MDCG 2021-5 Rev. 1

Guidance on standardisation for medical devices

Appendix: Transition to the 'EU REP' symbol in EN ISO 15223-1

June 2026

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 it is chaired by a representative of the European Commission.

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Background

Regulation (EU) 2017/745 on medical devices[1] (MDR) and **Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices**[2] (IVDR) prescribe that "Where appropriate, the information supplied by the manufacturer shall take the form of internationally recognised symbols, taking into account the intended users. Any symbol or identification colour used shall conform to the harmonised standards or CS [common specifications]. In areas for which no harmonised standards or CS exist, the symbols and colours shall be described in the documentation supplied with the device" (Section 23.1(h) of Annex I MDR; Section 20.1(h) of Annex I IVDR).

Accordingly, harmonised European standards, the references of which are published in the *Official Journal of the European Union* (OJEU), that contain indications on symbols and identification colours intended to be used by manufacturers of devices to supply the information required by the MDR or IVDR can be regarded as "compulsory standards", as an exception from the general rule of voluntary use of standards established by Article 2(1) of Regulation (EU) No 1025/2012 on European standardisation[3].

This is the case of the harmonised standard **EN ISO 15223-1:2021** ***Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements (ISO 15223-1:2021)***[4], the reference of which is published in the OJEU since January 2022 to confer a presumption of conformity in support of the MDR[5] and the IVDR[6].

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1 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, ELI: http://data.europa.eu/eli/reg/2017/745/oj).

2 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, ELI: http://data.europa.eu/eli/reg/2017/746/oj).

3 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, ELI: http://data.europa.eu/eli/reg/2012/1025/oj).

4 https://standards.cencenelec.eu/ords/f?p=CEN:110:::::FSP_PROJECT,FSP_ORG_ID:68559,581003&cs=19D620A9FF93853AD8A64862A3A63D1B4.

5 Commission Implementing Decision (EU) 2022/6 of 4 January 2022 amending Implementing Decision (EU) 2021/1182 as regards harmonised standards for biological evaluation of medical devices, sterilisation of health care products, aseptic processing of health care products, quality management systems, symbols to be used with information to be supplied by the manufacturer, processing of health care products and home light therapy equipment (OJ L 1, 5.1.2022, p. 11, ELI: http://data.europa.eu/eli/dec_impl/2022/6/oj).

6 Commission Implementing Decision (EU) 2022/15 of 6 January 2022 amending Implementing Decision (EU) 2021/1195 as regards harmonised standards for sterilisation of health care products, aseptic processing of health care products, quality management systems, symbols to be used with information to be supplied by

The symbol for authorised representatives: from 'EC REP' to 'EU REP'

According to Articles 2(32) MDR and 2(25) IVDR, "'authorised representative' means any natural or legal person established within the Union who has received and accepted a written mandate from a manufacturer, located outside the Union, to act on the manufacturer's behalf in relation to specified tasks with regard to the latter's obligations under this Regulation", and according to Articles 11(1) MDR and IVDR, "Where the manufacturer of a device is not established in a Member State, the device may only be placed on the Union market if the manufacturer designates a sole authorised representative".

The harmonised standard EN ISO 15223-1:2021, in its clause 5.1.2, presents the symbol 'EC REP' for "Authorized representative in the European Community/European Union". The references 'EC' for "European Community" and 'European Community' itself no longer correspond to the reality of the European Union that replaced and succeeded the European Community as per the Treaty of Lisbon signed on 13 December 2007 and entered into force on 1 December 2009[7].

Therefore, as part of Amendment 2[8] to the Commission's standardisation request in support of the MDR and IVDR (M/575)[9], in May 2024 the Commission requested CEN and CENELEC to revise EN ISO 15223-1 to "include a specific symbol for the authorised representative in the Union, as 'EU REP' instead of 'EC REP', removing any reference to the term 'European Community'" (Annex III, Part B, point 2.2).

