This information sheet addresses the mandatory notification, in accordance with Art. 3, para. 3 MepV[1], of classical and active implantable medical devices for which devitalised human tissue is used for their production or that contain such tissue (hereinafter "medical device with devitalised tissue").

The requirement regarding the conformity assessment of these devices is not harmonised within Europe at present. Whereas in Switzerland such devices are regulated in accordance with legislation on medical devices, different procedures are defined in other countries. For that reason, medical devices with devitalised tissue can neither obtain CE marking based on European law on medical devices, nor does the free exchange of goods between Switzerland and the EU, EFTA countries or Turkey exist. A notification with Swissmedic is therefore always required in order to place such devices on the Swiss market.

1 When must Swissmedic be notified of the devices?

At the latest at the moment they are placed on the market.

2 Which devices are concerned by mandatory notification?

A medical device with devitalised human tissue is understood as follows (for a more detailed definition, see Arts. 1 and 3 MepV):

- A product intended for medical use on humans,
- that is proved to contain no living cells or tissues and
- whose principal intended action is not achieved by pharmacological, immunological or metabolic means.
- Devitalisation means that the cells / tissues have been killed with the appropriate physical (e.g. cryopreservation, lyophilisation, autoclaving, sterilisation, ionising radiation, etc.) and / or chemical procedures.

In Switzerland, if products have a principal intended action that is pharmacological, immunological or metabolic or if they contain living cells (viable or partially viable), they are considered to be medicinal products, blood and blood products, or transplant products. Such products may not be placed on the market as medical devices. Please note that these products are governed by other regulations / laws. Information on the subject can be found on the Swissmedic website.

3 Who may submit notifications?

A notification may be submitted by those placing medical devices on the Swiss market

- Legal manufacturers
- Authorised EU representatives, if applicable
- Distributors
- Representatives of the person placing the device on the market, e.g.: advisers duly authorised by the person placing the device on the market, duly authorised external sterilisation service providers

4 Legal basis

A notification in accordance with Art. 6, para. 3 MepV must be submitted for each device or group of devices. When completing the form, the following aspects should be noted:

- The information required in Art. 6, para. 3 MepV is compulsory.
- Other information may be required within the framework of a compliance monitoring procedure in accordance with Arts. 26 and 27 MepV. The documentation on the product must be kept up to date by the person first placing the device on the market.
- Missing, inadequate or incorrect information may lead to market recalls, bans or seizures within the framework of a compliance monitoring procedure (Art. 6 TPA[2]; Arts. 26 and 27 MepV). If

[1] MepV: Medical Devices Ordinance of 17 October 2001, SR 812.213

[2] Federal Act of 15 December 2000 on Medicinal Products and Medical Devices (Therapeutic Products Act), SR 812.21

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appropriate, Swissmedic may initiate penal proceedings against persons who infringe the requirements.

5 What information and documents must be submitted?

Notifications in accordance with Art. 6, para. 3 MepV must be submitted using the form "Notification in accordance with Art. 3, para. 3, MepV for classical or implantable medical devices with DEVITALISED HUMAN TISSUE". The form is available at www.swissmedic.ch/md-market-access (> Notification of devitalised human tissue) and requires the following information:

Compulsory:
- Name and address of the following parties concerned: manufacturer, person or entity placing the product on the Swiss market, contracted manufacturer, external sterilisation service provider, originator of the report (if different from those cited above)
- Information on the product, including the general technology and use
- Traceability from the product to the donor
- Licences and certificates available
- Product surveillance system in accordance with Section 5 MepV
- Information on the devitalisation and sterilisation procedures

Optional:
- Information on tissue / cell banks and other parties concerned
- Information on the risk and harmlessness of the product and on the starting materials
- Information on the manufacturing process, product and in-process controls and on product release
- Information on the sterilisation process

Swissmedic prefers to receive the optional information as well as the compulsory details. The optional information fosters transparency and safety with regard to the conformity status of a product. The optional information moreover corresponds to the expected future requirements regarding these products (see point 10).
Swissmedic constantly endeavours to provide rapid, high-quality work. The submission of complete, correct documentation is an aspect that makes this possible.
Should any of the information be unclear, Swissmedic will request further information and documentary proof.
Incomplete documentation can lead to queries and thus to delays.
Should you have obtained approval or authorisation for the products in another country, it is also possible to use the dossier submitted to the relevant authorities in that country. In this case, we ask you to state, via the list of contents, which parts of the questionnaire relate to which section of the dossier. Any documents that are not included in the dossier but that are required by Swissmedic should also be included with the submission.

6 When must Swissmedic be notified of changes?

Compulsory information: Swissmedic must be notified of all changes related to compulsory information. When doing so, an updated form including the new information must be submitted, and the changes must be mentioned briefly in the cover letter.
Optional information: All changes relating to optional information must be sent to Swissmedic once a year collectively.

7 Product surveillance in accordance with Section 5 MepV

Please note that all of Section 5 of the MepV applies to medical devices with devitalised human tissue.
This means that the person placing the device on the market must maintain a product surveillance system.
Recalls, safety measures and serious incidents must be reported to Swissmedic in accordance with Art. 15 MepV.

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8 What processing times can I expect?

Notifications are processed by Swissmedic in the order in which they are submitted:

- Within 30 working days following reception of the complete information

9 Who should I send the report to?

Swissmedic prefers notifications to be submitted in electronic form. Please send the notifications to the address stated in the form "Notification in accordance with Art. 3, para. 3, MepV for classical or implantable medical devices with DEVITALISED HUMAN TISSUE" or under point 11 of this information sheet.

10 Contact for questions

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

Change history

Version	Valid and binding as of:	New minor version	Description, comments (by author)	Author's initials
2.1		31.08.2018	Change of contact address and internet links	bul
2.0	**23.06.2017**		**Para 10 Outlook on the forthcoming revision of the EU Regulation was deleted**	**bul**
1.0	**28.11.2016**		**New QM ident: BW530_00_001e_MB** **Old QM ident: MU107_00_001e_MB** **Link corrected** **The remaining content of the document was not reviewed and stays unchanged.**	**wkn**
03	**01.10.2016**		**New email address**	**bul**
02	**01.10.2014**		**Telephone and fax numbers within the document updated, telephone and fax number in the footer updated, new change history inserted in the document, document name modified in the header**	**sel**