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

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

The applicable medical device provisions of the Therapeutic Products Act (TPA, SR 812.21) and the Medical Devices Ordinance (MedDO; SR 812.213) 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 investigations and performance evaluation) are not covered by this information sheet.

2 New medical devices regulation in Switzerland and Europe

2.1 Revision of medical devices law

The Federal Council enacted Switzerland's revised medical devices legislation on **26 May 2021**. To ensure that quality, safety and efficacy standards match those in EU member states, this legislation is based on the new EU Regulation on medical devices (**MDR**¹). The European Regulation on in vitro diagnostics (**IVDR**²) is due to be implemented in Switzerland on 26 May 2022. The MDR and IVDR are referred to hereafter as **the new regulation**.

Under the **previous regulation (Directives 90/385/EEC, 93/42/EEC/ and 98/79/EC)**, the Swiss-EU Mutual Recognition Agreement (MRA) gave Switzerland access to the European single market for medical devices on an equal partnership basis. As a result, it was possible to monitor the medical devices market efficiently and effectively by working in cooperation with the relevant authorities in the EU member states and thus to avoid technical barriers to trade. Moreover, Swiss patients benefited from access to the full range of medical devices available in Europe.

The Swiss-EU agreement on mutual recognition should have been updated concurrently with the entry into force of Switzerland's new medical devices regulation. However, the EU Commission decided not to proceed any further with updating the agreement 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 Swiss-EU agreement on mutual recognition not being updated, Switzerland made it mandatory – subject to transitional periods – for foreign manufacturers to appoint an authorised representative in Switzerland (often called the CH-REP) and for economic operators to register with Swissmedic.

2.2 UDI and EUDAMED

Manufacturers are required to mark their medical devices with a harmonised, pan-European unique device identifier (UDI)³. The obligation to label devices and their packaging with a UDI will be phased in gradually, but all medical devices will need to show a UDI from 2027.

To increase transparency, the EU is planning a public database (EUDAMED⁴), the contents of which will include data on EU certificates and products. The Commission has repeatedly delayed full implementation. As far as we are aware at present, EUDAMED will be available at the end of 2022.

¹ **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, OJ L 117, p. 1 (Medical Device Regulation, MDR)

² **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 and Commission Decision 2010/227/EU, OJ L 117, p. 176 (In Vitro Diagnostic Medical Devices Regulation, IVDR)

³ Art. 17 MedDO

⁴ <https://ec.europa.eu/tools/eudamed/#/screen/home>

3 What are 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**⁵

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. Medical devices can be subdivided into two groups: in vitro diagnostic medical devices (IVDs) and all other medical devices (MDs), see Tables 1 and 2. The term "medical devices" (MDs) is used in this information sheet to refer to these devices. In vitro diagnostic medical devices (IVDs) are referred to explicitly as such in this information sheet.

As a new feature, devices without a medical purpose⁶ 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. Swissmedic will provide information on this new requirement separately.

⁵ Art. 3 MedDO

⁶ Art. 1 para. 1 letter b MedDO, list in Annex I MedDO

Table 1: In vitro diagnostic medical devices and accessories

Common abbreviation	IVDs
Description⁷	In vitro diagnostic medical devices are medical devices which are used as a reagent, reagent device, calibrator, control material, kit, instrument, apparatus, equipment or system for the in vitro examination of specimens obtained from the human body.
Swiss regulation	Art. 105 MedDO > oMedDO
Regulatory framework (EU)⁸	Previous regulation: Directive 98/79/EC on in vitro diagnostic medical devices New regulation from 26 May 2022: Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR)
Subdivision into risk classes (ascending order)⁹	Previous regulation: "IVD others", IVD for self-testing, List B and List A New regulation: Classes A, B, C and D
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
Transition¹⁰	The new regulation enters into force in the EU on 26 May 2022 and basically applies to all in vitro diagnostic medical devices. Exception: IVDs with a valid EU certificate under the previous regulation. Manufacturers may place IVDs covered by this exception on the market until 26 May 2024. They may make them available in the distribution chain until 27 May 2025. After 27 May 2025 no in vitro diagnostic medical devices covered by the previous regulation may be made available on the market!

