Medical Devices Ordinance
(MedDO)

of 1 July 2020 (Status as of 26 May 2021)

The Swiss Federal Council,

based on the Therapeutic Products Act of 15 December 2000[1] (TPA),
Article 21 number 2 of the Electricity Act of 24 June 1902[2],
Article 5 of the Federal Act of 17 June 2011 on Metrology[3],
Article 4 paragraph 1 of the Federal Act of 12 June 2009[4] on Product Safety,
Article 37 of the Radiological Protection Act of 22 March 1991[5] and
in implementation the Federal Act of 6 October 1995[6] on Technical Barriers to Trade,

ordains:

Chapter 1 General Provisions
Section 1 Scope and Exceptions

Art. 1 Scope

[1] This Ordinance applies to:

a. medical devices and the associated accessories, as defined in Article 3;

b. groups of products without an intended medical purpose in accordance with Annex 1.

[2] In this Ordinance, the term *devices* is used to designate the products defined in paragraph 1.

[3] This Ordinance also applies to:

a. devices which, when placed on the market or put into service, incorporate as an integral part a medicinal product that has an action ancillary to that of the device;

AS **2020** 2977
1 SR **812.21**
2 SR **734.0**
3 SR **941.20**
4 SR **930.11**
5 SR **814.50**
6 SR **946.51**

b. devices intended to deliver a medicinal product;

c. devices manufactured:
   1. from tissue or cells of animal origin or their derivatives which are non-viable or have been rendered non-viable,
   2. from derivatives of tissue or cells of human origin that are non-viable or have been rendered non-viable;

d. devices which, when placed on the market or put into service, incorporate as an integral part non-viable tissue or non-viable cells of human origin or their derivatives that have an action ancillary to that of the device;

e. devices that incorporate as an integral part an in vitro diagnostic medical device; such constituent parts shall be subject to the provisions for in vitro medical devices.

Art. 2 Exceptions

[1] This Ordinance does not apply to:

a. human blood, blood products, plasma or blood cells of human origin, or devices which, when placed on the market or put into service, incorporate such blood products, plasma or cells with the exception of the devices specified in Article 1 paragraph 3 letter a;

b. vital organs, tissues or cells and transplant products of human origin;

c. vital organs, tissues or cells and transplant products of animal origin;

d. any items other than those listed in letters a–c that are composed of or contain viable biological substances or viable organisms, including living micro-organisms, bacteria, fungi or viruses, in order to achieve or support the intended purpose of the device;

e. in vitro diagnostic medical devices; these are subject to Articles 105 and 107;

f. non-separable combinations of a medicinal product and device intended to deliver a medicinal product that are intended solely for use in this combination and are not reusable;

g. combinations which, when placed on the market or put into service, incorporate as an integral part a medicinal product in addition to the device, where the medicinal product assumes a primary function in such combinations;

h. combinations which, when placed on the market or put into service, incorporate as an integral part non-viable tissue or non-viable cells of human origin or their derivatives in addition to the device, where such tissue, cells or derivatives assume a primary function in the device;

i. medical devices intended solely for use in animals or veterinary diagnostics.

[2] In the cases specified in paragraph 1 letters f–h, the part of the combination that fulfils the role of device must satisfy the general safety and performance requirements set out in Article 6.

Section 2 Definitions and References to European Legislation

Art. 3 Medical device and accessories

[1] *Medical devices* are instruments, apparatus, appliances, software, implants, reagents, materials or other objects:

a. that are intended by their manufacturer for use in human beings;

b. that do not achieve their principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which action can be assisted by such means; and

c. that serve to fulfil one or more of the following specific medical purposes either alone or in combination:

1. diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,

2. diagnosis, monitoring, treatment, alleviation or compensation of injuries or handicaps,

3. investigation, replacement or modification of the anatomy or of a physiological or pathological process or condition,

4. acquisition of information by means of in vitro investigation of samples obtained from the human body, including donated organs, blood or tissue.

[2] Medical devices also include:

a. contraceptive or fertility-enhancing products;

b. items intended specifically to clean, disinfect or sterilise the devices listed in Article 1, paragraph 1 and in paragraph 1 of this Article.

[3] *Medical device accessory* means any article that is not a medical device in its own right, but which is intended by its manufacturer to be used together with one or more particular medical devices and:

a. which makes it possible to use the medical device or devices in accordance with its or their intended purpose; or

b. which specifically and directly supports the medical function of the medical device or devices in line with its or their intended purpose.

Art. 4 Further definitions

[1] In this Ordinance:

a. *making available on the market* means any supply of a device, other than an investigational device, for distribution, consumption or use on the Swiss market in the course of a commercial activity, whether in return for payment or free of charge;

b. *placing on the market* means the first making available of a device, other than an investigational device, on the Swiss market;

c. *putting into service* means the stage at which a device, other than an investigational device, has been made available to the final user as being ready for use on the Swiss market for the first time for its intended purpose;

d. *maintenance* means measures such as mechanical maintenance, software updates, inspection, repair, preparation for first use and reprocessing for reuse or measures to keep a device in functional condition or restore it to functional condition;

e. *reprocessing* means a process carried out on a used device in order to allow its safe reuse including cleaning, disinfection, sterilisation and related procedures, particularly packing, transport and storage, as well as testing and restoring the technical and functional safety of the used device;

f. *manufacturer* means a 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 name or trademark; this definition is subject to the clarifying explanations and exceptions in Article 16 paragraphs 1 and 2 of Regulation (EU) 2017/745[7] on medical devices (EU-MDR);

g. *authorised representative* means any natural or legal person domiciled in Switzerland who has received and accepted a written mandate from a manufacturer located in another country to act on the manufacturer's behalf in relation to specified tasks with regard to the latter's obligations under this Ordinance;

h. *importer* means any natural or legal person established within Switzerland that places a device from a foreign country on the Swiss market;

i. *distributor* means any natural or legal person in the supply chain, other than the manufacturer or the importer, that makes a device available on the Swiss market, up until the point of putting into service;

j. *economic operator* means the manufacturer, authorised representative, importer, distributor or natural or legal person as specified in Article 22 paragraphs 1 and 3 EU-MDR;

k. *healthcare facility* means any organisation whose primary purpose is to provide care or treatment for patients or to promote public health;

l. *hospital* means any healthcare institution in which inpatient treatments for illnesses, inpatient medical rehabilitation and inpatient medical measures for cosmetic purposes are provided by medical or nursing interventions;

m. *contracting state* means any state that is bound to mutually recognise conformity assessments and conformity procedures for devices by an agreement with Switzerland under international law based on equivalent legislation.

