swissmedic

# Information sheet

# Procurement of medical devices in healthcare institutions

| | |
|---|---|
| **Identification number:** | MU600_00_006 |
| **Version:** | 5.1 |
| **Valid from:** | 01.11.2023 |

List of contents



# 1 What is the aim of this information sheet and who is the target readership?

This information sheet is aimed at healthcare institutions (e.g. hospitals, practices and purchasing organisations) and describes the documentation and evidence for demonstrating the conformity of medical devices.

The applicable medical device provisions of the Therapeutic Products Act (TPA; SR 812.21), the Medical Devices Ordinance (MedDO; SR 812.213) and the Ordinance on In Vitro Diagnostic Medical Devices (IvDO; SR 812.219) have been generalised for this information sheet. The current legal provisions apply in all cases. Special cases (e.g. medical devices manufactured in-house, custom-made devices, non-CE-marked devices for clinical trials and performance evaluation and devices for performance studies) are not covered by this information sheet.

Furthermore, devices without an intended medical purpose[1], but which involve risks similar to those applicable to medical devices (e.g. lasers for hair removal, hyaluronic acids for anti-wrinkle injections) are subject to the medical devices regulation. However, these devices are not covered by this information sheet. Information about devices without an intended medical purpose in accordance with Annex 1 MedDO can be found at www.swissmedic.ch > Medical devices.

## 2 Medical devices regulation in Switzerland and Europe

Following the entry into force of the revised Medical Devices Ordinance (MedDO) on **26 May 2021**, the Federal Council enacted the new Ordinance on In Vitro Diagnostic Medical Devices (IvDO) on **26 May 2022**. To ensure that quality, safety and efficacy standards match those in EU member states, this legislation is based on the new EU regulations on medical devices (EU **MDR**[2]) and in vitro diagnostic medical devices (EU **IVDR**[3]). The MedDO and IvDO are referred to hereafter as ***the new regulation***.

The Swiss-EU agreement on mutual recognition (MRA) should have been updated concurrently with the entry into force of Switzerland's new medical devices regulation. However, the EU Commission did not proceed any further with updating the MRA with effect from 26 May 2021 owing to the broader political context, specifically the lack of progress on the institutional framework agreement between Switzerland and the EU.
To limit the impact of the MRA not being updated,Switzerland established the following measures, among others:

- Designation of an authorised representative ("CH-REP") for devices from manufacturers domiciled outside Switzerland,
- Requirement for economic operators to register with Swissmedic,
- Reporting to Swissmedic of serious incidents, and
- Recognition of EU certificates of conformity in Switzerland.

In view of the bottlenecks at the designated (notified) bodies and the resulting delays in issuing EU certificates (in accordance with EU MDR), including for devices covered by the old legislation, the EU extended the validity of certificates issued under the old legislation (in spite of the date of validity having passed) until 2027/2028 (depending on the classification) under certain conditions, and the deadlines for putting into service and placing on the market (EU MDR and EU IVDR) were lifted, among other measures. These amendments also entered into force in Switzerland on 1 November 2023.

[1] Art. 1 para. 1 let. b MedDO, list in Annex I MedDO.

[2] **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 (AIMDD) and 93/42/EEC (MDD), OJ L 117, p. 1 (Medical Device Regulation, EU MDR).

[3] **Regulation (EU) 2017/746** of the European Parliament and of the Council of 5 April 2017 on in vitro-diagnostic medical devices and repealing Directive 98/79/EC (IVDD) and Commission Decision 2010/227/EU, OJ L 117, p. 176 (In Vitro Diagnostic Medical Devices Regulation, EU IVDR).

The information sheet “Obligations Economic Operators CH” on the Swissmedic website[4] includes an overview of these amended transitional provisions and a detailed description of the conditions for placing products covered by the old legislation on the market.

### 2.1 UDI, medical devices database and EUDAMED

Manufacturers of medical devices “covered by the new legislation” (EU MDR / EU IVDR devices) are required to mark their medical devices with a harmonised, pan-European unique device identifier (UDI)[5]. The obligation to label medical devices and their packaging with a UDI will be phased in gradually, but all medical devices will need to show a UDI from 2027.

Healthcare institutions shall store and keep (preferably by electronic means) the UDI for class III implants with which they have been supplied, or which they have supplied[6].

To increase transparency, the EU is planning a public database (EUDAMED[7]), the contents of which will include data on EU certificates and medical devices The European Commission has repeatedly delayed full implementation. Currently (as at 1 November 2023) not all modules are available; in particular, it is not yet mandatory for all actors, certificates and devices to be registered in EUDAMED.

In line with the EU, and in relation to the requirements for device registration connected with the new regulation, Switzerland is setting up its own database for medical devices (swissdamed – Swiss Database on Medical Devices)[8]. It will register economic operators in addition to medical devices.

## 3 What are medical devices and in vitro diagnostic medical devices?

The definition of medical devices, their subdivision and classification, as well as exceptions from the scope of the legislation, are specified in the Medical Devices Ordinance and the Ordinance on In Vitro Diagnostic Medical Devices.

Medical devices are instruments, apparatus, software, materials, accessories or other medical technology articles

- that are intended for **diagnostic or therapeutic purposes** and advertised as such, and
- whose **principal action in or on the human body is not achieved by pharmacological, immunological or metabolic means**[9]

Medical devices can be subdivided into two groups:

- in vitro diagnostic medical devices (**IVDs**), which are referred to explicitly as such in this information sheet.

---

[4] www.swissmedic.ch > Medical devices > Market access > Obligations for authorised representatives, importers and distributors; https://www.swissmedic.ch/swissmedic/en/home/medical-devices/market-access/pflichten-bevollmaechtigte.html.

[5] Art. 17 MedDO; Art. 16 IvDO.

[6] Art. 65 MedDO.

[7] https://ec.europa.eu/tools/eudamed/#/screen/home.

[8] swissdamed – Swiss Database on Medical Devices (swissmedic.ch); https://www.swissmedic.ch/swissmedic/en/home/medical-devices/medizinprodukte-datenbank.html.

