MDCG 2021-5

Guidance on standardisation for medical devices

April 2021

This document has been endorsed by the Medical Device Coordination Group (MDCG) established by Article 103 of Regulation (EU) 2017/745. The MDCG is composed of representatives of all Member States and a representative of the European Commission chairs it.

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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** consists of three current Directives[1] and two new Regulations[2]:

- **Directive 90/385/EEC on active implantable medical devices**[3] (AIMDD), applicable from 1 January 1993 until 25 May 2021;
- **Directive 93/42/EEC on medical devices**[4] (MDD), applicable from 1 January 1995 until 25 May 2021;
- **Directive 98/79/EC on *in vitro* diagnostic medical devices**[5] (IVDMDD), applicable from 7 June 2000 until 25 May 2022;
- **Regulation (EU) 2017/745 on medical devices**[6] (MDR), fully applicable from 26 May 2021;
- **Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices**[7] (IVDR), fully applicable from 26 May 2022.

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**"[8] policies. In this kind of legislation, the

[1] Current Directives: https://ec.europa.eu/health/md_sector/current_directives.

[2] New Regulations: https://ec.europa.eu/health/md_sector/new_regulations, https://ec.europa.eu/health/md_newregulations/overview.

[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). Current consolidated version: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:01990L0385-20071011.

[4] Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ L 169, 12.7.1993, p. 1). Current consolidated version: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:01993L0042-20071011.

[5] 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). Current consolidated version: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:01998L0079-20120111.

[6] 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/legal-content/EN/TXT/?uri=CELEX:02017R0745-20200424.

[7] 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/legal-content/EN/TXT/?uri=CELEX:02017R0746-20170505.

[8] 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

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

Products designed and manufactured according to applicable harmonised European standards the references to 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.[9]. However, in general the use of harmonized 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**[10] ("the Standardisation Regulation"), directly applicable in all Member States from 1 January 2013. It lays down 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);

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).

[9] 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": https://ec.europa.eu/docsroom/documents/18027/ and the Commission's website on CE marking: https://ec.europa.eu/growth/single-market/ce-marking/.

[10] 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/legal-content/EN/TXT/?uri=CELEX:02012R1025-20151007.

- **Rulings of the Court of Justice of the European Union** issued in specific cases[11] relevant for the whole EU standardisation system;

- **Vademecum on European standardisation**[12], 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;

- **Communication from the Commission** - Harmonised standards: Enhancing transparency and legal certainty for a fully functioning Single Market[13];

- **Action plan** - Structural solutions to decrease the stock of non-cited harmonised standards[14].

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:

- **Procedures and guidance for the CEN-Cenelec Management Centre** (CCMC)[15] and the their relevant Technical Committees developing standards (through the "Business Operation Support System"[16]);

- **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.

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 cited in the *Official Journal of European Union* or any other standard) in the medical devices sector is and

[11] Among others: Case C-613/14 James Elliott Construction Limited v Irish Asphalt Limited; Case T-474/15 Global Garden Products Italy SpA (GGP Italy) v European Commission; Case C-630/16 Anstar Oy. See: https://curia.europa.eu/.

[12] https://ec.europa.eu/growth/single-market/european-standards/vademecum.

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

[14] https://ec.europa.eu/docsroom/documents/25881.

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

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

remains **voluntary**. This is clearly stated in the Standardisation Regulation (EU) 1025/2012 ruling the whole system:

- 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 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[17]. 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 of symbols and identification colours that "*shall conform to the harmonised standards*"[18] when harmonised standards containing indications on symbols or colour coding are available[19].

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 cited or not cited in the OJEU, or by non-harmonised European standards, or by any other

[17] Recitals and Articles 5(1) AIMDD, MDD and IVDMDD; Recitals and Articles 8(1) MDR and IVDR.

[18] MDD, Annex I, point 13.2.; IVDMDD, Annex I, point 8.2.; MDR, Annex I, point 23.1 h); IVDR, Annex I, point 20.1 h).

[19] For instance, the harmonised European standards EN ISO 15223-1:2016 *Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements (ISO 15223-1:2016, Corrected version 2017-03)*, and EN ISO 5359:2008 *Low-pressure hose assemblies for use with medical gases (ISO 5359:2008)*+A1:2011.

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.

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 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. 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 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.

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. 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 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 legal requirements not covered or partially covered, allowing the manufacturer to identify them and to implement additional action in order to comply with 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[20].

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 contain specific provisions on **harmonised standards** and the **presumption of conformity** conferred by its voluntary use when their references are published in the OJEU: they can be found in the Recitals and in the respective Articles 5(1) of the current Directives AIMDD, MDD and IVDMDD, and in the Recitals and the respective Articles 8(1) of the new Regulations MDR and IVDR. It is worth noting that the new 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[21].