7 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 L117 of 5.5. 2017, p. 1; last amended by Regulation (EU) 202/561, OJ L 130 of 24.4.2020, p. 18.

2 The definitions set out in Article 2 numbers 3–26, 31, 37, 38, 40–44, 46, 48, 51–53, 57–69 and 71 EU-MDR, taking account of the amendments to the definitions in Article 2 numbers 18–21 EU-MDR, effected by the European Commission by means of delegated acts[8].

Art. 5 References to European legislation

1 The equivalent terms specified in Annex 2 and as used in EU-MDR[9] and this Ordinance shall apply.

2 Where this Ordinance makes reference to provisions of EU-MDR that in turn refer to other provisions of EU-MDR or other EU acts of law, those provisions shall also apply. The interpretation in the footnote to Article 4 paragraph 1 letter f is authoritative for references to EU-MDR, while the interpretations of the relevant EU act set out in Annex 3 number 1 apply to references to other EU acts. This provision excludes onward references to the EU acts listed in Annex 3 number 2; here the Swiss terms listed in the Annex shall apply.

Chapter 2 Making available on the Market and Putting into Service

Section 1 Requirements

Art. 6 General safety and performance requirements

1 A device may be placed on the market or put into service only if it complies with this Ordinance when duly supplied and properly installed, maintained and used in accordance with its intended purpose.

2 Devices must conform to the general safety and performance requirements set out in Annex I to EU-MDR[10], taking account of their intended purpose.

3 Appropriate evidence that the part of the combination that is deemed to be a device under the cases set out in Article 2 letters f–h fulfils the product requirements must be presented to the competent authority on demand.

4 Compliance with the essential requirements of this Ordinance, as covered by designated technical standards[11], common specifications or prescriptions of the pharmacopoeia[12], is presumed if the device is in conformity with these standards, specifications or prescriptions.

5 The presumption made in paragraph 4 also applies to compliance with the system or process requirements that economic operators must comply with under this Ordinance, including requirements associated with quality management systems, risk

8 See Annex 4.
9 See the footnote to Art. 4 para. 1 let. f.
10 See the footnote to Art. 4 para. 1 let. f.
11 The electrical standards can be obtained from the industry association Electrosuisse, Luppmenstrasse 1, 8320 Fehraltorf, www.electrosuisse.ch; the remaining standards can be obtained from the Swiss Association for Standardization (SNV), Sulzerallee 70, 8404 Winterthur, www.snv.ch.
12 SR **812.211**

management, post-market surveillance systems, clinical trials, clinical evaluation or post-market clinical follow-up.

6 Compliance with the common specifications in paragraph 4 is required unless the manufacturer can provide appropriate proof that the solutions it has chosen guarantee equivalent conformity with the safety and performance requirements. The above is subject to Article 8 paragraph 1.

Art. 7 Distance sales

1 Devices marketed by means of information society services – specifically an online service – that fulfil the conditions set out in paragraph 4 must comply with this Ordinance.

2 Similarly, devices that are not placed on the market but are used in the context of a commercial activity, whether in return for payment or free of charge, for the provision of a diagnostic or therapeutic service offered by means of information society services or by other means of communication must also comply with this Ordinance.

3 Upon request by the Swiss Agency for Therapeutic Products (Swissmedic), any natural or legal person offering a device in accordance with paragraph 2 or providing a service must be able make available a copy of the declaration of conformity.

4 A device is deemed to be supplied via an information society service if that service:

a. is provided by distance selling, specifically without the contracting parties being physically present at the same time;

b. is provided electronically; and

c. is provided at the individual request of the recipient or the recipient's representative.

5 To protect public health, Swissmedic may require a provider of information society services to discontinue its activities in Switzerland.

Art. 8 Specific requirements

1 Devices without an intended medical purpose in accordance with Article 1 paragraph 1 letter b must comply with the common specifications stipulated by Swissmedic.

2 Devices that have both a medical and non-medical intended purpose must fulfil both the requirements for devices with a medical intended purpose and the requirements for devices without an intended medical purpose.

3 Devices that are also machines within the meaning of Article 1 of the Machine Ordinance of 2 April 2008[13] must satisfy the pertinent general safety and health protection requirements of the Machine Ordinance where these requirements are more specific than those of Chapter II of Annex I to EU-MDR[14].

13 SR **819.14**
14 See the footnote to Art. 4 para. 1 let. f.

Art. 9 Devices manufactured and used in healthcare institutions

[1] Devices manufactured and used solely within healthcare institutions are deemed to have been put into service. Such devices are subject to the pertinent general safety and performance requirements of Annex I to EU-MDR[15] but not to any of the other requirements set out in this Ordinance, provided the requirements of Article 5 paragraph 5 letters a–h EU-MDR are fulfilled.

[2] Paragraph 1 does not apply to devices manufactured on an industrial scale.

Art. 10 Custom-made devices

[1] Custom-made devices are subject to the requirements of Annex XIII to EU-MDR[16]. The declaration according to Section 1 of Annex XIII to EU-MDR must be enclosed when the devices are placed on the market.

[2] In addition to the procedure under paragraph 1, manufacturers of class III implantable custom-made devices must also conduct a conformity assessment procedure as specified in Chapter I of Annex IX to EU-MDR. Alternatively, they may opt for a conformity assessment in accordance with Part A of Annex XI to EU-MDR.

[3] Manufacturers must create and update the documentation specified in Section 2 of Annex XIII to EU-MDR and ensure it can be made available to the competent authorities.

Art. 11 Systems and procedure packs

[1] The requirements of Articles 22 and 29 paragraph 2 EU-MDR apply to the placing on the market of systems and procedure packs[17].

