1 Terms, definitions, abbreviations

CH-REP: Abbreviation for *authorised representative* in Switzerland as per Art. 4 para. 1 let. g of the Medical Devices Ordinance (MedDO; SR 812.213).
MDR: Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices

2 Appointment of a Swiss authorised representative

If the manufacturer of a medical device does not have its registered place of business in Switzerland, its products may only be placed on the market once an authorised representative domiciled in Switzerland has been appointed (Art. 51 para. 1 MedDO). This also applies to manufacturers with their registered place of business in the EU.

3 Mention of the Swiss authorised representative on the product

3.1 Mention of the Swiss authorised representative on the packaging

The name of the Swiss authorised representative must be stated on the packaging ("product labelling") as per MDR Annex I section 23.2 (d). It is not mandatory for the Swiss authorised representative to be stated on the product itself, in the instructions for use as per MDR Annex I section 23.4 (a) or in the documents enclosed with the product (delivery note, commercial invoice).

3.2 Use of the "CH-REP" symbol on the packaging

The name and address of the authorised representative must appear adjacent to the symbol. The address must enable contact to be established with the Swiss authorised representative. It is not sufficient only to state the P.O. box number, an e-mail address or a telephone number.

Name and address of the authorised representative's registered place of business

The symbol can be downloaded using the following link: Swiss authorised representative, CH-REP (www.swissmedic.ch). The relative size of the symbol and the size of the name are not defined, but they must be clearly legible to the naked eye.

When symbols are used, they must as a rule conform to the harmonised standards. If no such standards exist for the area concerned, the symbols must be explained in the product documentation enclosed. In this case Swissmedic accepts and recommends the sole use of the symbol without any description of the symbol in the package leaflet.

3.3 The symbol description is as follows:

"Indicates the authorised representative in Switzerland"

Instead of the symbol it is permissible to write "CH authorised representative" / "CH-REP" / "Authorised representative for Switzerland".

4 Transitional rules

The transitional periods defined in Art. 104a MedDO apply to the authorised representative.

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