory without publication of that standard in the OJEU, does not infringe EU primary law, including the Charter of Fundamental Rights, nor the principle of legal certainty. In summary, the Court ruled with regard to the use of mandatory standards in EU legislation the following:

- the European legislator, while adopting legal acts, has wide margin of manoeuvre in the choice on the means to define the content of these acts which, however, must be precisely defined and understandable. Within this margin of manoeuvre, the European legislator is entitled to make use of mandatory standards within a legal act;
- an act of the Union cannot be enforced against individuals in a Member State before they have the opportunity to make themselves acquainted with it by its publication in the OJEU. In the absence of publication of a mandatory standard, the general public is not able to know its contents applicable to certain products;
- however, provided that companies have access to the official and authentic text of the standard made mandatory in the Union act, via the system established by ISO and its members whereby access to standards is ensured through the ISO national members, i.e.

[57] Case T-185/19 "Public.Resource.Org, Inc. and Right to Know CLG v European Commission". The applicants lodged an appeal against this judgment at the ECJ, Case C-588/21 P).

[58] Case C-588/21 P "Public.Resource.Org, Inc. and Right to Know CLG v European Commission and Others".

[59] Case C-160/20 "Stichting Rookpreventie Jeugd and Others v Staatssecretaris van Volksgezondheid, Welzijn en Sport".

the respective national standardisation organisations, those ISO standards can be enforced against such companies.

The "Orona" case

On 13 September 2023, on the "Orona" case[60], the Court confirmed that a manufacturer is allowed to choose equivalent alternative solutions to those prescribed by harmonised standards the references of which are published in the OJEU. Actually, if only the implementation of safety measures identical to those provided for by such harmonised standards is considered to ensure compliance with the essential requirements laid down by EU legislation, this would have the consequence of preventing all alternative measures, however effective and safe as they are, and would hinder any technical innovation which is not in strict compliance with such harmonised standards. Furthermore, such harmonised standards represent the "state of the art" but are not necessarily to be taken into account unequivocally as "state of the art", as it would depend on their contents and clarity with regard to compliance with the essential requirements.

3.7. European Pharmacopoeia

The provisions on "Use of harmonised standards" laid down in Articles 8 MDR / IVDR mention, in paragraph 2, "*the monographs of the European Pharmacopoeia adopted in accordance with the Convention on the Elaboration of a European Pharmacopoeia, in particular on surgical sutures and on interaction between medicinal products and materials used in devices containing such medicinal products*", as included in the references in the Regulations to harmonised standards, "*provided that references to those monographs have been published in the* Official Journal of the European Union". These provisions are similar to those in the previous AIMDD and MDD.

The monographs of the European Pharmacopoeia (Ph. Eur.)[61] are produced by the European Pharmacopoeia Commission of the European Directorate for the Quality of Medicines & HealthCare of the Council of Europe (which is not an institution of the European Union), on the basis of the "Convention on the Elaboration of a European Pharmacopoeia". They are intended to provide official quality standards for medicines and their ingredients in Europe, as a scientific basis for the quality control of a product throughout its life cycle, supporting the pharmaceutical industry and healthcare systems. Ph. Eur. standards are not standards as defined in the EU legislation, however they may assume a legal value in conferring presumption of conformity in a similar way as for harmonised standards when their references are published in the OJEU.

[60] Case T-349/21 "Germany v Commission".

[61] https://www.edqm.eu/en/european-pharmacopoeia.

In December 1997 the Commission published in the OJEU a list of references to these monographs under the MDD[62]. This publication concerned four monographs on sterile catgut, sterile non-absorbable sutures, sterile synthetic absorbable monofilament sutures and sterile synthetic absorbable braided sutures.

No similar publications took place under the current Regulations so far.