[9] Art. 3 MedDO.

- all “other” medical devices, which are referred to explicitly in this information sheet as "**medical devices, excluding IVDs**".

Accordingly, the term "**medical devices**" as used in this information sheet includes all medical devices ***including IVDs***.

**Table 1: Medical devices, excluding IVDs**

| | |
|---|---|
| **Common abbreviations** | MD (for “medical device”)<br>AIMD (for “active implantable medical device”) |
| **Description**[10] | Medical devices are any medical equipment, instruments or consumables that predominantly come into contact with the human body and/or that investigate the human body, as well as accessories for these devices.<br>Medical devices, excluding IVDs, are summarised in this table. See Table 2 for IVDs.<br>Accessory for a medical device means an article which, whilst not being itself a medical device, is intended by its manufacturer to be used together with one or several particular medical device(s).<br>Devices without an intended medical purpose are also subject to the new Medical Devices Ordinance, but are not covered by the definition of a "medical device".[11] |
| **Swiss regulation** | Federal Act of 15 December 2000 on Medicinal Products and Medical Devices (TPA); SR 812.21<br>Since 26 May 2021: Medical Devices Ordinance (MedDO) of 1 July 2020; SR 812.213[12] |
| **Regulatory framework (EU)** | Until 25 May 2021: Directive 93/42/EEC concerning medical devices (MDD)<br>Directive 90/385/EEC on active implantable medical devices (AIMDD)<br>Since 26 May 2021: Regulation (EU) 2017/745 on medical devices (EU MDR)[13] |
| **Subdivision into risk classes (ascending order)**[14] | Until 25 May 2021: Classes I, IIa, IIb, III and AIMD<br>Since 26 May 2021: Classes I, IIa, IIb and III |
| **Examples** | Scalpel for single use, sterile dressing material, suction cannulas, ultrasound scanner for sonography, lubricating gel for the insertion of a transurethral catheter, software for controlling x-ray equipment, implantable defibrillator, programming unit for cardiac pacemaker, disinfectant for surgical instruments, apps for promoting conception |

[10] Art. 3 MedDO, but excluding in vitro diagnostic medical devices; accessories for devices without an intended medical purpose according to Annex I MedDO are not subject to the regulation.
[11] However, these devices without an intended medical purpose are not covered by this information sheet; information about them is available at www.swissmedic.ch > Medical devices.
[12] SR 812.213 - Medical Devices Ordinance of 1 July 2020 (MedDO) (admin.ch); https://www.fedlex.admin.ch/eli/cc/2020/552/en.
[13] EU MDR: Consolidated TEXT: 32017R0745 — EN — 20.03.2023 (europa.eu); https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:02017R0745-20230320.
[14] Art. 5 oMedDO in conjunction with Annex IX 93/42/EEC and Art. 15 MedDO in conjunction with Annex VII EU MDR.

**Table 2: In vitro diagnostic medical devices and accessories**

| | |
|---|---|
| **Common abbreviation** | IVD |
| **Description**[15] | An in vitro diagnostic medical device is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, piece of equipment, software or system<br>▪ to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body<br>▪ and principally for the purpose of providing information concerning physiological or pathological processes or states, congenital impairments, the predisposition to a particular medical condition or a disease, to determine the safety and compatibility with potential recipients, to predict treatment response or reactions, to define or monitor therapeutic measures.<br>Specimen receptacles shall also be deemed to be in vitro diagnostic medical devices.<br><br>An accessory for an in vitro diagnostic medical device is also subject to the provisions of the new regulation. |
| **Swiss regulation** | Therapeutic Products Act (TPA): Federal Act of 15 December 2000 on Medicinal Products and Medical Devices; SR 812.21.<br>Since 26 May 2022: Ordinance on In Vitro Diagnostic Medical Devices (IvDO) of 4 May 2022; SR 812.219[16] |
| **Regulatory framework (EU)**[17] | Until 25 May 2022: Directive 98/79/EC on in vitro diagnostic medical devices (IVDD)<br>Since 26 May 2022: Regulation (EU) 2017/746 on in vitro diagnostic medical devices (EU IVDR)[18] |
| **Subdivision into risk classes (ascending order)**[19] | Until 25 May 2022: "IVD others", IVDs for self-testing, List B and List A<br>Since 26 May 2022: Classes A, B, C and D (according to EU IVDR) |
| **Examples** | Tests for the determination of blood groups, HIV tests, pregnancy tests, reagents and reagent products for the determination of toxoplasmosis, software for analysing blood parameters, software for controlling a medical laboratory analyser, sample containers |

# 4 How are medical devices “authorised”?

In contrast with the situation for medicinal products, **no official authorisations** exist for medical devices in Switzerland or the whole of Europe.

Every medical device must satisfy the general safety and performance requirements[20] that apply in Switzerland and throughout Europe.

The **manufacturer** assesses the conformity with the general requirements for each medical device (“conformity assessment”). If the medical device satisfies these requirements, the manufacturer can

[15] Art. 3 IvDO; Art. 3 para. 1 and 2 MedDO; Art. 2 nos. 2-4 EU IVDR.
[16] SR 812.219 - Ordinance of 4 May 2022 on In Vitro Diagnostic Medical Devices (IvDO) (admin.ch); https://www.fedlex.admin.ch/eli/cc/2022/291/en.
[17] Available at http://eur-lex.europa.eu/homepage.html.
[18] EU IVDR: EUR-Lex - 02017R0746-20230320 - EN - EUR-Lex (europa.eu); https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02017R0746-20230320&qid=1693294976873.
[19] Nos. 11-14 Annex 3 oMedDO in conjunction with Annex II 98/79/EC; Art. 14 IvDO in conjunction with Art. 47 and Annex VIII EU IVDR.
[20] Abbreviated to GSPR, see Art. 45 para. 3 let. a TPA, Art. 6 MedDO, Art. 6 IvDO, Annexes I EU MDR and EU IVDR.

affix a CE mark (or an MD mark, only for the Swiss market) on medical devices with low risks (e.g. certain class I devices or class A IVDs) on its own initiative and place these devices on the market.