[2] Any natural or legal person who sterilises systems or procedure packs for placing on the market must apply a conformity assessment procedure for the sterilisation process and involve in that procedure a conformity assessment body that is designated under this Ordinance or recognised under an international agreement (designated body). The modalities for doing so are governed by Article 22 paragraph 3 EU-MDR.

[3] Any natural or legal person who places the following systems or procedure packs on the market must fulfil the obligations of a manufacturer under Articles 46–50 and conduct the pertinent conformity assessment procedure under Article 23: Systems or procedure packs that:

a. contain devices that do not carry a conformity marking;

b. consist of a combination of devices that is not compatible with their original intended purpose; or

c. have not been sterilised in accordance with the manufacturer's instructions.

15 See the footnote to Art. 4 para. 1 let. f.
16 See the footnote to Art. 4 para. 1 let. f.
17 See the footnote to Art. 4 para. 1 let. f.

Art. 12 Parts and components

[1] Any natural or legal person who makes available on the market an item intended to replace an identical or similar integral part or component of a device that is defective or worn in order to maintain or restore the function of the device without changing its performance or safety characteristics or its intended purpose shall ensure that the item does not adversely affect the safety and performance of the device. Supporting evidence must be kept available for the competent authority.

[2] An item that is intended specifically to replace a part or component of a device and that significantly changes the performance or safety characteristics or the intended purpose of the device shall be considered to be a device and shall meet the requirements laid down in this Ordinance.

Art. 13 Conformity marking and identification number

[1] Devices placed on the market in Switzerland or made available on the Swiss market must bear a conformity marking in accordance with Annex 5. The conformity marking presented in Annex V to EU-MDR[18] is also a permissible conformity marking.

[2] The following must not bear a conformity marking:

a. custom-made devices;

b. devices exclusively for demonstration and exhibition purposes;

c. systems and procedure packs;

d. investigational devices, subject to the provisions of Article 6 of the Ordinance of 1 July 2020[19] on Clinical Trials with Medical Devices;

e. devices manufactured and used in healthcare institutions.

[3] Where devices' conformity has to be assessed by a designated body, the identification number of this body must be appended to the conformity marking.

Art. 14 Location of conformity marking and identification number

[1] The conformity marking and, where necessary, associated identification number must appear on the device itself or on its sterile packaging.

[2] Where this is not possible or practicable owing to the composition of the device, the conformity marking and, where necessary, identification number must be displayed on the packaging.

[3] The conformity marking must also appear on the instructions for use and trade packaging.

[4] The requirements of Article 20 paragraphs 3–6 EU-MDR[20] and the general principles of Regulation (EC) No. 765/2008[21] must also be observed when affixing the conformity marking.

18 See the footnote to Art. 4 para. 1 let. f.
19 SR **812.213.3**

Section 2
Classification, Labelling and Device Identification

Art. 15 Classification

[1] Devices shall be divided into classes I, IIa, IIb and III, taking into account the intended purpose of the devices and their inherent risks. This classification must comply with the provisions of Annex VIII to EU-MDR[22].

[2] The procedure for resolving disputes between the manufacturer and a designated body as regards the classification of a device is governed by Article 51 paragraph 2 EU-MDR.

Art. 16 Product information

[1] Product information comprises the labelling and instructions for use. It is governed by Chapter III of Annex I to EU-MDR[23].

[2] It must be written in all three official languages of Switzerland. Symbols established by means of technical standards may be used to replace written statements.

[3] The product information may be provided in fewer than the three official languages of Switzerland or in English, provided that:

a. the device is supplied exclusively to professionals or is a custom-made device or a medical device manufactured and used in a healthcare institution;

b. it is certain that the user meets the necessary professional and linguistic requirements and qualifications, and is in agreement;

c. the protection of patients, users and third parties is ensured; and

d. the efficacy and performance of the medical device are not placed at risk.

[4] If requested, additional information must be provided to users in one of the official languages of Switzerland.

[5] If a product cannot be, or cannot yet be, placed on the market as a medical device but may be confused with such a device, the claims relating to the said product must indicate clearly and legibly that it is not a medical device and is not suitable for medical purposes.

[6] Devices intended solely for demonstration and exhibition purposes must be specifically labelled as such. The information must be clearly visible and comprehensible.

20 See the footnote to Art. 4 para. 1 let. f.
21 Regulation (EC) No. 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93, version according to OJ L 218 of 13.8.2008, p. 30.
22 See the footnote to Art. 4 para. 1 let. f.
23 See the footnote to Art. 4 para. 1 let. f.

7 Misleading or contradictory information on a device's intended purpose, safety and performance is forbidden.

Art. 17 Unambiguous product identification

1 Any manufacturer or natural or legal person who assembles systems and procedure packs in accordance with Article 22 paragraphs 1 and 3 EU-MDR[24] shall assign the product, system or procedure pack, with the exception of custom-made devices, and all superordinate packaging layers a unique device identifier (UDI[25]) prior to placing it on the market.[26]

2 It must state the UDI on the labelling of the device, system or procedure pack and all superordinate packaging layers. Transport containers are not regarded as a superordinate packaging layer.[27]

3 It shall maintain a list of all the UDIs it has assigned. This list is part of the technical documentation specified in Annex II to EU-MDR. It must be kept up-to-date at all times.[28]

4 The obligations and modalities associated with product identification and registration are governed by Articles 27 and 29 and Annex VI to EU-MDR, taking account of the amendments to this Annex made by the European Commission by means of delegated acts[29].

5 ...[30]

Section 3 Reporting Obligations and Information

Art. 18 Obligation to report the use of devices manufactured in healthcare institutions

1 Healthcare institutions that manufacture and use devices as specified in Article 9 shall provide the following information to Swissmedic prior to putting the devices into service:

a. their name and address;

b. the name and intended purpose of the device;

c. the risk class of the device in accordance with Article 15 paragraph 1.

2 Any other relevant information about these devices must be submitted to Swissmedic at Swissmedic's request. The declaration required under Article 5 paragraph 5 letter e EU-MDR[31] must be made publicly available.