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)**[22] for most of the types of medical devices, and the **European Committee for Electrotechnical Standardization (Cenelec)**[23] especially for medical electrical equipment.

[20] 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 Boards 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.

[21] See for instance Case C-630/16 Anstar Oy.

[22] https://www.cen.eu/.

[23] https://www.cenelec.eu/.

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 standards 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[24].

For the current Directives AIMDD, MDD and IVDMDD, such requests have 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 must necessarily expire in parallel to the Directives themselves.

For the new 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, 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), the "*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 mandates[25] 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.

The MDR/IVDR Standardisation Request 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.

[24] See footnote 11.

[25] https://ec.europa.eu/growth/tools-databases/mandates/.

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

On the basis of the relevant standardisation mandates or requests, **CEN and Cenelec develop harmonised European standards** in the field of medical devices through their specific Technical Committees (TCs). The process include 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[26].

During the standardisation process, specific assessment of the draft 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 standardisation request (mandate). 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 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 four HAS consultants for 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[27].

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

[26] More information on the development of European standards is available on the websites of the European standardisation organisations, CEN: https://www.cen.eu/ and Cenelec: https://www.cenelec.eu/, and their Management Centre: https://www.cencenelec.eu/.

[27] More information: https://assets.ey.com/content/dam/ey-sites/ey-com/en_be/topics/advisory/ey-has-call-for-expression-of-interest.pdf.

Commission the **publication of the references to 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 standardisation mandate or request, taking into account the assessment reports by the HAS consultants (which are however not binding for the Commission), 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 the current Directives on medical devices must have the format of **Commission Implementing Decisions**[28] 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[29] and is a logical consequence of the jurisprudence of the Court of Justice of the European Union[30].

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)**[31] and the **International Electrotechnical Commission (IEC)**[32], on the basis of the Vienna Agreement (1991) and the Dresden Agreement (1996) reconfirmed by the Frankfurt Agreement (2016) respectively[33]. Within such agreements, the normative texts of the respective standards are substantially the same, while harmonised European standards 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

[28] Latest publication under the current Directives on medical devices: OJ L 090I, 25.3.2020, pp. 1, 25 and 33.

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

[30] In particular, the ruling in Case C-613/14 James Elliott Construction Limited v Irish Asphalt Limited.

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

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

[33] CEN-Cenelec international cooperation: https://www.cencenelec.eu/intcoop/.

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.

On the other hand, the **International Medical Device Regulators Forum (IMDRF)** is a voluntary group of medical device regulators from around the world (the management committee is currently integrated by Australia, Brazil, Canada, China, European Union, Japan, Russia, Singapore, South Korea and United States of America), 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. The specific IMDRF Standards Working Group developed different initiatives and documents, such as "*IMDRF recognised standards*"[34], "*Standards - Improving the quality of international medical device standards for regulatory use*"[35], "*Optimizing standards for regulatory use*"[36] and "GHTF/SG1/N044:2008 *Role of Standards in the Assessment of Medical Devices*"[37] of the Global Harmonisation Task Force (GHTF).

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

As in other harmonised sectors, the EU legislation on medical devices – both the current Directives and the new Regulations – contains a number of references to the need to "***take into account the generally acknowledged state of the art***"[38] 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 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*

[34] http://www.imdrf.org/workitems/wi-imdrfstandards.asp.

[35] http://www.imdrf.org/workitems/wi-standards.asp.

[36] http://www.imdrf.org/consultations/cons-swg-optimising-standards-n51-180524.asp.

[37] http://www.imdrf.org/docs/ghtf/final/sg1/procedural-docs/ghtf-sg1-n044-2008-standards-in-assessment-of-medical-devices-080305.pdf.

[38] Among others, in particular in the AMDD, MDD and IVDMDD in their respective Annexes I "Essential requirements", and in the MDR and IVDR in their respective Annexes I "General safety and performance requirements".

standards regularly" ("The 'Blue Guide' on the implementation of EU product rules"[39], section 4.1.2.5., p. 49).

- "*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[40], 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[41], section 7., p. 16).

- "*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[42], 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[43], section 1.2., pp. 5-6).

[39] https://ec.europa.eu/docsroom/documents/18027/.

[40] https://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupMeetingDoc&docid=35082.

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

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

[43] https://ec.europa.eu/docsroom/documents/40904.

- "*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)*[44], 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, due to the non-legal status of the concept of "state of the art" and its complexity, with so many different and dynamic aspects to be taken into account, **the mere compliance with the most recent version of a standard which reference is not listed 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 documentation of the product. Actually, "state-of-the-art" standards 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 Directives or Regulations on medical devices, but cannot make 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.