For medical devices with moderate or high risks, the manufacturer must consult an officially **designated body (or in the EU a notified body)**. This body reviews and monitors the medical devices and the manufacturer's quality management system. If the manufacturer can demonstrate that it complies with the relevant requirements, the designated body issues one or more certificates for the medical devices ("EU certificates"). The manufacturer may then affix a CE mark (an MD mark is only sufficient for the Swiss market) with the four-digit number of the designated body (CE nnnn) to the medical device and place it on the market.

## 5 Swiss authorised representatives and importers

Manufacturers of medical devices, including IVDs, which are domiciled abroad must designate a **Swiss authorised representative (CH-REP)** if they wish to place medical devices on the market in Switzerland[21].
The required information about the CH-REP (name and address) is different for medical devices and IVDs covered by the old legislation and those covered by the new legislation. More details can be found in the information sheet "Obligations Economic Operators CH" on our website: Obligations for authorised representatives, importers and distributors (swissmedic.ch)[22].

In addition, the Swiss **importer** (not to be confused with the EU importer) must be shown on all medical devices, their packaging or a document accompanying the devices[23].

## 6 Duty of care of the healthcare institution

The manufacturers are basically responsible for the flawless quality and conformity of their medical devices. Accordingly, the healthcare institutions procuring the medical devices bear considerable responsibility in their selection of suppliers and medical devices.
**Any person handling medical devices is subject to a duty of care** and must take all measures that are required, according to the state of the art, to ensure that health is not jeopardised.[24]

Only those medical devices that bear a valid conformity marking (CE mark or MD mark) may be used. Guidance on how to identify a valid CE or MD mark can be found in Annexes 1 and 2. This information can be used only to check plausibility and not to draw any conclusions about regulatory requirements, since the requirements have been simplified for this information sheet.

[21] Art. 51 MedDO, Art. 44 IvDO.
[22] www.swissmedic.ch > Medical devices > Market access > Obligations for authorised representatives, importers and distributors; https://www.swissmedic.ch/swissmedic/en/home/medical-devices/market-access/pflichten-bevollmaechtigte.html.
[23] Art. 53 para. 2 MedDO, Art. 46 para. 2 IvDO.
[24] Art. 3 TPA.

# 7 Medical devices imported by professionals – responsibilities

If a professional (in this context including healthcare institutions) **imports** conforming medical devices and **uses them directly** without making them available on the market, the medical devices are not considered to have been placed on the market[25] in Switzerland. Accordingly, from the standpoint of medical devices legislation (MedDO and IvDO), the professional or healthcare institution does not assume the role of importer, i.e. they are not subject to the testing, registration or documentation obligations that apply to importers[26].

This is also applicable if

- the medical devices are moved within the same legal entity (i.e. within the healthcare institution) logistically or for accounting purposes (e.g. central procurement for use by professionals in one and the same healthcare institution) or
- the medical devices remain in, and become the property of, the patient in connection with a treatment (e.g. an implant).

**Responsibilities**

The professional who imports and directly uses a medical device from another country is responsible for its **conformity**[27]. A procuring professional, or the procuring healthcare institution where the professional works, must therefore check and ensure that such a medical device carries a conformity marking recognised by the MedDO and/or the IvDO, and that a conformity assessment procedure has been carried out, if applicable with the involvement of a designated body (for documentation, see Annexes 1 and 2 of this information sheet). However, as mentioned above, if such medical devices are not placed on the market in Switzerland, from the standpoint of therapeutic products legislation, the naming of a Swiss authorised representative (CH-REP) on the medical device is not compulsory.

The Swiss authorised representative is jointly and severally liable with the manufacturer vis-à-vis any party injured by a defective medical device[28]. The representative is also responsible for the formal and safety-related aspects of placing the device on the market[29]. Swissmedic explicitly points out to professionals and their healthcare institutions importing medical devices **without** Swiss authorised representatives and using them directly that these medical devices are not covered by the legal liability statement in Art. 47d TPA, and that no Swiss economic operator is responsible for formal and safety-related aspects. One consequence of this is that Swissmedic is not necessarily informed of any field safety corrective actions for such medical devices and cannot necessarily either publish them or answer any related questions. **In this situation, the professionals and the healthcare institutions take full responsibility for ensuring the information flow, obtaining any required information, implementing corrective actions and clarifying questions of legal liability.**

[25] Art. 4 para. 1 let. b MedDO, Art. 4 para. 1 let. b IvDO.
[26] Art. 53 and 55 MedDO, Art. 46 and 48 IvDO.
[27] See definitions according to Art. 4 para. 1 let. a, b and h and Art. 70 para. 1 MedDO, Art. 4 para. 1 let. a, b and g and Art. 63 IvDO.
[28] Art.47d para. 2 TPA.
[29] Art. 51 para. 2 MedDO, Art. 44 para. 2 IvDO.

For the reasons already stated, healthcare professionals and institutions should usually procure medical devices from a Swiss manufacturer or one with a Swiss authorised representative and directly use medical devices from abroad **without a Swiss authorised representative only in justified exceptional cases**.

If the professionals or healthcare institutions in Switzerland (e.g. in the role of a purchasing organisation) supply or transfer medical devices from another country to another Swiss legal entity (e.g. another healthcare institution) in return for payment or free of charge, they are placing these devices on the market. As a result, they satisfy the definition of importer[30] in the therapeutic products legislation and must comply with the corresponding obligations. Since the medical devices are placed on the market, a Swiss authorised representative must also be mandated[31].

# 8 New requirement with implications for procurement in healthcare institutions

The new regulation will introduce additional requirements for healthcare institutions, which may need to be taken into account as early as the procurement stage. The list below (Table 3) does not claim to be complete.

