

New labelling requirements for Class I Medical Devices

We would like to draw your attention on the labelling of class I devices:

Until 31. July 2023, the CH-REP could be indicated by adding the CH-REP on the label itself **OR** on a document accompanying the device.

From 01. August 2023, the CH-REP must be indicated on the label itself*.

1 Use of the “CH-REP” symbol on the packaging

(Text from <https://www.swissmedic.ch/swissmedic/en/home/medical-devices/market-access/ch-rep.html>)

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.

Example 1



Example 2 (Swiss AR Services Symbol)



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 the sole use of the symbol without any description of the symbol in the product documentation enclosed.

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”.

* Please check

https://www.swissmedic.ch/dam/swissmedic/en/dokumente/medizinprodukte/mep_urr/mu600_00_016d_mb_plichten_wirtschaftsakteure_ch.pdf.download.pdf/MU600_00_016e_MB_Obligations_Economic_Operators_CH.pdf (chapter 6) for details.



2 Labelling procedure

It is not required to have the CH-REP indication on the label when sending the products to Switzerland.

Your importer is held responsible to check the CH-REP indication on the label before placing the product on the Swiss market (and not the customs).

As manufacturer, you may have the following options to indicate the CH-REP on the packaging:

2.1 Printing on the label

You may print the Swiss AR Services Logo or the CH-REP sign and the address directly on the label. No further actions required.

Please provide updated label (one example per Tech File) to Swiss AR Services.

2.2 Attach specific sticky labels with CH-REP sign and address

2.2.1 Labelling On site

If you attach the sticky labels in your own factory/storage, please provide updated label and process to Swiss AR Services.

2.2.2 Labelling at your importer/distributor

To assure correct labelling, an agreement between the manufacturer and the importer/distributor is strongly recommended. This way it is guaranteed, that the importer/distributor always know the correct CH-REP, the correct label and the place which you intended to attach the label.

Please provide according agreement to Swiss AR Services.

Considerations: The importer role is usually not actively assigned by the manufacturer. An importer will turn into an importer, when placing product from foreign manufacturer on the Swiss Market the first time.

Therefore you may not be aware of all importers of your products to Switzerland.

2.3 Labels

Basically you can design your own sticky label according to the requirements above.

However, we offer special CH-REP stickers on request with a basic security feature to prevent copying.

Please contact info@swissarservices.ch for a quote and further information.

3 Further questions

If you have further questions regarding the labelling, labelling options or even anything else, don't hesitate to contact us via:

- Issue Tracker (preferred option, "report new issue")
- Email to info@swissarservices.ch

We are looking forward to hear from you!

Team Swiss AR Services.