⁷ Art. 1 para. 3 oMedDO (Medical Devices Ordinance of 17 October 2001, version of 1 August 2020); Art. 2 nos 2-4 IVDR

⁸ Available at <http://eur-lex.europa.eu/homepage.html>

⁹ Nos 11-14 Annex 3 oMedDO and Annex II 98/79/EC and Art. 47 and Annex VIII IVDR

¹⁰ Art. 110 IVDR, not yet implemented in Swiss law

Table 2: Medical devices

Common abbreviations	MD (for “medical device”) AIMD (for “active implantable medical device”)
Description¹¹	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.
Swiss regulation	MedDO
Regulatory framework (EU)	Previous regulation: Directive 93/42/EEC concerning medical devices Directive 90/385/EEC on active implantable medical devices New regulation: Regulation (EU) 2017/745 on medical devices (MDR)
Subdivision into risk classes (ascending order)¹²	Previous regulation: Classes I, IIa, IIb, III and AIMD New regulation: 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, "cosmetic" abdominal muscle implant made of silicone, implantable defibrillator, programming unit for cardiac pacemaker, disinfectant for surgical instruments, apps for promoting conception
Transition¹³	The new Medical Devices Ordinance entered into force on 26 May 2021 and basically applies to all medical devices. Exception 1: Class I devices with a declaration of conformity dated prior to 26 May 2021 and which require an EU certificate according to the new regulation (e.g. reusable surgical instruments ¹⁴ , devices that are attributed to a higher risk class according to the new regulation) Exception 2: medical devices with a valid EU certificate under the previously valid regulation. Medical devices covered by exceptions 1 and 2 may be placed on the market by manufacturers until 26 May 2024. They may make them available in the distribution chain until 26 May 2025. After 26 May 2025 no medical devices covered by the previously valid regulation may be made available on the market!

¹¹ Art. 3 MedDO excluding in vitro diagnostic medical devices according to Art. 1 para. 3 a MedDO; accessories for devices without a medical purpose according to Annex I MedDO are not subject to the regulation.

¹² Art. 5 oMedDO and Annex IX 93/42/EEC and Art. 15 MedDO and Annex VII MDR

¹³ Art. 101 MedDO, Art. 120 MDR

¹⁴ Art. 23 MedDO and Art. 52 para. 7 letter c MDR

4 How are medical devices “authorised”?

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

Every medical device must satisfy the general safety and performance requirements that apply in Switzerland and throughout Europe¹⁵.

The **manufacturer** assesses the conformity with the general requirements for each medical device (“conformity assessment”). If the medical devices satisfy these requirements, the manufacturer can affix a CE mark on devices with low risks (e.g. certain class I devices) on its own initiative and place these products on the market.

For medical devices with moderate or high risks, the manufacturer must consult an officially **designated body (notified body/NB)**. 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 notified body issues one or more certificates for the devices (“EU certificates”). The manufacturer may then affix a CE mark with the four-digit number of the notified body (CE_{xxxx}) to the device and place it on the market.

5 Swiss authorised representatives and importers

With the Swiss-EU agreement on mutual recognition not being updated, foreign manufacturers of medical devices who want to place products on the market in Switzerland are required to appoint a **Swiss authorised representative**¹⁶.

The following deadlines apply to manufacturers domiciled in an EU/EEA state¹⁷ or which have an authorised representative in an EU/EEA state¹⁸.

- High-risk medical devices (Class III, IIb implantable and AIMDs): 31 December 2021
- Moderate-risk medical devices (non-implantable Class IIb, Class IIa): 31 March 2022
- Low-risk medical devices (Class I): 31 July 2022
- Systems and procedure packs: 31 July 2022

All other foreign manufacturers are required to appoint a Swiss authorised representative with effect from 26 May 2021.

In addition, the Swiss **importer** must be named on the product, the packaging or a document accompanying the device¹⁹.

¹⁵ Abbreviated to GSPR, see Art. 45 para. 3 let. a TPA, Art. 6 MedDO, Annexes I MDR and IVDR.

¹⁶ Art. 51 MedDO

¹⁷ EU member states, Iceland, Norway and Liechtenstein. The deadlines do not apply to manufacturers outside the EU/EEA that do not have authorised representatives in Europe.

¹⁸ Art. 104a MedDO

¹⁹ Art. 53 para. 2 MedDO

6 Duty of care of the health institution

The manufacturers are basically responsible for the flawless quality and conformity of their medical devices. Accordingly, the health institutions procuring the devices bear considerable responsibility in their selection of suppliers and devices.

Any person that deals with medical devices or in vitro diagnostic 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.²⁰

Only those medical devices that bear a valid CE mark may be used. Guidance on how to identify a valid CE mark can be found in Annexes 1–4. 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.

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 devices are not considered to be placed on the market²¹ in Switzerland. Accordingly, from the standpoint of medical devices legislation, 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 importers²².

This is also applicable if

- the 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 the healthcare institution) or
- the 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 is responsible for its **conformity**²³. A procuring professional, or the procuring healthcare institution where the professional works, must therefore check and ensure that such a device carries a conformity marking recognised by the MedDO, 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, if such devices are, as mentioned above, 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 devices is **not** compulsory.

The Swiss authorised representative shall be jointly and severally liable with the manufacturer vis-à-vis any party injured by a defective medical device²⁴. The representative is also responsible for the formal and safety-related aspects in the context of placing the device on the market²⁵. Swissmedic explicitly points out to professionals and their healthcare institutions importing devices without Swiss authorised representatives that these devices may not be 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 devices and therefore cannot publish those 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,**

²⁰ Art. 3 TPA

²¹ Art. 4 para. 1 let. b MedDO.

²² Art. 53 and 55 MedDO

²³ See definitions according to Art. 4 para. 1 let. a, b and h and Art. 70 para. 1 MedDO

²⁴ Art. 47d para. 2 TPA

²⁵ Art. 51 para. 2 MedDO

implementing the corrective actions and clarifying questions of legal liability. For those reasons, Swissmedic recommends that professionals and healthcare institutions give preference to devices with a Swiss economic operator (Swiss manufacturers or Swiss authorised representatives).

If the professionals or healthcare institutions in Switzerland (e.g. in the role of a purchasing organisation) supply or transfer 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 in therapeutic products legislation²⁶ and must comply with the corresponding obligations. Since the devices are placed on the market, a Swiss authorised representative must also be mandated²⁷.

8 New requirement with implications for procurement in health institutions

The new regulation will introduce additional requirements for health 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 health institutions with implications for procurement

1	Traceability for devices according to the new regulation ²⁸	At least for implantable class III devices, the health institution must record the UDI for the devices with which it has been supplied or which it has supplied (preferably electronically).
2	Implant card ²⁹ for implants according to the new regulation	Manufacturers must produce an implant card in the three national languages for an implantable device ³⁰ . The health institutions must enter patient identification details on the implant cards and give the cards to the patients. This additional requirement has an impact on the internal logistics of the devices and the enclosed implant cards.
3	Reprocessed single-use devices	EU countries can permit the reprocessing of single-use devices ³¹ . In Switzerland the use of reprocessed single-use devices is prohibited ³² .

²⁶ Art. 4 para. 1 let. h MedDO *Importer*: any natural or legal person established within Switzerland that places a device from a foreign country on the Swiss market

²⁷ For more information see www.swissmedic.ch > Medical devices > Market access

²⁸ Art. 65 para. 1 MedDO

²⁹ Art. 20 MedDO and Art. 18 MDR

³⁰ According to Art. 18 para. 3 MDR, the following devices are exempt from the obligation to produce an implant card: sutures, staples, dental filling, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors.

³¹ Art. 17 MDR

³² Art. 73 MedDO

9 Quality deficiencies and non-conforming medical devices

Health institutions are required in any case to report serious incidents to the supplier **and** to Swissmedic (“materiovigilance”).³³ Information can be found on our website at www.swissmedic.ch/md_materiovigilance_anwender.