**Table 3: New requirements for healthcare institutions with implications for procurement**

| | | |
|---|---|---|
| 1 | **Traceability** for medical devices according to the new regulation[32] | At least for implantable class III medical devices, the healthcare institution must record the UDI for the medical devices with which it has been supplied or which it has supplied (preferably electronically).<br>The list of in vitro diagnostic medical devices that must be stored and kept by healthcare facilities is specified in implementing acts of the EU Commission (Art. 58 IvDO). No implementing act of this type had yet been issued at the time this information sheet was prepared. |
| 2 | **Implant card**[33] for implants according to the new regulation | Manufacturers of implantable medical devices covered by the new legislation (implantable EU MDR devices) must provide an implant card in the three national languages[34].<br>The healthcare institutions must enter patient identification details on the implant cards and give the cards to the patients.<br>This additional requirement has an impact on the internal logistics of the devices and the enclosed implant cards. |
| 3 | **Reprocessed single-use devices** | EU Member States can permit the reprocessing of single-use devices[35].<br>In Switzerland the use of reprocessed single-use devices is **prohibited**[36]. |

[30] Art. 4 para. 1 let. h MedDO; Art. 4 para. 1 let. g IvDO *Importer:* any natural or legal person established within Switzerland that places a device from a foreign country on the Swiss market.

[31] For more information see www.swissmedic.ch > Medical devices > Market access

[32] Art. 65 para. 1 MedDO, Art. 58 IvDO

[33] Art. 20 MedDO and Art. 18 EU MDR

[34] According to Art. 18 para. 3 EU MDR, the following medical devices are exempt from the obligation to provide an implant card: sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors. According to MDCG 2021-25 - Regulation (EU) 2017/745 - application of MDR requirements to 'legacy devices' and to devices placed on the market prior to 26 May 2021 in accordance with Directives 90/385/EEC or 93/42/EEC, the obligation to provide an implant card applies only to devices covered by the new legislation (EU MDR devices).

[35] Art. 17 EU MDR

[36] Art. 73 MedDO

# 9 Quality deficiencies and non-conforming medical devices

Healthcare institutions are required in any case to report serious incidents to the supplier **and** to Swissmedic ("materiovigilance").[37] Information can be found on our website (http://www.swissmedic.ch\md_materiovigilance_user).

If you discover an irregularity during the procurement of a medical device (e.g. if you suspect that the EU certificates are counterfeit) please notify Swissmedic (medical.devices@swissmedic.ch). Swissmedic will review your notification and implement the necessary corrective actions in line with the associated risks.

# 10 Contact

Swissmedic, Swiss Agency for Therapeutic Products
Medical Devices Surveillance Division
Hallerstrasse 7
3012 Bern, Switzerland

| | |
|---|---|
| Tel. general information | +41 58 462 02 23 |
| Internet | www.swissmedic.ch/md |
| E-mail | questions.devices@swissmedic.ch |

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

[37] Art. 66 para. 4 and 5 MedDO, Art. 15 para. 2 oMedDO, Art. 59 para. 4 and 5 IvDO.

# Annex 1: Formal requirements for conforming medical devices

| | |
|---|---|
| CE<br>MD | **Every medical device** that is placed on the market in Switzerland must bear a conformity marking (CE mark or MD mark)[38]. |
| **Four-digit identification number**<br>CE nnnn<br>MD nnnnn | **Most medical devices** bear, after the CE or MD mark, a four-digit number identifying the designated body that was involved in the assessment of the medical device.<br>**Note**: The EU's publicly accessible NANDO information system lists the European designated bodies and the corresponding identification numbers[39]. Designated body for Switzerland: SQS, identification number 1250. |
| **Manufacturer information**<br>  | **Every medical device** must be identified with unique manufacturer information, including the address of the manufacturer. |
| **Swiss authorised representative**<br>CH REP | Products of manufacturers domiciled **outside** Switzerland: Details of the Swiss authorised representative "CH-REP" (name and address).<br>The required information about the CH-REP (name and address) is different for medical devices and IVDs covered by the old legislation and those covered by the new legislation. More details can be found in the information sheet "Obligations Economic Operators CH" on our website: Obligations for authorised representatives, importers and distributors (swissmedic.ch)[40]. |
| **Importer (CH)** | Products of manufacturers domiciled **outside** Switzerland: Details of the importer domiciled in Switzerland (name and address).<br>Not to be confused with the EU importer (importer domiciled within the EU)<br>May be shown on the device, the packaging or in an accompanying document[41]. |
| **Declaration of conformity**<br>Declaration of Conformity (DoC) | The declaration of conformity is an accompanying document and can be requested from the supplier.<br>A declaration of conformity must exist for **every medical device** marketed in Switzerland.<br>The declaration of conformity<br>▪ is issued by the **manufacturer**<br>▪ certifies that the medical device complies with the medical device provisions.<br>Medical devices, excluding IVDs: Directive 93/42/EEC (MDD), 90/385/EEC (AIMDD) or Regulation (EU) 2017/745 (EU MDR)<br>IVDs: Directive 98/79/EC (IVDD) or Regulation (EU) 2017/746 (EU IVDR) |

[38] Art. 13 para. 1 MedDO, Art. 12 para. 1 IvDO No conformity marking is required for medical devices, excluding IVDs, specified in Art. 13 para. 2 MedDO and IVDs specified in Art. 12 para. 2 IvDO.

[39] https://ec.europa.eu/growth/tools-databases/nando/ > Notified bodies.

[40] www.swissmedic.ch > Medical devices > Market access > Obligations for authorised representatives, importers and distributors; https://www.swissmedic.ch/swissmedic/en/home/medical-devices/market-access/pflichten-bevollmaechtigte.html.

