International Standard

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AMENDMENT 1
2025-03

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

Reference number
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Part 1: General requirements

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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  	*Authorized representative*	Indicates the *authorized representative* in the identified country or jurisdiction	The [XX] text of the *symbol* 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 *symbol* shall be accompanied by the name and address of the *authorized representative* adjacent to the *symbol*.	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 *symbols* (i.e. *Authorized representative, Importer*, *Distributor*, Translation, or Repackaging) identify the same responsible entity, the name and address need not be duplicated, and all applicable *symbols* 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

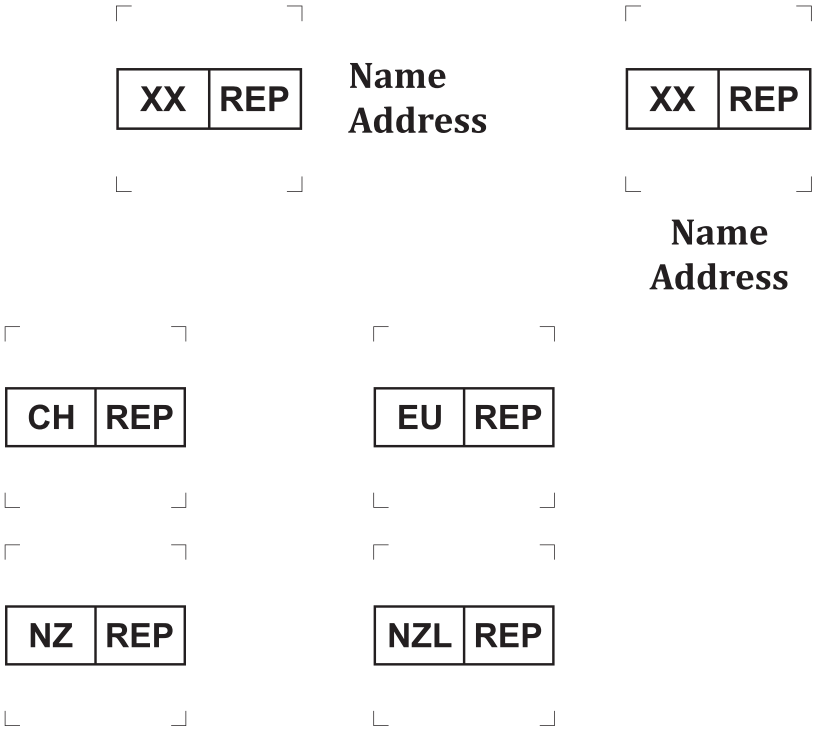
Annex A

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:

Examples of use for an *authorized representative* in different countries or jurisdictions



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