If you discover an irregularity during the procurement of a medical device (e.g. if you suspect the 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 Legal framework

The placing on the market, dispensing and handling of medical devices are governed by the following Swiss laws:

- **Therapeutic Products Act (TPA):** Federal Act of 15 December 2000 on Medicinal Products and Medical Devices; SR 812.21.
- **Medical Devices Ordinance (MedDO)** of 1 July 2020; SR 812.213
- **Medical Devices Ordinance under the old law (oMedDO)** of 17 October 2001 (version of 1 August 2020); SR 812.213 (provisions for in vitro diagnostic medical devices)

11 Contact




Swissmedic, Swiss Agency for Therapeutic Products
 Medical Device Surveillance department
 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 on the Internet at www.swissmedic.ch/md

³³ Art. 66 paras. 4 and 5 MedDO, Art. 15 para. 2 a MedDO.

Annex 1: Formal requirements for conforming medical devices

	<p>Every medical device that is placed on the market in Switzerland must bear a conformity marking (CE mark).³⁴</p>
<p>Four-digit identification number</p>	<p>Most medical devices show, after the CE mark, a four-digit number of the notified body that was involved in the assessment of the medical device.</p>
	<p>Note: The EU's publicly accessible NANDO Information System lists all European notified bodies and the corresponding identification numbers³⁵. Notified body for Switzerland: SQS, identification number 1250.</p>
<p>Manufacturer information</p>	<p>Every medical device must be identified with unique manufacturer information, including the address of the manufacturer.</p>
	
<p>Authorised representative</p>	<p>Manufacturer outside Switzerland or the EU/EEA: Indication of an authorised representative in Switzerland or Europe.</p>
<p>EC-REP, CH-REP</p>	<p>Indication of the swiss authorised representative, including transition periods, depends on the product risk class; see section 5.</p>
<p>Declaration of conformity</p>	<p>The declaration of conformity is a document and can be requested from the supplier. A declaration of conformity must exist for every medical device marketed in Switzerland.</p>
<p>Declaration of conformity</p>	<p>The declaration of conformity</p> <ul style="list-style-type: none"> ▪ is issued by the manufacturer ▪ certifies that the medical device complies with the medical device provisions. <ul style="list-style-type: none"> IVD: Directive 98/79/EC or Regulation (EU) 2017/746 MD: Directive 93/42/EEC, 90/385/EEC or Regulation (EU) 2017/745
<p>EU certificate</p>	<p>The EU certificate is a document and can be requested from the supplier.</p>
<p>EU certificate</p>	<p>For most medical devices the manufacturer must be able to present one (or more) valid (i.e. not expired) EU certificate(s). The EU certificate is issued by an independent Swiss or European notified body. This shows:</p> <ul style="list-style-type: none"> ▪ the address of the manufacturer (for the manufacturer stated on the device) ▪ the devices subject to certification ▪ the selected conformity assessment procedure annex (e.g. Annex II excluding section 4 of Directive 93/42/EEC, Annex IX excluding Chapter 2 of MDR or similar).
	<p>See Annex 2 for more information about EU certificates.</p>

³⁴ Art. 8 para. 1 oMedDO and Art. 13 para. 1 MedDO. No CE-mark is required for MDs specified in Art. 13 para. 2 MedDO or IVDs specified in Art. 8 para. 2 oMedDO.

³⁵ <http://ec.europa.eu/growth/tools-databases/nando> > Body

Annex 2: EU certificates for in vitro diagnostic medical devices and medical devices³⁶

The required EU certificates are based on the risk class of the device (see Tables 2 and 3 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 EU certificates can be issued for medical devices:

1. **Certificate concerning QS:** Relates to the manufacturer's **quality management** or **Quality Assurance system**. The notified body checks and monitors the quality assurance or quality management system by means of **audits**. In many cases, a single QS certificate covering its products is issued to each manufacturer.
2. **Certificate concerning design:** Relates to an approved design of a device. The notified body **checks the Technical Documentation** and, if necessary, the device itself (type examination). Changes to the approved device will be checked and need to be approved by the notified body.
3. **Certificate concerning product verification:** Relates to individual devices examined by the notified 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 chosen by manufacturers.

