



International Standard

ISO 15223-1

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

*Dispositifs médicaux — Symboles à utiliser avec les informations
à fournir par le fabricant —*

Partie 1: Exigences générales

*AMENDEMENT 1: Ajout du terme défini représentant autorisé
(mandataire) et modification du symbole EC REP pour ne pas
être spécifique d'un pays ou d'une région*

Fourth edition
2021-07

AMENDMENT 1
2025-03



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Published in Switzerland

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This document was prepared by Technical Committee ISO/TC 210, *Quality management and corresponding general aspects for products with a health purpose including medical devices*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/CLC/JTC 3, *Quality management and corresponding general aspects for medical devices*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

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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

Clause 3

Add the following term after 3.19:

3.20

authorized representative

natural or legal person established within a country or jurisdiction who has received a written mandate from the *manufacturer* to act on his behalf for specified tasks with regard to the latter's obligations under that country or jurisdiction's legislation

[SOURCE: ISO 13485:2016, 3.2]

Clause 5, Table 1

Replace item 5.1.2 with the following:

5.1.2 ┌┐ └┘	<i>Authorized representative</i>	Indicates the <i>authorized representative</i> in the identified country or jurisdiction	The [XX] text of the <i>symbol</i> shall 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. This <i>symbol</i> shall be accompanied by the name and address of the <i>authorized representative</i> adjacent to the <i>symbol</i>.	NOTE 1 Additional guidance can be found in ISO 20417^[15], ISO 18113-1^[10], ISO 18113-2^[11], ISO 18113-3^[12], ISO 18113-4^[13] and ISO 18113-5^[14]. NOTE 2 If multiple <i>symbols</i> (i.e. <i>Authorized representative</i>, <i>Importer</i>, <i>Distributor</i>, <i>Translation</i>, or <i>Repackaging</i>) identify the same responsible entity, the name and address need not be duplicated, and all applicable <i>symbols</i> can be grouped together next to the single address. NOTE 3 Not all authorities having jurisdiction recognize the two-letter or three-letter country codes found in ISO 3166-1.	—	N/A
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Annex A

Change the title of Clause A.4 to:

Example of use of symbol 5.1.2 “Authorized representative”

Change the content of Clause A.4 to: