# Information sheet
# FAQ Notifications

| | |
|---|---|
| **Identification number:** | BW630_30_009 |
| **Version:** | 1.4 |
| **Valid from:** | 15.07.2023 |

# 1 What medical devices must be notified to Swissmedic and who must submit the notification?

a. Custom-made devices according to Art. 19 of the Medical Devices Ordinance (MedDO)[1]

   The notification obligation applies to persons (manufacturers, authorised representatives, importers or distributors) based in Switzerland before making such devices available on the market.

b. Repackaged or relabelled medical devices according to Art. 53 or 54 MedDO.

   The notification obligation applies to persons (importers and distributors) based in Switzerland.

c. Medical devices manufactured and used in healthcare institutions according to Art. 18 MedDO.

   The notification obligation applies to healthcare institutions in Switzerland prior to putting the devices into service.

d. Class I medical devices (I, Is, Im, Ir, Ims) according to Art. 108 MedDO in conjunction with Art. 6 oMedDO[2] and class I medical devices according to Directive 93/42/EEC that belong to classes Ir, IIa, IIb or III according to MDR.

   The notification obligation applies only to manufacturers based in Switzerland. Swiss authorised representatives are not subject to the notification obligation according to Art. 108 MedDO

e. Systems or procedure packs according to Art. 108 MedDO.

   The notification obligation applies to persons (assemblers) based in Switzerland that assemble systems or procedure packs prior to placing such devices on the market

For IVD and Devit notifications please refer to the following pages: Notification of IVD (swissmedic.ch) and Notification of devitalised human tissue (swissmedic.ch)

# 2 Should class I devices with a manufacturer from the EU/EEA be notified to Swissmedic if they are placed on the market in Switzerland?

Class I, IIa, IIb and III medical devices with a manufacturer in the EU or the EEA do not need to be notified in Switzerland, see Art. 108 MedDO: SR 812.213 – Medical Devices Ordinance of 1 July 2020 (MedDO) (admin.ch)

# 3 Should class I devices from third countries (outside the EU/EEA) be notified to Swissmedic?

Class I medical devices with a manufacturer from a third country do not need to be notified in Switzerland, see Art. 108 MedDO: SR 812.213 – Medical Devices Ordinance of 1 July 2020 (MedDO) (admin.ch). The medical devices must be compliant with the Medical Devices Ordinance. Where the

[1] Medical Devices Ordinance of 1 July 2020 (version: 26 May 2022)
[2] Medical Devices Ordinance of 17 October 2001 (version: 1 August 2020)

manufacturer of a medical device is not domiciled in Switzerland, the device may only be placed on the market in Switzerland if it has authorised a person based in Switzerland (Art. 51 para. 1 MedDO).

## 4 Can I notify a system/procedure pack according to Art. 12 of Directive 93/42/EEC (MDD) to Swissmedic?

No.

## 5 Can I notify a system/procedure pack according to Art. 22 of the MDR to Swissmedic if some of the devices do not yet comply with MDR?

Even if the devices are not yet MDR-certified, since 26 May 2021 a system/procedure pack may be placed on the market for the first time, and thus notified, only if a statement is drawn up according to Art. 22 MDR. Systems or procedure packs according to Art. 11 MedDO (Art. 22 MDR) can include both MDR and MDD devices, provided the MDD devices are still allowed to be placed on the market. Therefore, these devices do not yet need an MDR certificate.

## 6 Who has access to Eudamed?

Eudamed 2 may be accessed only by authorities.
The link https://ec.europa.eu/tools/eudamed/#/screen/home leads to the new Eudamed (known as Eudamed 3). All entries relating to manufacturers and devices in Eudamed 3 are made by the company.

## 7 Do devices with a declaration of conformity according to MDD that are already notified according to Art. 6 oMedDO need to be notified to Swissmedic again?

Class I medical devices that were notified to Swissmedic according to Art. 6 oMedDO (declaration of conformity according to MDD) and that now need to satisfy the requirements of MDR must be notified to Swissmedic again.

## 8 Do devices with a declaration of conformity according to MDR that are already notified according to Art. 6 oMedDO need to be notified to Swissmedic again?

A medical device that was notified as a medical device according to MDR before 26 May 2021 does not need to be notified again.

## 9 Where can a device code be obtained (EMDN/GMDN/UMDNS/EDMA)?

The new EMDN nomenclature is issued by the European Commission:
https://webgate.ec.europa.eu/dyna2/emdn/
The GMDN codes are issued by the GMDN agency (www.gmdnagency.org), the UMDNS codes by the ECRI institute (www.ecri.org/solutions/umdns). The EDMA codes can be used only for in vitro diagnostic medical devices.

## 10 Does the device code (EMDN/GMDN/UMDNS/EDMA) absolutely have to be stated in the notification?

Yes. The device code is required for a notification according to Art. 108 MedDO

## 11 How much does a notification cost?

A fee is charged (CHF 300 per notification) for all notifications according to Art. 18, 19, 53/54 and 108 MedDO. The decisive factor in charging this fee will be the date of receipt of the complete notification via the relevant form. A fee is not charged for amendments to a notification.
A **notification form** must be completed for **each device** or each device group. If several devices come under the same code (EMDN, GMDN or UMDNS), a joint notification can be submitted for this device group. In this case, a device list with all the necessary details of the devices must be submitted.

## 12 Must a CHRN be applied for in advance before a notification is submitted?

No. Economic operators must register for a CHRN within three months of placing a device on the Swiss market for the first time.
The registration obligation of economic operators is processed by Swissmedic independently of the notification obligation for devices. Please proceed according to the corresponding requirements and take into account any transitional periods.

## 13 How long does it take to process a notification?

Processing a notification takes approximately one month from receipt. This assumes that the notification contains all the necessary information and documentation. However, the statutory notification obligation is fulfilled with the submission of the notification.

## 14 When must a notification of variation be submitted?

Variations only need to be notified to Swissmedic if the name or address of the economic operators, the intended purpose, qualification, classification, or the name of the device changes, or if the device list changes in respect of the intended purpose, qualification, classification of name of one or more devices.

## 15 Fees

The ordinance of the Swiss Agency for Therapeutic Products on its fees (GebV-Swissmedic) specifies the following fees:

An administrative fee (Art. 4 GebV-Swissmedic) of CHF 200 per hour will be charged for additional administrative work, e.g. due to incomplete or inappropriate documentation, withdrawal of a notification after work has already been carried out, requests for information or the correction of a notification as a result of a mistake made by the notifying company.

*Please note that, as the supervisory authority for medical devices, Swissmedic does not provide any advice regarding the development, qualification, classification, registration, certification or placing on the market of medical devices. Please contact a private consultant directly for such advice*