Information sheet
Notifications devitalised human tissue

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List of contents

1 Scope

This information sheet provides guidance on the notification requirement for all products containing devitalised human tissue (DEVIT), including:

a) MD-DEVIT products, which are now considered to be medical devices according to MedDO[1] / MDR[2]
b) DEVIT products that continue to be subject to regulation according to oMedDO[3].

[1] MedDO: Medical Devices Ordinance of 1st July 2020, SR 812.213
[2] MDR: Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC
[3] oMedDO: Medical Devices Ordinance of 17 October 2001, SR 812.213 (Status as of 1 August 2020)

2 Terms

Devitalisation means killing of cells/tissues with appropriate physical (e.g.: cryopreservation, freeze drying, autoclaving, sterilisation, ionising radiation, etc.) and/or chemical processes.

Based on Art. 4 para. 2 MedDO in combination with Art. 2 MDR, the following terms are defined:
(16) **"non-viable"** means having no potential for metabolism or multiplication;
(17) **"derivative"** means a "non-cellular substance" extracted from human or animal tissue or cells through a manufacturing process. The final substance used for manufacturing the device in this case does not contain any cells or tissues.

3 When must products be notified to Swissmedic?

At the latest when they are placed on the market.

4 Which products have to be notified?

A distinction is made between two groups of notifiable products containing devitalised human tissue.

a) MD-DEVIT products, which are now considered to be medical devices according to MedDO / MDR
b) DEVIT products that continue to be subject to regulation according to oMedDO.

4.1 MD-DEVIT products

As of 26 May 2021, the following products must undergo a conformity assessment procedure for medical devices and require **CE marking**:

1st According to Art. 1, para. 3 letter c number 2 MedDO: products manufactured from **derivatives** of tissue or cells of **human origin** that are not viable or that have been killed off.
2nd According to Art. 1 para. 3 letter d MedDO: products which contain **non-viable** tissue or non-viable cells of human origin, or the derivatives of such tissue or cells, as an integral constituent part at the time the products are placed on the market or put into service and where such tissue, cells or derivatives assume **a supporting function** in such products.

These products are subject to notification according to Art. 108 para. 1 letter b MedDO in conjunction with Art. 6 para. 3 oMedDO until Art. 17 para. 5 MedDO comes into force. Please use the following form for notifying these products:
FO_Notification_for_MD-DEVIT_products

Transitional provisions:
Please note that a conformity assessment procedure and CE marking are absolutely essential for these products. The only exceptions are those products that were notified **before** 26.05.2021 according to the old law under Art. 6 para. 3 oMedDO (see Art. 103 para. 1 MedDO).

4.2 DEVIT products

DEVIT products according to Art. 2a para. 2 TPA[4], have to be notified until a special ordinance is issued in accordance with Art. 103 para. 2 MedDO in combination with Art. 6 para. 3 oMedDO. These include:

1st All products made from devitalised human tissue or cells, with the exception of derivatives of such tissue or cells
2nd Products which contain non-viable tissue or non-viable cells of human origin, or the derivatives of such tissue or cells, as an integral constituent part at the time the products are placed on the market or put into service and where such tissue, cells or derivatives assume a primary function in such products.

Please use the following form for notifying these products:
FO_Notification_for_DEVIT_products

If products have a pharmacological, immunological or metabolic primary effect, or contain living cells that are either capable and incapable of division, they are classed in Switzerland as medicinal products, blood and blood products or transplant products. Such products cannot be placed on the market as DEVIT products with a notification requirement according to Art. 103 para. 2 MedDO in combination with Art. 6 para. 3 oMedDO. Please note that these products are subject to different regulations and/or laws. Please refer to the Swissmedic website for further information.

5 Who can submit notifications?

5.1 MD-DEVIT products

Notifications must be submitted by the person or entity that first places the MD-DEVIT products on the market in Switzerland:

- Legal manufacturer
- Authorised representative, if there is one

5.2 DEVIT products

Notifications can be submitted by the person or entity that places the DEVIT products on the Swiss market:

- Legal manufacturer
- Authorised representative, if there is one
- Importers
- Distributor
- Representative of the person or entity placing the product on the market, e.g.: consultant with power of attorney

[4] TPA: Therapeutic Products Act of 15 December 2000, SR 812.21 (Status as of May 26, 2021)

6 What must be notified

6.1 MD-DEVIT products

A notification in accordance with Art. 108 para. 1 letter b MedDO in combination with Art. 6 para. 3 oMedDO must be submitted for each product or product group.

