

Applies to Class 1 Medical Devices:

Declaration of a Swiss Representative (CH-REP) with effect from 31.07.2022

Background:

The Swiss law for medical devices was revised and came into force on 26th May 2021. A previous regulation by the medical device directive (93/42/EWG) was an agreement between Switzerland and the EU declaring them to be equal partners with respect to mutual recognition of conformity assessments as well as ensuring Switzerland access to the European internal market.

Upon revising the new Swiss medical device regulation, this agreement between Switzerland and the EU should have been updated. It was, however, left undone. Due to this, Switzerland took measures to cushion the negative effects of this development. Amongst these measures was the appointment of a Swiss representative (CH-REP), a compulsory registration requirement for economic actors at Swissmedic, reporting of serious incidents to Swissmedic and the recognition of the EU documents of compliance in Switzerland.

What does this mean?

All manufacturers with registered offices in an EU or EEA state will require the appointment of a Swiss representative (CH-REP) for class 1 medical devices by 31st July 2022. The CH-REP shall be stated either on the product itself or on a document accompanying the product (delivery note, guarantee certificate, customs documents, as a sticker on the packing or on the instructions for use).

Product

Class 1 medical devices

CH-REP

stated by 31.07.2023:
On the product label or an accompanying document

After 31.07.2023:

On the product label

Which products are affected?

Gloves and masks, which are declared as medical devices.

What has been done so far?

We have declared the name of our Swiss representative on all our delivery notes for shipments by Unigloves into Switzerland up to **31.07.2022**. We shall be updating our labels/repackaging of these products by **31.07.2023** so that the Swiss representative is duly stated on all mentioned products by the expiry of the deadline.

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What does this mean for you?

In the event that you wish to sell our medical gloves or medical masks in Switzerland, you are required to state the name of our Swiss representative on one of the documents accompanying the product by 31.07.2022. Once the label is updated and the Swiss representative is noted on the product itself, there is no necessity for further indication on the documents accompanying the product.

For inquiries regarding our Swiss representative or how to proceed, we would be glad to be of assistance.

Source:

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

[dated: 19.05.2022] „Merkblatt Pflichten Wirtschaftsakteure CH“, Swissmedic, [dated: 20.12.2021]

UNIGLOVES GERMANY

Arzt- & Klinikbedarf
Handelsgesellschaft mbH

📍 Camp-Spich-Straße 71
D-53842 Troisdorf
☎ +49 (0) 2241-9323-0
✉ unigloves@unigloves.de
🌐 unigloves.de