CEN and CENELEC accepted the request in June 2024 and worked with ISO to draft a specific amendment, adopted by ISO in March 2025 and made available by CEN and CENELEC in November 2025 as **EN ISO 15223-1:2021/A1:2025** ***Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements - Amendment 1: Addition of defined term for authorized representative and modified EC REP symbol to not be country or region specific (ISO 15223-1:2021/Amd 1:2025)***[10].

The amendment adds a definition of "authorized representative" generally referred to "a country or jurisdiction" (3.20) and introduces in clause 5.1.2 the generic symbol 'XX REP' for the "*authorized representative* in the identified country or jurisdiction", where the 'XX' text is

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the manufacturer and requirements for establishing metrological traceability of values assigned to calibrators, trueness control materials and human samples (OJ L 4, 7.1.2022, p. 16, ELI: http://data.europa.eu/eli/dec_impl/2022/15/oj).

7 See https://eur-lex.europa.eu/EN/legal-content/summary/the-treaty-of-lisbon.html.

8 See C(2024)3371 – Standardisation request M/575 Amd 2 https://ec.europa.eu/growth/tools-databases/enorm/mandate/575Amd2_en.

9 See C(2021)2406 – Standardisation request M/575 https://ec.europa.eu/growth/tools-databases/enorm/mandate/575_en.

10 https://standards.cencenelec.eu/ords/f?p=CEN:110:::::FSP_PROJECT,FSP_ORG_ID:77231,581003&cs=171F4D5F8B84F0D6BC09C4C269D86E5B4.

intended to be "replaced by either the two-letter country code or the three-letter country code defined in ISO 3166-1 or other text required by the authority having jurisdiction". Among the "examples of use for an *authorized representative* in different countries or jurisdictions", the symbol 'EU REP' is indicated for the authorised representative in the European Union.

Consequently, according to the harmonised standard EN ISO 15223-1:2021 as amended by EN ISO 15223-1:2021/A1:2025, **to indicate the authorised representative established within the Union required by the MDR and IVDR for a manufacturer located outside the Union, in the generic symbol 'XX REP' the 'XX' text must be replaced by 'EU', to get the EU specific symbol to use, 'EU REP'**.

It is important to clarify that, as such, **the change in the symbol for the authorised representative in the Union, from 'EC REP' to 'EU REP', is purely editorial in nature. It reflects a terminology update only and has no impact on the health, safety and performance characteristics of the device, nor on the role and responsibilities, location or legal obligations of the authorised representative**.

In this sense, the manufacturer of the device does not need a prior approval from a notified body (if its involvement is required) for a labelling change.

Citation in the OJEU of EN ISO 15223-1:2021/A1:2025 and transition period

The amendment EN ISO 15223-1:2021/A1:2025 was offered by CEN-CENELEC to the Commission in February 2026 for publication of its reference in the OJEU, in view to have the harmonised standard EN ISO 15223-1:2021 with its amendment EN ISO 15223-1:2021/A1:2025 suitable to confer a presumption of conformity to be used by manufacturers of medical devices and *in vitro* diagnostic medical devices to comply with the requirements of the MDR and IVDR on the information to be provided with the device.

The publications took place on 17 June 2026 for the MDR[11] and for the IVDR[12], with the addition of a new entry (harmonised standard with its amendment):

EN ISO 15223-1:2021 Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements (ISO 15223-1:2021) EN ISO 15223-1:2021/A1:2025

[11] Commission Implementing Decision (EU) 2026/1231 of 11 June 2026 amending Implementing Decision (EU) 2021/1182 as regards harmonised standards for biological evaluation of medical devices, symbols to be used with information to be supplied by the manufacturer, medical electrical equipment, transfusion equipment for medical use, ophthalmic optics, non-active surgical implants, washer-disinfectors, prosthetics and sharps injury protection (OJ L, 2026/1231, 17.6.2026, ELI: http://data.europa.eu/eli/dec_impl/2026/1231/oj).