24 See the footnote to Art. 4 para. 1 let. f.
25 Stands for «Unique Device Identification»
26 Amended by No I of the O of 19 May 2021, in force since 26 May 2021 (AS **2021** 281).
27 Amended by No I of the O of 19 May 2021, in force since 26 May 2021 (AS **2021** 281).
28 Amended by No I of the O of 19 May 2021, in force since 26 May 2021 (AS **2021** 281).
29 See Annex 4.
30 To enter into force in due course (Art. 110 para. 2).
31 See the footnote to Art. 4 para. 1 let. f.

3 Changes to the information required in paragraph 1 must be reported to Swissmedic within 30 days.

4 Depending on the risk inherent in a device and its use, Swissmedic may exempt devices manufactured and used in accordance with Article 9 from the reporting obligation.

Art. 19 Reporting obligation for natural and legal persons who make custom-made devices available on the market

1 Any natural or legal person who makes custom-made devices available on the Swiss market must provide the following information to Swissmedic before making the devices available:

a. the name and address of the manufacturer and all manufacturing sites;

b. the name and address of the authorised representative if applicable;

c. the codes required to identify the relevant product categories, as specified by the European Commission by means of implementing acts[32].

2 Changes to this information must be reported to Swissmedic within 30 days of the changes taking effect.

3 Depending on the risk inherent in a device and its use, Swissmedic may exempt custom-made devices from the reporting obligation under paragraph 1.

Art. 20 Information on implantable devices

1 For implantable products, the manufacturer must provide, in addition to the product information required under Article 16, the information required under Article 18 paragraph 1 EU-MDR[33], including the implantation certificate. The exemptions specified under Article 18 paragraph 3 EU-MDR apply, taking account of the amendments adopted by the European Commission by means of delegated acts[34].

2 The implantation certificate must be written in all three official languages of Switzerland.

3 Healthcare institutions must enter the details of the implant recipient in the implantation certificate and give the certificate to the recipient. They provide the essential information needed by the recipient in a quickly accessible form.

32 See Annex 4.
33 See the footnote to Art. 4 para. 1 let. f.
34 See Annex 4.

Chapter 3 Conformity Assessment, Certificate and Declaration
Section 1 Conformity assessment

Art. 21 Principle

1 Any natural or legal person who is domiciled in Switzerland and makes devices available on the market in Switzerland or in a contracting state must, upon request, provide the authorities responsible for controls as part of market monitoring with the declaration of conformity.

2 Any natural or legal person who is domiciled in Switzerland and places a device on the market in Switzerland or in a contracting state or puts a device into service in Switzerland or in a contracting state without placing it on the market must carry out and be able to produce documentary evidence of an evaluation of the device's conformity with the general safety and performance requirements.

3 The demonstration of compliance with the general safety and performance requirements must also include a clinical evaluation in accordance with Article 61 EU-MDR[35].

Art. 22 Exemptions

1 In response to a justified application, Swissmedic may authorise the placing on the market and putting into service of a specific device the use of which is in the interests of public health or patient safety or health even though:

a. the relevant conformity assessment procedure according to Article 23 has not been carried out; or

b. the language requirements in Article 16 paragraph 2 have not been met.

2 Individual devices that have not undergone the relevant conformity assessment procedure may be placed on the market and used without authorisation from Swissmedic provided:

a. they serve to avert life-threatening conditions or to resolve the permanent impairment of a bodily function;

b. no conforming device is available for this specific indication;

c. they are used exclusively by healthcare professionals on individual persons;

d. the healthcare professional using the device has informed the individual concerned about the non-conformity of the medical device and the related risks; and

e. the individual concerned has consented to the use of the device.

3 For devices placed on the market exclusively within the armed forces or within the framework of their specific tasks, the Federal Department of Home Affairs (FDHA) may, in agreement with the Federal Department of Defence, Civil Protection and Sports, grant exemptions.

35 See the footnote to Art. 4 para. 1 let. f.

Art. 23 Procedure

The conformity assessment procedure is governed by Articles 52 and 54 and by Annexes IX–XI to EU-MDR[36], taking account of the amendments to Article 52, paragraph 4, sub-paragraph 2 EU-MDR adopted by the European Commission by delegated act[37].

Art. 24 Involvement of a designated body

1 When a designated body is involved, all the information necessary for the conformity assessment must be made available to it.

2 Manufacturers must not apply to more than one designated body in Switzerland or a contracting state to conduct a conformity assessment procedure for the same product.

3 Any natural or legal person who applies to a designated body must inform that body whether an application to a different designated body in Switzerland or a contracting state has been withdrawn before a decision was issued or rejected by a different designated body in Switzerland or a contracting state.

4 If a manufacturer withdraws its application to have a conformity assessment procedure conducted before the designated body has issued its decision on the assessment, the designated body in question will notify Swissmedic and the other designated bodies.

5 The information required in paragraph 4 must be supplied exclusively via Eudamed.

6 Where a manufacturer voluntarily changes designated body, it must comply with the requirements of Article 58 EU-MDR[38].

Section 2 Certificate of Conformity

Art. 25 Issuing and content

1 The designated bodies issue certificates of conformity in accordance with Annexes IX–XI to EU-MDR[39] (Certificates).

2 The certificates must be issued in one of the three official languages of Switzerland or in English.

3 They must, as a minimum, include the information required in Annex XII to EU-MDR, taking account of the amendments to this Annex adopted by the European Commission by means of delegated acts[40].

36 See the footnote to Art. 4 para. 1 let. f.
37 See Annex 4.
38 See the footnote to Art. 4 para. 1 let. f.
39 See the footnote to Art. 4 para. 1 let. f.
40 See Annex 4.

4 Certificates issued by bodies designated under EU law and domiciled in an EU or EEA state but not recognised by an international agreement are deemed equivalent to certificates issued by Swiss bodies if it can be credibly demonstrated that:

a. the conformity assessment procedures used meet Swiss requirements; and

b. the certificates were issued by a body with an equivalent qualification to that required in Switzerland.[41]

Art. 26 Validity

1 Certificates are valid for a maximum of five years. The expiry date must appear on the certificate.

2 At the manufacturer's request, the validity of the certificate can be extended by a maximum of five years following a new assessment carried out in accordance with the relevant conformity assessment procedure. Certificates can be extended more than once.

3 Any addendum to a certificate is valid for the same period as the certificate to which it belongs.

Art. 27 Suspension, restriction and revocation

1 If a designated body finds that a manufacturer no longer fulfils the requirements of this Ordinance, it shall impose on that manufacturer a suitable deadline for restoring compliance.

2 If this deadline passes without the manufacturer taking suitable corrective action, the designated body shall suspend, revoke or restrict the certificate in question.

3 A certificate that has been amended, suspended or revoked by a designated body must no longer be used in its original form.

Art. 28 Documentation requirements

1 The designated body will provide Swissmedic and the other designated bodies with:[42]

a. all information on certificates it has issued and any amendments or addenda to such certificates;

b. information on suspended, reactivated or revoked certificates;

c. information on certificates it has rejected;

d. information on restrictions imposed on certificates.

2 It will also provide Swissmedic with information on whether or not a conformity assessment procedure should be applied in accordance with Article 54 paragraph 1 EU-MDR[43]. Notifications of certificates for devices that have undergone a proce-

41 Inserted by No I of the O of 19 May 2021, in force since 26 May 2021 (AS **2021** 281)
42 Amended by No I of the O of 19 May 2021, in force since 26 May 2021 (AS **2021** 281).
43 See the footnote to Art. 4 para. 1 let. f.

dure of this type must include the documents specified in Article 55 paragraph 1 EU-MDR.[44]

Section 3 Declaration of Conformity

Art. 29

[1] If the applicable conformity assessment procedure has demonstrated that the requirements of this Ordinance have been fulfilled, the manufacturer of devices that are not custom-made or investigational issues a declaration of conformity. This declaration shall be subject to ongoing updating.

[2] The declaration of conformity must include the information required in Annex IV to EU-MDR[45], taking account of the amendments to this Annex adopted by the European Commission by means of delegated acts[46]. It must be written in one of the three official languages of Switzerland or English or translated into one of these languages.

[3] If a device also requires a manufacturer's declaration of conformity for aspects not covered by this Ordinance but nevertheless required by other legislation in order to demonstrate compliance with that legislation, one single declaration of conformity will be issued.

[4] By issuing the declaration of conformity, the manufacturer assumes responsibility for ensuring that the device complies with the requirements of this Ordinance as well as with any other legislation to which the device is subject.

Chapter 4 Requirements applicable to Tissues and Cells of Human Origin that are incorporated into or used in the Production of Devices

Art. 30 Establishment licence

[1] An establishment licence issued by Swissmedic is required by any natural or legal person who:

a. removes tissue or cells from humans for the purpose of devitalising the tissue or cells and using them to manufacture devices or supplying them for use in device manufacture;

b. stores tissue or cells removed for the purposes in letter a;

c. imports or exports tissue or cells removed for the purposes in letter a.

[2] A licence shall be issued if:

44 Amended by No I of the O of 19 May 2021, in force since 26 May 2021 (AS **2021** 281).
45 See the footnote to Art. 4 para. 1 let. f.
46 See Annex 4.

a. the requirements in terms of professional qualifications and operational infrastructure are fulfilled;

b. a quality assurance system that complies with current scientific and technological standards is in place;

c. the facility has a Responsible Person with the necessary specialist knowledge, experience and directive authority in their area of responsibility and who is responsible for quality;

d. the obligations specified in Articles 31 and 32 are fulfilled.

3 Swissmedic shall verify that the conditions for issuing an establishment licence are fulfilled in the course of an inspection.

4 Articles 39–43 of the Medicinal Products Licensing Ordinance of 14 November 2018[47] (MPLO) also apply.

Art. 31 Collection, donation and testing

1 The requirements of Articles 3, 4, 6–15 and 30–33 of the Transplantation Act of 8 October 2004[48] and of Articles 2–12 of the Transplantation Ordinance of 16 March 2007[49] apply mutatis mutandis to collection, donation and testing.

2 Holders of an establishment licence issued under Article 30 must verify the suitability of donors.

Art. 32 Duty to keep records and traceability

1 It must be possible to trace all tissue and cells harvested from humans for the purpose of devitalisation and use in devices from the donor to the recipient and vice versa. Art. 35, paragraphs 1 and 2, MPLO[50] also apply.

2 Moreover, the provisions of Articles 34 and 35 of the Transplantation Act of 8 October 2004[51] apply mutatis mutandis to traceability.

Chapter 5 Designated Bodies

Section 1 Designation

Art. 33 Requirements and application

1 Swissmedic will only designate conformity assessment bodies that have completed an assessment procedure in accordance with Article 34 and which satisfy the requirements set out in Annex VII to EU-MDR[52].

47 SR **812.212.1**
48 SR **810.21**
49 SR **810.211**
50 SR **812.212.1**
51 SR **810.21**
52 See the footnote to Art. 4 para. 1 let. f.

2 Applications for designation must be submitted to Swissmedic. They must in particular include:

a. details of the activities and the types of product for which designation is sought;

b. proof that the requirements of Annex VII to EU-MDR are met.

3 Swissmedic shall verify whether the application for designation is complete within thirty days, and request the applicant to submit any information that may be missing.

4 It shall review the application and accompanying documents and issue a preliminary assessment report.

Art. 34 Assessment

1 Swissmedic shall conduct an on-site assessment of the conformity assessment body and, if relevant, of all sub-contractors and subsidiaries.

2 If Swissmedic identifies non-compliances in the course of its assessment, it shall draw up a list of non-compliances for the applicant. Swissmedic shall set the conformity assessment body a deadline by which the latter must submit to Swissmedic a corrective action plan to remedy the non-compliances and a plan setting out preventive measures.

3 The plans must indicate the root cause of the identified non-compliances and must include a timeframe for implementing the measures.

4 Swissmedic will decide whether the proposed action is suitable and whether the timeframe for implementation is appropriate.

Art. 35 Assessment report

1 If Swissmedic approves the plans required under Article 34 paragraph 2, it shall prepare an assessment report.

2 This shall comprise the following:

a. the result of the assessment;

b. confirmation that suitable corrective and preventive measures have been planned and where necessary implemented;

c. the scope of the designation.

Art. 36 Issue and extension of designation

1 Swissmedic shall grant the designation if the conformity assessment body meets the requirements.

2 The extension of designations is subject to the requirements and procedures laid out in Articles 33–35.

Art. 37 Sub-contractors and subsidiaries

[1] Designated bodies that delegate part of the work to sub-contractors or to a subsidiary bear full responsibility for the work carried out on their behalf by the sub-contractor or by the subsidiary.

[2] They must ensure that the sub-contractor or the subsidiary meets the applicable requirements of Annex VII to EU-MDR[53].

[3] They must notify Swissmedic if they delegate work under the terms of paragraph 1. They must be able to demonstrate to Swissmedic that the sub-contractor or the subsidiary is capable of carrying out the tasks assigned to it.

[4] Work may only be delegated if the designated body has notified the natural or legal person who requested the conformity assessment accordingly.

[5] The designated bodies must publish a list of their subsidiaries.

Art. 38 Duty of cooperation and notification requirement

[1] The designated bodies, including their subsidiaries and sub-contractors, are required to keep available for Swissmedic at all times all data that is necessary for assessment, designation, monitoring and re-assessment, including the documents required to assess the qualifications of sub-contractors or subsidiaries. The data must be kept up-to-date at all times.

[2] The designated bodies shall notify Swissmedic within 15 days of any change that affects their ability to meet the requirements of Annex VII to EU-MDR[54] or to carry out conformity assessments.

Art. 39 Tariffs

The designated bodies shall issue lists of the standard tariffs charged for their activities and make these lists publicly accessible.

Section 2 Cessation of Conformity Assessment Activities

Art. 40

[1] If a designated body ceases to carry out its conformity assessment activities, it shall notify Swissmedic and the manufacturers concerned as soon as possible. In the case of planned cessation of activities, notice must be given one year before the activities cease. Swissmedic will revoke the designation from the date on which the activities cease.

[2] The certificates will remain valid for a maximum of nine months following cessation of activities, provided another designated body assumes responsibility for certifying the products concerned and confirms this in writing.

53 See the footnote to Art. 4 para. 1 let. f.
54 See the footnote to Art. 4 para. 1 let. f.

3 The designated body assuming responsibility in accordance with paragraph 2 shall conduct a full assessment of the products concerned before the nine-month period expires and before issuing new certificates for the products.

Section 3 Suspension, Restriction or Revocation of Designation

Art. 41 Principle

1 Designation shall be suspended, restricted or revoked if the designated body:

a. no longer or only partly meets the requirements; or

b. fails to carry out corrective action ordered by Swissmedic.

2 Suspensions will be imposed for a maximum of twelve months. They may be extended by a maximum of a further twelve months.

3 If designation is suspended, restricted or revoked, the designated body must inform all affected manufacturers accordingly within ten days.

Art. 42 Unduly issued certificates

1 In the event of its designation being restricted, suspended or revoked, the designated body will suspend or withdraw any certificates which were unduly issued.

2 If the designated body fails to fulfil this requirement, Swissmedic will instruct it to suspend or revoke the certificates and set an appropriate deadline for doing so.

Art. 43 Validity of certificates in the event of suspension or restriction of designation

1 If Swissmedic suspends or restricts the designation of a designated body, the certificates concerned remain valid provided Swissmedic:

a. confirms within a month that no safety issue exists in connection with the products concerned; and

b. outlines a timeline and measures to remedy the suspension or restriction.

2 The certificates also remain valid if Swissmedic:

a. confirms that, during the suspension or restriction, no certificates relevant to the suspension will be issued, amended or re-issued; and

b. states that the designated body is able to continue to monitor and retain responsibility for existing certificates during the suspension or restriction.

3 The designated body shall notify the manufacturers concerned or the persons or entities placing the devices concerned on the market.

4 Should Swissmedic ascertain that the designated body is unable to continue to oversee existing certificates, these certificates will retain their validity if the manufacturer of the product in question confirms to Swissmedic or, if it is domiciled in a

contracting state, to the competent authority there, in writing and within three months of designation being suspended or restricted that:

a. another qualified designated body is temporarily assuming the oversight duties; and

b. this designated body will be responsible for the certificates during the period of suspension or restriction.

Art. 44 Validity of certificates in the event of designation being revoked

1 If Swissmedic revokes the designation of a designated body, the certificates affected remain valid for nine months provided:

a. Swissmedic or, if the manufacturer is domiciled in a contracting state, the competent authority there confirms that the products in question present no safety issues;

b. another designated body confirms in writing that it is assuming immediate responsibility for the certificates for these products and can complete the assessment of the products within twelve months of designation being revoked.

2 Swissmedic may, within the limits of its competence, extend the provisional validity of the certificates for further periods of three months, which altogether must not exceed twelve months.

Section 4 Monitoring and Re-assessment of Designated Bodies

Art. 45

1 Swissmedic shall monitor the designated bodies and their subsidiaries and subcontractors and carry out re-assessments. In the course of monitoring and re-assessing designated bodies and reviewing their assessments, Swissmedic shall take account of the requirements and procedures set out in Articles 44 and 45 EU-MDR[55].

2 It will verify whether designated bodies still satisfy the requirements of Article 36 paragraph 1 and Annex VII to EU-MDR three years after designation, and then every four years, in the course of a full re-assessment. This provision is subject to changes in assessment intervals resulting from delegated acts[56] issued by the European Commission.

3 Swissmedic will carry out an on-the-spot assessment at least once a year to ascertain whether the designated bodies and, if applicable, their subsidiaries and subcontractors are fulfilling the requirements and obligations of Annex VII to EU-MDR.

4 For this purpose, it may at any time:

55 See the footnote to Art. 4 para. 1 let. f.
56 See Annex 4.

a. carry out on-site assessments with or without advance notice;

b. carry out audits of the employees of the designated body and its subsidiaries or sub-contractors or observe audits that the designated body carries out on manufacturers' premises.

Chapter 6 Requirements for Economic Operators

Section 1 Manufacturers

Art. 46 Conformity marking and clinical evaluation

1 Manufacturers guarantee that their products have been designed and manufactured in accordance with the requirements of this Ordinance when they place them on the market or put them into service.