³⁶ Art. 10 para. 1 and Annex 3 point 2 letters a, b, and d and point 3 letter a oMedDO, Art. 23 MedDO and Art. 52 MDR

EU certificates for in vitro diagnostic medical devices

IVD without EU certificate(s)	"IVD others" Class A (non-sterile)
IVD with EU certificate(s)	IVD for self-testing, List B, List A Classes A (sterile), B, C and D
Rules of thumb: IVD with EU certificate(s)	4-digit number after CE mark Device for self-testing by patients 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 groups, tumoral marker PSA, and trisomy 21.
Risk class	Certificates of commonly used conformity assessment procedures
List A Previous regulation	2 associated EU certificates, e.g. <ul style="list-style-type: none"> • 1 x relating to design (e.g. Annex IV (4) 98/79/EC). • 1 x relating to QS (e.g. Annex IV excluding (4) 98/79/EC).
List B Previous regulation	1 EU certificate relating to QS (Annex IV excluding (4) 98/79/EC). OR 2 associated EU certificates, e.g. <ul style="list-style-type: none"> • 1 x relating to design (e.g. Annex V 98/79/EC). • 1 x relating to QS (e.g. Annex VII 98/79/EC).
IVD for self-testing Previous regulation	1 EU certificate relating to QS (Annex IV excluding (4) 98/79/EC) OR 1 EU certificate relating to design (e.g. Annex III (6) 98/79/EC)
D C for self-testing / near-patient testing and/or companion diagnostic New regulation	2 associated EU certificates, e.g. <ul style="list-style-type: none"> • 1 x relating to design (e.g. EU technical documentation assessment certificate according to Annex IX Chapter II IVDR). • 1 x relating to QS (e.g. EU quality management certificate according to Annex IX excluding Chapter II IVDR).
C New regulation	1 EU certificate relating to QS (EU quality management certificate according to Annex IX excluding Chapter II IVDR) OR 2 associated EU certificates, <ul style="list-style-type: none"> • 1 x relating to design (EU type-examination certificate according to Annex X IVDR) • 1 x relating to QS (EU production quality assurance certificate according to Annex IX IVDR)
B for self-testing / near-patient testing New regulation	2 associated EU certificates, e.g. <ul style="list-style-type: none"> • 1 x relating to design (e.g. EU technical documentation assessment certificate according to Annex IX Chapter II IVDR). • 1 x relating to QS (e.g. EU quality management certificate according to Annex IX excluding Chapter II IVDR).
B New regulation	1 EU certificate relating to QS (EU quality management certificate according to Annex IX excluding Chapter II IVDR)
A (sterile) New regulation	1 EU certificate relating to QS (e.g. EU quality management certificate according to Annex IX excluding Chapter II IVDR)

EU certificates for medical devices

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 ³⁷ , IIa, IIb, III, AIMD
Rules of thumb: MD with EU certificate(s)	4-digit number after CE mark Sterile devices Surgically invasive and for single use Surgically invasive and connected to a device (e.g. drill, suction apparatus) Implantable devices Devices that administer energy to the body (e.g. laser)
Risk class	Certificates of commonly used conformity assessment procedures
AIMD Only previous regulation	2 associated EU certificates, e.g. <ul style="list-style-type: none"> • 1 x relating to design (e.g. Annex 2 (4) 90/385/EEC). • 1 x relating to QS (e.g. Annex 2 excluding (4) 90/385/EEC).
III Previous and new regulation IIb implantable* ³⁸ Only new regulation	2 associated EU certificates, e.g. <ul style="list-style-type: none"> • 1 x relating to design (e.g. Annex II (4) 93/42/EEC or EU technical documentation assessment certificate according to Annex IX Chapter II MDR) • 1 relating to QS (e.g. Annex II excluding (4) 93/42/EEC or EU quality management certificates according to Annex IX excluding Chapter II MDR)
IIb Previous and new regulation	1 EU certificate relating to QS (e.g. Annex II excluding (4) 93/42/EEC or EU quality management certificates according to Annex IX excluding Chapter II MDR) OR 2 associated EU certificates, e.g. <ul style="list-style-type: none"> • 1 relating to design (e.g. Annex III 93/42/EEC or EU type-examination certificate according to Annex X MDR) • 1 relating to QS (e.g. Annex V 93/42/EEC or EU quality assurance certificate according to Annex XI Part A MDR)
IIa Previous and new regulation	1 EU certificate relating to QS (e.g. Annex II excluding (4) 93/42/EEC or EU quality management certificate according to Annex IX excluding Chapter II MDR)
I sterile, I with measuring function Previous and new regulation I reusable surgical instruments Only new regulation	1 EU certificate relating to QS (e.g. Annex II excluding (4) 93/42/EEC or EU quality management certificate according to Annex IX excluding Chapter II MDR)