[12] Commission Implementing Decision (EU) 2026/1313 of 15 June 2026 amending Implementing Decision (EU) 2021/1195 as regards the harmonised standard for symbols to be used with information to be supplied by the manufacturer (OJ L, 2026/1313, 17.6.2026, ELI: http://data.europa.eu/eli/dec_impl/2026/1313/oj).

intended to replace the previous entry (harmonised standard without the amendment):

EN ISO 15223-1:2021 Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements (ISO 15223-1:2021)

in sequential order of the respective Commission Implementing Decisions (EU) 2021/1182[13] and (EU) 2021/1195[14] as amended.

According to the applicable rules and formats for the publication in the OJEU of references of harmonised European standards, the reference of the harmonised standard EN ISO 15223-1:2021 must be deleted, as it has been amended, and replaced by the reference of the harmonised standard EN ISO 15223-1:2021 with its amendment EN ISO 15223-1:2021/A1:2025. However, on the basis of information provided by ISO, CEN and CENELEC, and by Members (competent authorities of the Member States) and Observers (sectorial stakeholders) of the Subgroup on Standards (WG 2) of the Medical Device Coordination Group (MDCG)[15] about the significant impact of those modifications in time and resources on manufacturers and other economic operators, the Commission considered necessary and appropriate to give the concerned interested parties sufficient time to adapt their processes and devices, for a proportionate and resource efficient transition, by deferring the withdrawal of the reference of the harmonised standard EN ISO 15223-1:2021 by 60 months from the date of the publication of the reference of its amendment EN ISO 15223-1:2021/A1:2025, it is to say, until **17 June 2031**.

This corresponds to a **transition / coexistence period of 5 years** during which the harmonised standard EN ISO 15223-1:2021 with its amendment EN ISO 15223-1:2021/A1:2025, providing for the 'EU REP' symbol, may be already used by manufacturers to comply with the requirements of the MDR and IVDR, and at the same time the previous version EN ISO 15223-1:2021 without the amendment EN ISO 15223-1:2021/A1:2025, providing for the 'EC REP' symbol, may continue to be used by manufacturers to comply with the requirements of the MDR and IVDR as well.

During the transition time, within a staggered approach for the implementation, it is acceptable to use one or both symbols 'EC REP' and 'EU REP' on different levels of packaging, as well

[13] Commission Implementing Decision (EU) 2021/1182 of 16 July 2021 on the harmonised standards for medical devices drafted in support of Regulation (EU) 2017/745 of the European Parliament and of the Council (OJ L 256, 19.7.2021, p. 100, ELI: http://data.europa.eu/eli/dec_impl/2021/1182/oj).

[14] Commission Implementing Decision (EU) 2021/1195 of 19 July 2021 on the harmonised standards for in vitro diagnostic medical devices drafted in support of Regulation (EU) 2017/746 of the European Parliament and of the Council (OJ L 258 20.7.2021, p. 50, ELI: http://data.europa.eu/eli/dec_impl/2021/1195/oj).

[15] See in particular the meeting held on 4 February 2026 and the related documents in the "Register of Commission Expert Groups and Other Similar Entities": https://ec.europa.eu/transparency/expert-groups-register/screen/meetings/consult?lang=en&meetingId=69791.

as re-labelling/over-labelling solutions, provided that the information on the authorised representative remains clear and intelligible.

As from 17 June 2031, compliance with the applicable requirements of the MDR and IVDR is granted only by the use of the harmonised standard EN ISO 15223-1:2021 with its amendment EN ISO 15223-1:2021/A1:2025, providing for the 'EU REP' symbol for authorised representatives in the Union. Devices using the 'EC REP' symbol already placed on the EU market before that date may continue to be made available, as the change in the harmonised standard does not concern health, safety or performance issues of the device[16].

[16] See also Section 4.1.2.5. of "The 'Blue Guide' on the implementation of EU product rules": https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv%3AOJ.C_.2022.247.01.0001.01.ENG.