[41] More information on stating the CH importer can be found in the information sheet "Obligations Economic Operators CH" on our website: www.swissmedic.ch > Medical devices > Market access > Obligations for authorised representatives, importers and distributors; https://www.swissmedic.ch/swissmedic/en/home/medical-devices/market-access/pflichten-bevollmaechtigte.html.

| | |
|---|---|
| **Certificate of conformity**<br>EU certificate | The certificate of conformity (also known as the EU certificate or EC certificate) is an accompanying document and can be requested from the supplier.<br>For **most medical devices** the manufacturer must be able to present one (or more) valid EU certificate(s). Whether or not a certificate of conformity from a designated (notified) body must be available can be determined from the 4-digit identification number next to the CE mark.<br>The certificate of conformity is issued by an independent Swiss or European **designated body**. It shows:<br>▪ the address of the **manufacturer** (identical to the manufacturer stated on the device)<br>▪ the **medical devices** subject to certification<br>▪ **the selected conformity assessment procedure annex** (e.g. Annex II excluding section 4 of Directive 93/42/EEC (MDD), Annex IX excluding Chapter 2 of Regulation (EU) 2017/745 (EU MDR) or similar).<br>See Annex 2 for more information about certificates of conformity. |

## Annex 2: Certificates of conformity for medical devices[42]

The required certificates of conformity (EC certificates, EU certificates) are based on the risk class of the medical device (see Tables 1 and 2 for information on risk classes). The manufacturer can choose from the various conformity assessment procedures depending on the risk class. The information presented here is highly generalised. The examples cover common conformity assessment procedures. A complete overview can be obtained from the legal references stated in the footnotes.

In simplified terms, the following certificates of conformity can be issued for medical devices:

1. **Certificate concerning QA**: Relates to the manufacturer's **q**uality **m**anagement or **q**uality **a**ssurance system. The designated body controls and monitors the quality assurance or quality management system by means of **audits**. In many cases, a single QA certificate covering its devices is issued to each manufacturer.

2. **Certificate concerning design**: Relates to an approved design of a device. The designated body **controls the technical documentation** and, if necessary, the device itself (type examination). Changes to the approved device are checked and approved by the designated body.

3. **Certificate concerning product verification:** Relates to individual devices examined by the designated body and for which the body confirms that these conform to the approved type. The examination of individual devices for conformity assessment is only rarely arranged by manufacturers.

[42] Art. 10 para. 1 and Annex 3 point 2 let. a, b, and d and point 3 let. a oMedDO, Art. 23 MedDO and Art. 52 EU MDR, Art. 19 IvDO in conjunction with Art. 48 EU IVDR .

## Certificates of conformity (EC certificates, EU certificates) for medical devices, excluding IVDs

| | |
|---|---|
| MD **without** EU certificate(s) | I (non-sterile, without measuring function) |
| MD **with** EU certificate(s) | I sterile, I with measuring function, I reusable surgical instruments[43], IIa, IIb, III, AIMD |
| Rules of thumb: MD **with** EU certificate(s) | 4-digit number after CE mark<br>Sterile devices<br>Surgically invasive and for single use<br>Surgically invasive and connected to a device (e.g. drill, suction apparatus)<br>Implantable devices<br>Devices that administer energy to the body (e.g. laser) |
| Risk class | Certificates / commonly used conformity assessment procedures |
| **AIMD**<br>Only previous regulation | 2 associated EC certificates / EU certificates, e.g.<br>• 1 relating to design (e.g. Annex 2 (4) 90/385/EEC).<br>• 1 relating to QA (e.g. Annex 2 excluding (4) 90/385/EEC). |
| **III**<br>Previous and new regulation<br><br>**IIb** implantable*[44]<br>Only new regulation | 2 associated EC certificates / EU certificates, e.g.<br>• 1 relating to design (e.g. Annex II (4) 93/42/EEC or EU technical documentation assessment certificate according to Annex IX Chapter II EU MDR)<br>• 1 relating to QA (e.g. Annex II excluding (4) 93/42/EEC or EU quality management certificates according to Annex IX excluding Chapter II EU MDR) |
| **IIb**<br>Previous and new regulation | 1 EC certificate / EU certificate relating to QA (e.g. Annex II excluding (4) 93/42/EEC or EU quality management certificates according to Annex IX excluding Chapter II EU MDR)<br>OR<br>2 associated EC certificates / EU certificates, e.g.<br>• 1 relating to design (e.g. Annex III 93/42/EEC or EU type-examination certificate according to Annex X EU MDR)<br>• 1 relating to QA (e.g. Annex V 93/42/EEC or EU quality assurance certificate according to Annex XI Part A EU MDR) |
| **IIa**<br>Previous and new regulation | 1 EC certificate / EU certificate relating to QA (e.g. Annex II excluding (4) 93/42/EEC or EU quality management certificate according to Annex IX excluding Chapter II EU MDR) |
| **I** sterile,<br>**I** with measuring function<br>Previous and new regulation<br>**I** reusable surgical instruments<br>Only new regulation and classification | 1 EC certificate / EU certificate relating to QA (e.g. Annex II excluding (4) 93/42/EEC or EU quality management certificate according to Annex IX excluding Chapter II EU MDR) |

[43] Only according to the new regulation, see Art. 52 para. 7 let. c EU MDR.

[44] Exceptions according to Art. 52 para. 4 subpara. 2 MDR: sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors.

As stated in section 3, Switzerland has implemented transitional periods for the placing on the market of medical devices with certificates issued under the old regulation (MDD) in line with the EU.

With respect to certificates of conformity issued under the old legislation, this means that they may retain their validity in Switzerland under certain conditions (even if the date of validity on the certificate has been exceeded). An overview of these periods and the conditions for validity can be found in the information sheet “Obligations Economic Operators CH” on our website (www.swissmedic.ch -> Medical devices > Market access > Obligations for authorised representatives, importers and distributors[45])