44 https://standards.cen.eu/dyn/www/f?p=204:110:0::::FSP_PROJECT,FSP_ORG_ID:63920,581003&cs=17914C9013F1D49765AA9CD9E135F8AC9.

4. Governance structure for standards in the medical devices sector

4.1. The MDCG Subgroup on Standards

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"[45].

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 (CAs)"[46] for EU national competent authorities as members, and the "MDCG - Standards (Stks)"[47] for stakeholders' organisations as observers.

4.2. The CEN-Cenelec Advisory Board on Healthcare Standards (ABHS)

The **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 ABHS 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.

[45] https://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupDetail&groupID=3565.

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

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

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://ec.europa.eu/health/md_sector/overview
  - Current Directives: https://ec.europa.eu/health/md_sector/current_directives
  - New Regulations: https://ec.europa.eu/health/md_sector/new_regulations
  - Guidance documents: https://ec.europa.eu/health/md_sector/new_regulations/guidance
  - Market surveillance and vigilance: https://ec.europa.eu/health/md_sector/market-surveillance-and-vigilance
  - Contacts: https://ec.europa.eu/health/md_sector/contact
  - Latest updates: https://ec.europa.eu/health/md-sector/latest_updates
- Medical devices - New Regulations - Overview: https://ec.europa.eu/health/md_newregulations/overview
  - Getting ready: https://ec.europa.eu/health/md_newregulations/getting_ready
  - Guidance: https://ec.europa.eu/health/md_newregulations/guidance
  - Publications and factsheets: https://ec.europa.eu/health/md_newregulations/publications
- Medical devices - Topics of interest - Overview, Harmonised European standards: https://ec.europa.eu/health/md_topics-interest/overview
  - Notified bodies: https://ec.europa.eu/health/md_topics-interest/notified_bodies
- Medical devices - Dialogue between interested parties - Overview: https://ec.europa.eu/health/md_dialogue/overview
  - MDCG Working Groups: https://ec.europa.eu/health/md_dialogue/mdcg_working_groups
  - International cooperation: https://ec.europa.eu/health/md_dialogue/international_cooperation
- Medical Device Coordination Group (X03565) in the "Register of Commission expert groups and other similar entities": https://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupDetail&groupID=3565

- Medical device - Docsroom: https://ec.europa.eu/docsroom/documents?locale=en&keywords=medical%20device

- 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

- The 'Blue Guide' on the implementation of EU product rules: https://ec.europa.eu/docsroom/documents/18027/

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

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

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

- European standards: https://ec.europa.eu/growth/single-market/european-standards
  - Standardisation policy: https://ec.europa.eu/growth/single-market/european-standards/policy
  - Harmonised standards: https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards
    - Standardisation - Notification system: https://ec.europa.eu/growth/single-market/european-standards/notification-system
    - Standardisation mandates and requests: https://ec.europa.eu/growth/tools-databases/mandates/
    - References to harmonised European standards published in the *Official Journal of the European Union* (OJEU) in support of:
      - Directive 90/385/EEC: https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/implantable-medical-devices
      - Directive 93/42/EEC [and Regulation (EU) 2017/745]: https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/medical-devices
      - Directive 98/79/EC [and Regulation (EU) 2017/746]: https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/iv-diagnostic-medical-devices

- Notified bodies: https://ec.europa.eu/growth/single-market/goods/building-blocks/notified-bodies
  - NANDO (New Approach Notified and Designated Organisations) information system: https://ec.europa.eu/growth/tools-databases/nando/
    - for Directive 90/385/EEC: https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=directive.notifiedbody&dir_id=8
    - for Directive 93/42/EEC: https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=directive.notifiedbody&dir_id=13
    - for Directive 98/79/EC: https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=directive.notifiedbody&dir_id=20
    - for Regulation (EU) 2017/745: https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=directive.notifiedbody&dir_id=34
    - for Regulation (EU) 2017/746: https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=directive.notifiedbody&dir_id=35

- European standardisation organisations (ESOs):
  - European Committee for Standardization (CEN): https://www.cen.eu/
    - Business Operations Support System: https://boss.cen.eu/
    - Medical equipment, pharmaceuticals and personal care products: https://www.cen.eu/work/Sectors/Healthcare/Pages/Medicalequipment.aspx
  - European Committee for Electrotechnical Standardization (Cenelec): https://www.cenelec.eu/
  - CEN-Cenelec Management Centre (CCMC): https://www.cencenelec.eu/
    - Medical devices: https://www.cencenelec.eu/standards/Sectorsold/healthcare/MedicalDevices/Pages/default.aspx
    - International cooperation: https://www.cencenelec.eu/intcoop/

- 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): http://www.imdrf.org/