2 They must print the conformity marking on their products.

3 They must conduct a clinical evaluation in accordance with Article 61 EU-MDR[57] taking account of the amendments to this Article adopted by the European Commission by means of delegated acts[58] and in accordance with Annex XIV to EU-MDR. They must update this clinical evaluation in line with the results of post-market clinical follow-up.

Art. 47 Technical documentation

1 Manufacturers must list in the technical documentation the information required in Annexes II and III to EU-MDR[59], taking account of the amendments to these Annexes made by the European Commission by means of delegated acts[60].

2 Manufacturers must submit either the complete technical documentation or a summary of this documentation when requested to do so by the competent authority.

Art. 48 Document retention requirements

1 Manufacturers must ensure that the following are available to the competent authority for at least ten years after the final product covered by the declaration of conformity has been placed on the market:

a. complete technical documentation;

b. declaration of conformity;

c. a copy of the certificates issued, including any amendments and addenda.

2 The document retention period for implantable products shall be at least 15 years from the date the last product was placed on the market.

57 See the footnote to Art. 4 para. 1 let. f.
58 See Annex 4.
59 See the footnote to Art. 4 para. 1 let. f.
60 See Annex 4.

Art. 49 Person responsible for regulatory compliance

[1] Manufacturers must have available within their organisation at least one person responsible for regulatory compliance who possesses the requisite expertise in the field of medical devices.

[2] Proof that the person responsible for regulatory compliance possesses the requisite expertise, the responsibilities of this person, exceptions and further modalities are governed by Article 15 EU-MDR[61].

[3] The person responsible for regulatory compliance must have a deputy. If a number of persons are jointly responsible for regulatory compliance, their respective areas of responsibility shall be stipulated in writing.

[4] The person responsible for regulatory compliance must suffer no disadvantage within the manufacturer's organisation in relation to the proper fulfilment of their duties, regardless of whether or not they are employees of the organisation.

Art. 50 Further obligations

The further obligations incumbent on manufacturers, particularly the requirements to be fulfilled by their quality and risk management systems, are governed by Article 10 EU-MDR[62].

Section 2 Authorised Representative

Art. 51 Obligations

[1] Where the manufacturer of a device is not domiciled in Switzerland, the device may only be placed on the market if the manufacturer designates an authorised representative domiciled in Switzerland by means of a written mandate.

[2] The authorised representative is responsible for the formal and safety-related aspects of placing the device on the market.

[3] The authorised representative's rights and obligations and the scope of its mandate are governed by Article 11 EU-MDR[63].

[3bis] The manufacturer and authorised representative may contractually agree that instead of the authorised representative keeping available a copy of the technical documentation, the manufacturer shall, on request, submit the documentation straight to Swissmedic. The authorised representative must ensure that the documentation is submitted within seven days.[64]

[4] Changes in authorised representative are governed by Article 12 EU-MDR.

61 See the footnote to Art. 4 para. 1 let. f.
62 See the footnote to Art. 4 para. 1 let. f.
63 See the footnote to Art. 4 para. 1 let. f.
64 Inserted by No I of the O of 19 May 2021, in force since 26 May 2021 (AS **2021** 281)

5 Paragraphs 1–4 also apply to natural or legal persons who assemble systems and procedure packs in accordance with Article 22 paragraphs 1 and 3 EU-MDR and who are not domiciled in Switzerland.[65]

Art. 52 Person responsible for regulatory compliance

1 Authorised representatives must ensure that they have permanently and continuously at their disposal at least one person who possesses the requisite expertise as regards the requirements for medical devices under this Ordinance and who is responsible for regulatory compliance.

2 In other respects, Article 49 paragraphs 2–4 shall apply.

Section 3 Importers

Art. 53

1 Importers may only place on the market devices that comply with this Ordinance. Before placing devices on the market, they shall verify that:

a. the device carries the conformity marking;

b. the declaration of conformity has been drawn up;

c. the manufacturer is identified and has designated an authorised representative in accordance with Article 51;

d. the product is labelled in accordance with this Ordinance and accompanied by instructions for use;

e. the manufacturer has assigned a UDI where applicable.

2 Importers must print their name, place of business and contact address on the product, the product packaging or a document enclosed with the product.

3 Where an importer considers or has reason to believe that a device is not in conformity with the requirements of this Ordinance, it must not place the device on the market until it has been brought into conformity.

4 The further obligations of importers prior to and after placing a device on the market are governed by Articles 13 and 16 paragraphs 3 and 4 EU-MDR[66]. In particular, importers must comply with the following obligations:

a. storage, transport and quality management system;

b. cooperation with the manufacturer, authorised representative, designated body and competent authorities;

c. the provision of information to the manufacturer, authorised representative, designated body and competent authorities.

65 Inserted by No I of the O of 19 May 2021, in force since 26 May 2021 (AS **2021** 281)
66 See the footnote to Art. 4 para. 1 let. f.

Section 4 Distributors

Art. 54

1 When making a device available on the market, distributors must, in the context of their activities, act with due care in relation to the requirements applicable. Before making a device available on the market, distributors must verify that:

a. the device carries the conformity marking;

b. the declaration of conformity has been drawn up;

c. the device is accompanied by product information;

d. where devices have been imported the importer has provided the information required in Article 53 paragraph 2;

e. the manufacturer has assigned a UDI where applicable.

2 With the exception of paragraph 1 letter d, random sampling may be used for the purposes of verification.

3 Where a distributor considers or has reason to believe that a device is not in conformity with the requirements of this Ordinance, it must not make the device available on the market until it has been brought into conformity.

4 The further obligations of distributors prior to and after making a device available on the market are governed by Articles 14 and 16 paragraphs 3 and 4 EU-MDR[67]. In particular, distributors must fulfil the following obligations:

a. storage, transport and quality management system;

b. cooperation with the manufacturer, authorised representative, importer and competent authorities;

c. the provision of information to the manufacturer, authorised representative, importer and competent authorities.

Section 5[68] Registration of Economic Operators

Art. 55

1 Manufacturers or their authorised representatives and importers must register the information required by part A of Annex VI to EU-MDR[69] with Swissmedic within three months of placing a device on the market for the first time.