**Certificates of conformity (EC certificates, EU certificates) for in vitro diagnostic medical devices**

| | |
|---|---|
| IVD **without** EU certificate(s) | "IVDs others"[46] Class A (not sterile) |
| IVDs **with** EU certificate(s) | IVDs for self-testing, List B, List A<br>Classes A (sterile), B, C and D |
| Rules of thumb: IVDs **with** EU certificate(s) | 4-digit number after CE mark<br>IVDs for self-testing by patients<br>List in Annex II 98/79/EC, e.g. devices for determining blood groups, HIV, hepatitis B, C and D, Creutzfeldt-Jakob disease, rubella, toxoplasmosis, phenylketonuria, cytomegalovirus, chlamydia, HLA tissue types, tumour marker PSA, and trisomy 21. |
| **Risk class** | **Certificates / commonly used conformity assessment procedures** |
| **List A**<br>Previous regulation and classification | 2 associated EC certificates, e.g.<br>• 1 relating to design (e.g. Annex IV (4) 98/79/EC).<br>• 1 relating to QA (e.g. Annex IV excluding (4) 98/79/EC). |
| **List B**<br>Previous regulation and classification | 1 EC certificate relating to QA (Annex IV excluding (4) 98/79/EC)<br>OR<br>2 associated EU certificates, e.g.<br>• 1 relating to design (e.g. Annex V 98/79/EC).<br>• 1 relating to QA (e.g. Annex VII 98/79/EC). |
| **IVDs for self-testing**<br>Previous regulation and classification | 1 EC certificate relating to QA (Annex IV excluding (4) 98/79/EC)<br>OR<br>1 EU certificate relating to design (e.g. Annex III (6) 98/79/EEC) |
| **D**[47]<br>**C** for self-testing / near-patient testing and/or companion diagnostic<br>New regulation and classification | 2 associated EU certificates, e.g.<br>• 1 relating to design (e.g. EU technical documentation assessment certificate according to Annex IX Chapter II EU IVDR).<br>• 1 relating to QA (e.g. EU quality management certificate according to Annex IX excluding Chapter II EU IVDR). |

[45] More information on the transitional periods for the validity of certificates issued under the old regulation (MDD) can be found in the information sheet “Obligations Economic Operators CH” on our website: www.swissmedic.ch > Medical devices > Market access > Obligations for authorised representatives, importers and distributors; https://www.swissmedic.ch/swissmedic/en/home/medical-devices/market-access/pflichten-bevollmaechtigte.html.

[46] Classification under the previous regulation, see Table 2 for the validity of certificates issued under the old legislation.

[47] Classification according to regulation under the new legislation.

| | |
|---|---|
| **C**<br>New regulation and classification | 1 EU certificate relating to QA (EU quality management certificate according to Annex IX excluding Chapter II EU IVDR)<br>OR<br>2 associated EU certificates,<br>• 1 relating to design (EU type-examination certificate according to Annex X EU IVDR)<br>• 1 relating to QA (EU production quality assurance certificate according to Annex XI EU IVDR) |
| **B** for self-testing / near-patient testing<br>New regulation and classification | 2 associated EU certificates, e.g.<br>• 1 relating to design (e.g. EU technical documentation assessment certificate according to Annex IX Chapter II EU IVDR).<br>• 1 relating to QA (e.g. EU quality management certificate according to Annex IX excluding Chapter II EU IVDR). |
| **B**<br>New regulation and classification | 1 EU certificate relating to QA (EU quality management certificate according to Annex IX excluding Chapter II EU IVDR) |
| **A (sterile)**<br>New regulation and classification | 1 EU certificate relating to QA (e.g. EU quality management certificate according to Annex IX excluding Chapter II EU IVDR) |

The transitional periods for the validity of certificates of conformity covered by the old regulation (IVDD) and the placing on the market of IVDD devices covered by the old regulation, and the conditions and deadlines for validity associated with each risk class can be found in the information sheet “Obligations Economic Operators CH” on our website (www.swissmedic.ch -> Medical devices > Market access > Obligations for authorised representatives, importers and distributors[48]).

## Annex 3: Frequently asked questions on certificates of conformity (EU certificates) for medical devices

***For what devices is an EU certificate required?***

An EU certificate is required for most, but not all, medical devices. Whether an EU certificate is required depends on the risk class of the device. See also Annex 2.

***The supplier has submitted a document. How can I check whether this is an EU certificate for the device to be procured?***

*Previous regulation*: Although the devices are often listed on the EU certificates, there is no legally binding obligation to do so.

*New regulation*: The devices / device groups must be stated on the EU certificates.[49]

[48] More information on the transitional periods for the validity of certificates issued under the old regulation (IVDD) can be found in the information sheet “Obligations Economic Operators CH” on our website: www.swissmedic.ch > Medical devices > Market access > Obligations for authorised representatives, importers and distributors; https://www.swissmedic.ch/swissmedic/en/home/medical-devices/market-access/pflichten-bevollmaechtigte.html.

[49] For the content of the EU certificates see Annex XII EU MDR and EU IVDR.

**Although the submitted certificates relate to 93/42/, 90/385/ and 98/79/, the "letters after the numbers" do not match those on the information sheet. Why not?**
The directives are named according to the language version.
EN: 93/42/ and 90/385/EEC, 98/79/EC
IT: 93/42/ and 90/385/CEE, 98/79/CE
FR: 93/42/ and 90/385/CEE, 98/79/CE
DE: 93/42/ and 90/385/EWG, 98/79/EG

***The supplier has sent me certificates that relate to standards (e.g. ISO 13485, ISO 9001, IEC 60601-1). Are these sufficient?***
No. Standards certificates are not EU certificates and do not prove that a medical device is compliant.

***How can I check whether the existing EU certificate has been issued by an appropriately authorised designated body?***
The Swiss Association for Quality and Management Systems (SQS, identification number 1250) is the only designated body in Switzerland.
The NANDO information system[50] lists all European bodies that are currently authorised to issue EU certificates for medical devices.

Procedure for checking:
1. Go to “Free search” on the NANDO website: EUROPA – European Commission – Growth – Regulatory policy - SMCS
2. Search for the body using the 4-digit identification number after the CE mark or name of the body and click it.
3. NANDO now shows the *Notification* of the body (e.g. address, contact details, Notified Body number). Click the *Legislation* tab on this site to check whether the Directive or the Regulation mentioned on the EU certificate is listed (90/385/EEC (AIMDD), 93/42/EEC (MDD), 98/79/EC (IVDD), Regulation (EU) 2017/745 (EU MDR) or Regulation (EU) 2017/746 (EU IVDR)).