3.8. Common specifications

The Regulations on medical devices and *in vitro* diagnostic medical devices contain different references to "common specifications", defined as "*a set of technical and/or clinical requirements, other than a standard, that provides a means of complying with the legal obligations applicable to a device, process or system*" (Article 2(71) MDR, Article 2(74) IVDR). In some cases, the adoption by the Commission via implementing acts of common specifications with specific characteristics and requirements is a legal mandate: it is the case of common specifications for the groups of products without an intended medical purpose listed in Annex XVI MDR (Article 1(2) MDR), and of reprocessing of single-use devices (Article 17(3)(b) and (5) MDR). However, according to Articles 9 MDR / IVDR, common specifications may be also adopted by the Commission "*where no harmonised standards exist or where relevant harmonised standards are not sufficient, or where there is a need to address public health concerns,* […] *in respect of the general safety and performance requirements set out in Annex I, the technical documentation set out in Annexes II and III,* […]".

The possibility for the Commission to adopt common (technical) specifications replacing harmonised standards the references of which are published in the OJEU is provided in different pieces of EU legislation[63], as a safety net – the so-called "fallback option" – in very specific cases where there can be the need to compensate for the non-availability of harmonised standards, under certain conditions. While this option was never used so far by the Commission under the regimes where it is empowered to do so, it has been introduced in the medical devices area by way of exception to the general principles first under Directive 98/79/EC on *in vitro* diagnostic medical devices (IVDD)[64]. There, the concept "that manufacturers shall as a general rule be required to comply with the common technical specifications" has been established[65]. Only "for duly justified reasons" when "manufacturers do not comply with those specifications they must adopt solutions of a level at least equivalent thereto".

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[62] Commission Communication in the framework of the implementation of Council Directive 93/42/EEC in relation to medical devices (OJ C 369, 6.12.1997, p. 2).

[63] In addition to the Regulations on medical devices and *in vitro* diagnostic medical devices, it is the case of Regulation (EU) 2019/1009 on fertilising products, Directive (EU) 2016/2102 on the accessibility of the websites and mobile applications of public sector bodies, Regulation (EU) 2023/1230 on machinery, Regulation (EU) 2023/1542 concerning batteries and waste batteries, the Artificial Intelligence act, and others.

[64] See Directive 98/79/EC, Recitals (17) and (18).

[65] See Directive 98/79/EEC, Article 5.

In the development of the IVDR this concept has been kept and also included in the MDR. Where the common specifications under the IVDR[66] are mainly a continuation of the common technical specifications for high-risk *in vitro* diagnostics under the IVDD[67], common specifications under the MDR cover also other specific needs, in particular for Annex XVI products and for reprocessing of single-use devices, according to the relevant legal mandates. In addition, it is always possible to identify other cases where the need for common specifications may arise in the medical devices sector, according to the specific characteristics of the concerned devices and/or processes, also on the basis of the inputs from Member States and stakeholders.

4. Governance structure for standards in the medical devices sector

4.1. The MDCG Subgroup on Standards (Working Group 2)

Within the governance structure of the **Medical Device Coordination Group (MDCG)** established by Article 103 of Regulation (EU) 2017/745 and its 13 specific Subgroups, the **MDCG Subgroup on Standards (Working Group 2)** is devoted to standardisation issues. It aims to provide technical expertise for the positions of the MDCG and opinions of the Committee on Standards related to the sector, including standardisation requests, publication of references in the *Official Journal of the European Union*, formal objections to harmonised standards, and so on.

The MDCG Subgroup on Standards is chaired by the Commission and integrated by the national competent authorities of the EU Member States (as members) and of other countries where the EU legislation is applicable, as well as by stakeholders' organisations fulfilling certain criteria (as observers) after selection via public calls for applications. The list of members and observers, the key documents for its operation (Rules of Procedure, Terms of Reference, calls for applications) and the documents related to its meetings and other activities (Agendas, Minutes, others) are publicly available in the specific space of the "**Medical Device Coordination Group (X03565)**" in the "Register of Commission expert groups and other similar entities"[68].

The activities of the MDCG Subgroup on Standards are supported by two **CIRCABC interest groups**, for circulation of information and exchange of documents: the "MDCG - Standards

[66] Commission Implementing Regulation (EU) 2022/1107 of 4 July 2022 laying down common specifications for certain class D *in vitro* diagnostic medical devices in accordance with Regulation (EU) 2017/746 of the European Parliament and of the Council (OJ L 178, 5.7.2022, p. 3).

[67] See e.g. Commission Decision of 7 May 2002 on common technical specifications for *in vitro* diagnostic medical devices (OJ L 131, 16.5.2002, p. 17).

[68] https://ec.europa.eu/transparency/expert-groups-register/screen/expert-groups/consult?lang=en&groupID=3565.

(CAs)"[69] for EU national competent authorities as members, and the "MDCG - Standards (Stks)"[70] for stakeholders' organisations as observers.

4.2. The CEN-CENELEC - Sector Forum on Healthcare Standards (SFHS)

The **Sector Forum on Healthcare Standards (SFHS)**[71], former **Advisory Board on Healthcare Standards (ABHS)**, is the CEN and CENELEC sector forum for medical devices, established in 2005 to bring together European stakeholders interested in or impacted by standardisation in the healthcare field. It is integrated by experts in medical devices standardisation, mainly from national standardisation organisations, Technical Committees, European federations and societal stakeholders; the European Commission participates as observer. The SFHS usually meets once or twice per year, to present and discuss relevant issues related to standardisation in support of EU legislation on medical devices, cooperation with the European Commission and with the international standardisation organisations, agreements on common positions and guidance documents or "white papers", etc.

[69] https://circabc.europa.eu/ui/group/40ffa918-04f6-442e-b278-12e596c5e06a.

[70] https://circabc.europa.eu/ui/group/b47c1365-18cf-4015-9bf1-f6a146c72f32.

[71] https://www.cencenelec.eu/areas-of-work/cen-sectors/healthcare/sector-forum/.

References and sources of information

Both **horizontal and vertical/sectorial references** are listed here, mainly from the Commission but also from other relevant actors for standardisation in the medical devices field.

- EUR-Lex - Access to European Union law: https://eur-lex.europa.eu/
  - *Official Journal of the European Union* (OJEU): https://eur-lex.europa.eu/oj/direct-access.html
- Court of Justice of the European Union: https://curia.europa.eu/
- Medical devices sector - Overview: https://health.ec.europa.eu/medical-devices-sector/overview_en
  - New Regulations: https://health.ec.europa.eu/medical-devices-sector/new-regulations_en
  - Contacts: https://health.ec.europa.eu/medical-devices-sector/new-regulations/contacts_en
  - Events: https://health.ec.europa.eu/medical-devices-sector/events_en
  - Latest updates: https://health.ec.europa.eu/medical-devices-new-regulations/overview_en#latest-updates
- Medical devices - New Regulations - Overview: https://health.ec.europa.eu/medical-devices-new-regulations/overview_en
  - Getting ready for the new regulations: https://health.ec.europa.eu/medical-devices-new-regulations/getting-ready-new-regulations_en
  - Guidance: https://health.ec.europa.eu/medical-devices-new-regulations/guidance_en, Guidance - MDCG endorsed documents and other guidance https://health.ec.europa.eu/medical-devices-sector/new-regulations/guidance-mdcg-endorsed-documents-and-other-guidance_en
  - Publications and factsheets: https://health.ec.europa.eu/medical-devices-topics-interest/publications_en
- Medical devices - Topics of interest - Overview: https://health.ec.europa.eu/medical-devices-topics-interest/overview_en
  - Harmonised standards: https://health.ec.europa.eu/medical-devices-topics-interest/harmonised-standards_en
  - Notified Bodies: https://health.ec.europa.eu/medical-devices-topics-interest/notified-bodies_en
- Medical devices - Dialogue between interested parties - Overview: https://health.ec.europa.eu/medical-devices-dialogue-between-interested-parties/overview_en

  - Medical Device Coordination Group Working Groups: https://health.ec.europa.eu/medical-devices-dialogue-between-interested-parties/medical-device-coordination-group-working-groups_en
  - International Cooperation: https://health.ec.europa.eu/medical-devices-dialogue-between-interested-parties/international-cooperation_en

- Medical Device Coordination Group (X03565) in the "Register of Commission Expert Groups and Other Similar Entities": https://ec.europa.eu/transparency/expert-groups-register/screen/expert-groups/consult?lang=en&groupID=3565

- CIRCABC (Communication and Information Resource Centre for Administrations, Businesses and Citizens): https://circabc.europa.eu/
  - MDCG - Standards (CAs): https://circabc.europa.eu/ui/group/40ffa918-04f6-442e-b278-12e596c5e06a
  - MDCG - Standards (Stks): https://circabc.europa.eu/ui/group/b47c1365-18cf-4015-9bf1-f6a146c72f32

- "MEDICAL DEVICES NEWS" Newsletter (May 2024): https://ec.europa.eu/newsroom/sante/newsletter-archives/53480

- The 'Blue Guide' on the implementation of EU product rules 2022: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv%3AOJ.C_.2022.247.01.0001.01.ENG

- CE marking: https://single-market-economy.ec.europa.eu/single-market/ce-marking_en

- Technical documentation and EU declaration of conformity: https://europa.eu/youreurope/business/product-requirements/compliance/technical-documentation-conformity/

- Single market for goods: https://single-market-economy.ec.europa.eu/single-market/goods_en
  - New legislative framework: https://single-market-economy.ec.europa.eu/single-market/goods/new-legislative-framework_en
  - Market surveillance for products: https://single-market-economy.ec.europa.eu/single-market/goods/building-blocks/market-surveillance_en

- European standards: https://single-market-economy.ec.europa.eu/single-market/european-standards_en
  - Standardisation policy: https://single-market-economy.ec.europa.eu/single-market/european-standards/standardisation-policy_en
  - Harmonised Standards: https://single-market-economy.ec.europa.eu/single-market/european-standards/harmonised-standards_en
    - Standardisation - Notification system: https://single-market-economy.ec.europa.eu/single-market/european-standards/notification-system_en

  - European Commission standardisation requests ("eNorm Platform"): https://ec.europa.eu/growth/tools-databases/enorm/
  - References to harmonised European standards published in the *Official Journal of the European Union* (OJEU) in support of:
    - Medical devices - Regulation (EU) 2017/745: https://single-market-economy.ec.europa.eu/single-market/european-standards/harmonised-standards/medical-devices_en
    - In vitro diagnostic medical devices - Regulation (EU) 2017/746: https://single-market-economy.ec.europa.eu/single-market/european-standards/harmonised-standards/iv-diagnostic-medical-devices_en

- Notified bodies: https://single-market-economy.ec.europa.eu/single-market/goods/building-blocks/notified-bodies_en
  - Single Market Compliance Space (SMCS) - NANDO (New Approach Notified and Designated Organisations) information system: https://webgate.ec.europa.eu/single-market-compliance-space/#/notified-bodies
    - for Regulation (EU) 2017/745: https://webgate.ec.europa.eu/single-market-compliance-space/#/notified-bodies/notified-body-list?filter=legislationId:34
    - for Regulation (EU) 2017/746: https://webgate.ec.europa.eu/single-market-compliance-space/#/notified-bodies/notified-body-list?filter=legislationId:35

- European standardisation organisations (ESOs):
  - European Committee for Standardization (CEN), European Committee for Electrotechnical Standardization (CENELEC) and CEN-CENELEC Management Centre (CCMC): https://www.cencenelec.eu/
    - Healthcare: https://www.cencenelec.eu/areas-of-work/cen-sectors/healthcare/
    - Sector Forum: https://www.cencenelec.eu/areas-of-work/cen-sectors/healthcare/sector-forum/
    - International Cooperation: https://www.cencenelec.eu/european-standardization/international-cooperation/
    - Business Operations Support System: https://boss.cen.eu/

- International standardisation organisations:
  - International Organization for Standardization (ISO): https://www.iso.org/
  - International Electrotechnical Commission (IEC): https://www.iec.ch/

- International Medical Device Regulators Forum (IMDRF): https://www.imdrf.org/; IMDRF 2023: https://imdrf2023.com/