Please use the following form for notifying these products:
FO_Notification_for_MD-DEVIT_products

6.2 DEVIT products

A notification in accordance with Art. 103 para. 2 MedDO in combination with Art. 6 para. 3 oMedDO must be submitted for each product or product group.

Please use the following form for notifying these products:
FO_Notification_for_DEVIT_products

The following must be noted when completing the form:

- The information required by Art. 103 para. 2 MedDO in combination with Art. 6 para. 3 oMedDO is mandatory.
- Additional information may subsequently be demanded in the course of a market surveillance procedure under Art. 103, para. 2 MedDO in combination with Art. 26 and 27 oMedDO. The person or entity that first places the product on the market must keep the documentation up to date.
- Missing, insufficient or incorrect information can lead to market withdrawals, bans or the seizure of goods within the framework of a market surveillance procedure (Art. 66 TPA; Art. 103 para. 2 MedDO in combination with Art. 26 and 27 oMedDO). Swissmedic may open penal proceedings against those at fault.

7 When should variations be notified?

7.1 MD-DEVIT products

According to Art. 108 para. 1 letter b MedDO in combination with Art. 6 para. 4 oMedDO, variations should be collated and submitted to the Agency once a year.

Change of manufacturer:
Please arrange the deregistration by the original manufacturer and an initial notification by the new manufacturer, at the latest by the date when the products are placed on the market by the new manufacturer.

Change of authorised representative:
Please notify this within 30 days.

If **additional products** in a product group are to be notified, a notification of variation must be submitted, at the latest by the date when this additional product is placed on the market.

Please use the following form for notifying variations for MD-DEVIT products:
FO_Notification_for_MD-DEVIT_products

7.2 DEVIT products

According to Art. 103 para. 2 MedDO in combination with Art. 6 para. 4 oMedDO, variations should be collated and submitted to the Agency once a year.

However, please note that, since **every person or entity that places products on the market** has to submit an initial notification to Swissmedic, an initial notification is required in case of the selection of additional distributors in Switzerland.

If **additional products** in a product group are to be notified, a notification of variation must be submitted, at the latest by the date when these additional products are placed on the market.

Please use the following form for notifying variations for DEVIT products:
FO_Change_notification_for_DEVIT_products

8 Product surveillance and vigilance

8.1 MD-DEVIT products

All the requirements stated in the MedDO apply to MD-DEVIT products.
Vigilance reports must be submitted according to Art. 66 MedDO.

8.2 DEVIT products

Please note that the whole of section 5 of oMedDO applies to DEVIT products.
This means that the person or entity that places the product on the market must maintain a product surveillance system.
Recalls, safety measures and serious incidents must be notified to the Agency in accordance with Art. 103 para. 2 MedDO in combination with Art. 15 oMedDO.

9 What processing times should we expect?

Swissmedic processes notifications in order of submission:

- within 30 working days of receipt of full information.

10 To whom should I send my notification?

Swissmedic prefers electronic submission. Please send notifications to the address stated in the form FO_Notification_for_MD-DEVIT_products / FO_Notification_for_DEVIT_products or to the address stated in section 12 of this information sheet.

11 Fees

According to the Ordinance on Fees Levied by the Swiss Agency for Therapeutic Products (FeeO-Swissmedic, SR 812.214.5), notifications for the placing on the market of a medical device are subject to a fee. The amount of the fee is specified in Annex 2 section 1.1 of FeeO-Swissmedic (CHF 300).

The notifier can specify a different billing address.

12 Contact in case of questions

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Further information on medical devices can be found at www.swissmedic.ch/md

Change history

Version	Change	sig
1.1	New layout, no content adjustments to the previous version.	hem
1.0	New document	bul