***The EU certificate for a device installed in our institution (e.g. an x-ray machine) has expired and will not be renewed by the manufacturer. Do we now have to take the device out of service?***
No, there is no legal obligation to do this. Valid EU certificates must exist for devices **when they are placed on the market**. If these subsequently expire, this does **not** mean that the device is “non-compliant” and must be taken out of commission.

***I doubt the authenticity of an EU certificate and would like to check this. What can I do?***
Determine the relevant designated body in the NANDO information system and its contact details (see first question in this section). Many designated bodies provide an authenticity check on their websites. Alternatively, you can send a written request to the designated body. When the registration of the certificate in EUDAMED becomes mandatory, it should be possible to verify the authenticity of the certificate.

[50] http://ec.europa.eu/growth/tools-databases/nando/.

***Where can I find EUDAMED and how do I access it?***
EUDAMED is a European database with information on devices, manufacturers and EU certificates. The implementation of EUDAMED has been delayed. Currently (as at 1 November 2023) not all modules are available. Up-to-date information can be found at: https://ec.europa.eu/growth/sectors/medical-devices/new-regulations/eudamed_en.

***For how long will the "old" EC certificates for medical devices remain valid?***
The designated bodies may not issue any more EC certificates for medical devices, excluding IVDs, according to the "previous" Directives 93/42/EEC (MDD) and 90/385/EEC (AIMDD) after 25 May 2021. For in vitro diagnostic medical devices, from 26 May 2022 EC certificates may no longer be issued according to the "previous" Directive 98/79/EC (IVDD)on in vitro diagnostic medical devices.

Transitional provisions have been adopted for “old” EC certificates / EC certificates “issued under the previous regulation”, enabling them to retain their validity in Switzerland too under certain conditions and with prescribed deadlines in line with the approach in the EU (even if the validity date on the certificates has expired). The details of the conditions and the deadlines for each risk class are summarised in the information sheet “Obligations Economic Actors CH” on our website: Obligations for authorised representatives, importers and distributors (swissmedic.ch). Confirmations that the transitional provisions and the conditions for the continuing validity of the certificates have been fulfilled must be issued by the manufacturer and/or the designated bodies and can be requested from the supplier.

***Are EU certificates needed for custom-made devices?***
All custom-made devices must have a declaration issued by their manufacturer in accordance with Annex XIII EU MDR.
An EU certificate is not needed for most custom-made devices. Exception: Class III custom-made devices may still be placed on the market without an EU certificate under certain conditions until 26 May 2026.[51] The manufacturer must be asked to confirm whether the conditions are fulfilled. After 26 May 2026 an EU certificate in accordance with EU MDR must also be provided for class III implantable custom-made devices[52].

**How are transitional periods applicable to class I medical devices and IVD devices classified as "Other IVDs"?**
To determine whether the periods are applicable, the devices must be classified based on the provisions in the new regulations (EU MDR, EU IVDR). The classification can then be used to determine whether a deadline applies. The details of the deadlines for each risk class are summarised in the information sheet “Obligations Economic Actors CH” on our website: Obligations for authorised representatives, importers and distributors (swissmedic.ch).

[51] Art. 101 para. 1ter MedDO.
[52] Art. 10 para. 1 and 2 MedDO.

# Annex 4: Definitions and abbreviations

## Definitions

| | |
|---|---|
| **Authorised representative** | If the manufacturer of a device is not domiciled in Switzerland, its devices may only be placed on the market once an **authorised representative** domiciled in Switzerland has been designated.<br>The manufacturer has mandated (in writing) an authorised representative to act on the manufacturer's behalf in relation to specified tasks. |
| **Certificate of conformity** | Also known as an “EU certificate” or “EC certificate”. The certificate of conformity is issued by the designated / notified body which controls the manufacturer’s conformity assessment and confirms its compliance with the legal requirements in this certificate. Whether or not a designated body is involved in the conformity assessment procedure depends on the classification of the device; it is a requirement for medical devices associated with moderate and high risks. If a control by a designated body is required, the CE mark may only be affixed to a device if a corresponding certificate has been issued by the designated body. This CE mark (or also the MD mark in Switzerland) must then accompanied by the 4-digit identification number of the designated body (CE nnnn).<br>In this information sheet the term EU certificate is used analogously with the certificate of conformity specified in the new legislation (EU MDR, EU IVDR); the term EC certificate is used to refer to a certificate of conformity issued under the old legislation (MDD, AIMDD, IVDD). |
| **Conformity assessment** | **Conformity assessment** refers to the procedure used to determine whether the legal requirements of the MedDO / the IvDO (analogous to the EU MDR / EU IVDR) are fulfilled by a device. Depending on the risk class of the medical device, a designated / notified body must be involved in the conformity assessment procedure to control whether the legal requirements are being fulfilled. Once this procedure has been successfully concluded, the CE mark (or an MD mark for the Swiss market only) may be affixed to the device. |
| **Declaration of conformity** | Also referred to by the abbreviation DoC. This declaration is issued by the manufacturer in which they confirm that the device complies with the legal requirements. An EU declaration of conformity (which confirms the conformity of the device with EU MDR / EU IVDR or the regulations under the old legislation) is recognised in Switzerland. A declaration of conformity is a legally required evidence of conformity for all medical devices, irrespective of whether or not a designated / notified body was involved in the procedure. |
| **Designated bodies** | Designated bodies are organisations designated and monitored by the government. They act on behalf of the manufacturers, supporting and checking their conformity assessments of, for example, various types of medical devices (conformity assessment bodies). They are referred to in the EU MDR / EU IVDR as **notified bodies**. |
| **Distributor** | Any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a device available on the Swiss market, up until the point it is put into service. |
| **Economic operator** | Any manufacturer, authorised representative, importer, distributor or the person referred to in Article 22 para. 1 and 3 EU MDR. |
| **Importer** | Any natural or legal person established in Switzerland who places a device from a foreign country on the Swiss market. |