³⁷ Only according to new regulation, see Art. 52 para. 7 letter c MDR

³⁸ 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

Annex 3: Frequently asked questions on 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?

Existing regulation: Although the devices are often listed on the EU certificates, there is no legally binding obligation to state all devices on the certificates.

New regulation: The devices / device groups must be stated on the EU certificates.³⁹

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). 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 notified body?

The Schweizerische Vereinigung für Qualitäts- und Managementsysteme (SQS, identification number 1250) is the only notified body in Switzerland.

The [NANDO Information System](http://ec.europa.eu/growth/tools-databases/nando/)⁴⁰ lists all European bodies that are currently authorised to issue EC certificates for medical devices.

Procedure for checking:

1. On the NANDO website select the "Body" tab
2. Search for the body (4-digit 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, 93/42/EEC, 98/79/EC, 2017/745 or 2017/746).

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**. When these expire, this does **not** mean that the product 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 notified body in the [NANDO Information System](http://ec.europa.eu/growth/tools-databases/nando/) and its contact details (see first question in this section). Many notified bodies provide an authenticity check on their websites. Alternatively, you can send a written request to the notified body. When EUDAMED becomes accessible, it should be possible to verify the authenticity of the certificate in EUDAMED.

³⁹ For the content of the EU certificates see Annex XII MDR and IVDR.

⁴⁰ <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. The Commission is currently stating the end of 2022 as the implementation date. The latest information can be found here:

https://ec.europa.eu/growth/sectors/medical-devices/new-regulations/eudamed_en

For how long will the "old" EU certificates for medical devices remain valid?

The notified bodies may not issue any more EU certificates according to the "old" Directives 93/42/EEC and 90/385/EEC after 25 May 2021.

The "old" EU certificates basically remain valid until the expiry date, but not beyond 26 May 2024.

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 MDR.

An EU certificate is not needed for most custom-made devices. Exception: from 26 May 2021, an EU certificate according to the MDR will be mandatory for custom-made devices in Class III⁴¹.

⁴¹ Art. 10 para. 1 and 2 MedDO

Annex 4: Information issued by the European Commission on the revision of the regulations

Note: Switzerland's medical devices regulation is 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	<p>Factsheet for healthcare professionals and health institutions</p> <p>Published by the European Commission</p> <p>The factsheet contains detailed information on the revision of the regulations in Europe, focusing on health institutions.</p> <p>https://ec.europa.eu/docsroom/documents/35963 or https://ec.europa.eu/growth/sectors/medical-devices/new-regulations/spread-word_en</p>
2	<p>Factsheet for the Procurement Ecosystem of Medical Devices and in vitro Diagnostic Medical Devices</p> <p>Published by the European Commission</p> <p>https://ec.europa.eu/docsroom/documents/33861 or https://ec.europa.eu/growth/sectors/medical-devices/new-regulations/spread-word_en</p>
3	<p>MDCG 2019-8 Guidance document Implant Card relating to the application of Article 18 Regulation (EU) 2017/745 on medical devices</p> <p>Published by the European Commission</p> <p>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.</p> <p>https://ec.europa.eu/health/md_sector/new_regulations/guidance_en</p>
4	<p>Transition Timelines from the Directives to the Regulations</p> <p>Published by the European Commission</p> <p>https://ec.europa.eu/docsroom/documents/34907 or https://ec.europa.eu/growth/sectors/medical-devices/new-regulations/spread-word_en</p>