| | |
|---|---|
| **Incident** | Any malfunction or deterioration in the characteristics or performance of a device that has already been made available on the market, including use errors due to ergonomic features, as well as any inadequacy in the information supplied by the manufacturer and any undesirable side effect. |
| **Instructions for use** | Information provided by the manufacturer to inform the user of a device's intended purpose and proper use and of any precautions to be taken. |
| **Intended purpose** | The use for which a device is intended in accordance with the details provided by the manufacturer on the label, in the instructions for use or in promotional or sales material or information and the information stated in their clinical evaluation. |
| **Labelling** | Written, printed or graphic information appearing either on the device itself, or on the packaging of each unit or on the packaging of multiple devices. |
| **Making available** | The supply or transfer of a device in return for payment or free of charge.<br>The use of a device by a professional user does not constitute making available on the market. |
| **Manufacturer** | Any natural or legal person who manufactures or fully refurbishes a device or has a device designed, manufactured or fully refurbished, and markets that device under its own name or trademark. |
| **Placing on the market** | First time a device is made available on the Swiss market. |
| **Product information** | Product information comprises the labelling and instructions for use. |
| **Professional** | A person with formal training in the relevant field. |
| **Putting into service** | The stage at which the device is made available to the end user for the first time |
| **User** | Any healthcare professional, professional or layperson who uses a device. |

## Abbreviations

| | |
|---|---|
| AIMD | Active implantable medical device |
| AIMDD | Directive 90/385/EEC on active implantable medical devices |
| CH | Switzerland |
| CH-REP | Swiss authorised representative |
| DoC | Declaration of Conformity |
| EU | European Union |
| EU IVDR | Regulation (EU) 2017/746 on in vitro diagnostic medical devices |
| EU IVDR device | Device that has been CE-marked in accordance with the EU IVDR. |
| EU MDR | Regulation (EU) 2017/745 on medical devices |
| EU MDR device | Device that has been CE-marked in accordance with the EU MDR. |
| IVD | In vitro diagnostic medical device |
| IVDD | Directive 98/79/EC on in vitro diagnostic medical devices |
| IVDD device | Device that has been CE-marked in accordance with the previous Directive 98/79/EC on in vitro diagnostic medical devices. |
| IvDO | Ordinance on In Vitro Diagnostic Medical Devices of 4 May 2022 (SR 812.219)[53] |
| MD | Medical device |
| MDD | Directive 93/42/EEC concerning medical devices |

[53] SR 812.219 - Ordinance of 4 May 2022 on In Vitro Diagnostic Medical Devices (IvDO) (admin.ch); https://www.fedlex.admin.ch/eli/cc/2022/291/en.

| | |
|---|---|
| MDD/AIMDD device | Device that has been CE-marked under the previous Directive 93/42/EEC concerning medical devices (MDD) or Directive 90/385/EEC on active implantable medical devices (AIMDD). Often also referred to as a "legacy device". |
| MedDO | Medical Devices Ordinance of 1 July 2020 (SR 812.213)[54] |
| MRA | Mutual Recognition Agreement, agreement on the mutual recognition of conformity assessments[55]. |
| NB | Notified Body (notified / designated body) |
| TPA | Therapeutic Products Act (SR 812.21) |
| UDI | Unique Device Identifier |

[54] SR 812.213 - Medical Devices Ordinance of 1 July 2020 (MedDO) (admin.ch); https://www.fedlex.admin.ch/eli/cc/2020/552/en.

[55] SR 0.946.526.81 - Agreement of 21 June 1999 between the Swiss Confederation and the European Community on the mutual recognition of conformity assessments; https://www.fedlex.admin.ch/eli/cc/2002/276/de.

# Annex 5: Information issued by the EU Commission on the revision of the regulations

Note: Switzerland's medical devices regulation is fundamentally equivalent to its European counterpart. For this reason, Swissmedic bases its interpretation of the applicable provisions on European practice. Furthermore, some of the EU documents provide a good introduction to the Swiss and European regulatory systems for medical devices.

| | |
|---|---|
| 1 | **Factsheet for healthcare professionals and health institutions**<br>Published by the EU Commission<br>The factsheet contains detailed information on the revision of the regulations in Europe, focusing on health institutions.<br>https://ec.europa.eu/docsroom/documents/35963 or<br>https://ec.europa.eu/growth/sectors/medical-devices/new-regulations/spread-word_en |
| 2 | **Factsheet for the Procurement Ecosystem of Medical Devices and in vitro Diagnostic Medical Devices**<br>Published by the EU Commission<br>https://ec.europa.eu/docsroom/documents/33861 or<br>https://ec.europa.eu/growth/sectors/medical-devices/new-regulations/spread-word_en |
| 3 | **MDCG 2019-8 Guidance document - Implant Card on the application of Article 18 Regulation (EU) 2017/745 on medical devices**<br>Published by the EU Commission<br>Guidance document on the implant card. This document is aimed primarily at manufacturers, but can also be helpful for health institutions in defining the processes for ensuring that patients receive the implant card.<br>https://ec.europa.eu/health/md_sector/new_regulations/guidance_en |
| 4 | **Transition Timelines from the Directives to the Regulations**<br>Published by the EU Commission<br>https://health.ec.europa.eu/system/files/2023-07/mdr_proposal_extension-q-n-a.pdf |

## Change history

| Version | Description | sig |
|---|---|---|
| 5.1 | Format adaptations | nem |
| 5.0 | Amendment due to revision of MedDO / IvDO | nem |
| 4.1 | New layout, no content adjustments to the previous version | hem |
| 4.0 | Amendments due to entry into force of IvDO. | nem |
| 3.0 | Clarification in section 7 | kom |
| 2.1 | Correction of typos and terminology, no changes in content | kom |
| 2.0 | Section 7 (Information on Art. 70 para. 1 MedDO) inserted | kom |
| 1.0 | Doc newly created owing to revision of MD regulatory provisions; old doc ID: MU500_00_012d_MB | kom |