2 The economic operator in question must report any changes to the information to Swissmedic within one week.

67 See the footnote to Art. 4 para. 1 let. f.
68 Amended by No I of the O of 19 May 2021, in force since 26 May 2021 (AS **2021** 281).
69 See the footnote to Art. 4 para. 1 let. f.

3 Further obligations and registration modalities are governed by Articles 30 paragraph 3 and 31 EU-MDR.

4 Swissmedic will verify the information provided by the economic operators and assign them a unique identification number.

5 Any natural or legal person placing systems and procedure packs on the market for the first time under Article 11 must register their name and the address at which they can be contacted with Swissmedic within three months of placing the system or procedure pack on the market. Where an authorised representative is required under Article 51 paragraph 5, the name and address of the authorised representative must also be registered with Swissmedic.

Chapter 7 Device Surveillance

Section 1 Post-market Surveillance

Art. 56 System

1 For each device, manufacturers must plan, establish, document, implement, maintain and update a post-market surveillance system in a manner that is proportionate to the risk class and appropriate for the type of device. This system forms an integral part of the manufacturer's quality management system.

2 The system must be suited to actively and systematically gathering, recording and analysing relevant data on the quality, performance and safety of a device throughout its entire lifetime, and to drawing the necessary conclusions and to determining, implementing and monitoring any preventive and corrective actions.

3 The modalities of the system, particularly the resulting actions, updates and amendments to technical documentation, are governed by Article 83 paragraph 3 EU-MDR[70].

Art. 57 Incidents and actions

1 Should it become evident in the course of post-market surveillance that preventive and/or corrective action is necessary, manufacturers must take suitable steps, notifying the competent authorities and, if applicable, the designated body.

2 If a manufacturer becomes aware of a serious incident in connection with a device that has been made available on the market, or takes action to prevent or minimise the risk of such an incident for medical or technical reasons (field safety corrective actions), it must report the fact in accordance with Article 66.

70 See the footnote to Art. 4 para. 1 let. f.

Art. 58 Plan

The post-market surveillance plan must satisfy the requirements of Section 1 of Annex III to EU-MDR[71]. With the exception of custom-made devices, the plan is part of the technical documentation specified in Annex II to EU-MDR.

Art. 59 Report

1 Manufacturers of class I devices must draw up a report on post-market surveillance.

2 This report must contain:

a. a summary of the results and conclusions of the analyses of the data gathered as a result of the plan specified in Article 58;

b. a rationale and description of any preventive and corrective actions taken.

3 The report forms part of the post-market surveillance technical documentation specified in Annex III to EU-MDR[72].

4 The manufacturer must update the report when necessary and make it available to the competent authority upon request.

Section 2 Safety Report

Art. 60 Obligation

1 Manufacturers of class IIa, class IIb and class III devices shall prepare a safety report for each device and where relevant for each category or group of devices.

2 Manufacturers of class IIa devices shall update the safety report when necessary and at least every two years. Manufacturers of class IIb and class III devices must update this report at least annually.

Art. 61 Content

1 The safety report must contain:

a. a summary of the results and conclusions of the analyses of the post-market surveillance data gathered as a result of the post-market surveillance plan as specified in Article 58;

b. a rationale and description of any preventive and corrective actions taken.

2 Throughout the lifetime of the device concerned, the safety report must set out:

a. the conclusions of the benefit-risk determination;

b. the key results of post-market clinical follow-up;

c. the total sales volume of the device;

71 See the footnote to Art. 4 para. 1 let. f.
72 See the footnote to Art. 4 para. 1 let. f.

d. an estimate of the size of the population using the device;

e. characteristics of the population in letter d;

f. the frequency of device usage, where practicable.

3 The safety report forms part of the technical documentation specified in Annexes II and III to EU-MDR[73]. For custom-made devices, the report forms part of the documentation specified in Section 2 of Annex XIII to EU-MDR.

Art. 62[74] Review

1 Manufacturers will make their safety reports available to the designated body involved in the conformity assessment.

2 The designated body will review the safety report for class III devices or implantable devices and record the outcome of its review with details of any action taken.

3 Manufacturers or their authorised representatives will, upon request, make the safety report and the outcome of the designated body's review, with details of any action taken, available to the competent authority.

Section 3 Summary of Safety and Clinical Performance

Art. 63

1 For class III devices and for implantable devices, other than custom-made or investigational devices, the manufacturer must draw up a summary of safety and clinical performance.

2 The summary of safety and clinical performance shall be written in a way that is clear to the intended user and, if relevant, to the patient.

3 The minimum content of the summary is governed by Article 32, Paragraph 32 EU-MDR[75].

4 The draft summary of safety and clinical performance must be submitted to the designated body involved in the conformity assessment pursuant to Article 24 for validation by that body.

5 The manufacturer will publish the summary after it has been validated.[76]

6 The manufacturer must mention on the label or instructions for use where the summary is available.

73 See the footnote to Art. 4 para. 1 let. f.
74 Amended by No I of the O of 19 May 2021, in force since 26 May 2021 (AS **2021** 281).
75 See the footnote to Art. 4 para. 1 let. f.
76 Amended by No I of the O of 19 May 2021, in force since 26 May 2021 (AS **2021** 281).

Section 4 Traceability and Recording of Product Identification

Art. 64 Traceability

[1] Distributors and importers shall co-operate with manufacturers or authorised representatives to achieve an appropriate level of traceability of devices.

[2] The duty of disclosure under Article 47*c* TPA continues for at least 10 years, or for at least 15 years for implantable products, after the last product covered by the conformity assessment was placed on the market.

Art. 65 Recording the UDI

[1] Economic operators shall store and keep, preferably by electronic means, the UDI of the class III implantable devices which they have supplied or with which they have been supplied.

[2] Swissmedic may extend this obligation to other devices, or categories or groups of devices.

Section 5 Vigilance

Art. 66 Reporting obligation

[1] Manufacturers of devices made available in Switzerland or natural or legal persons who assemble systems or procedure packs in accordance with Article 22 paragraphs 1 and 3 EU-MDR[77] must report to Swissmedic:

a. any serious incidents involving the device in question that have occurred in Switzerland, as soon as they become aware of them;

b. any field safety corrective actions undertaken in Switzerland.[78]

[2] Exemptions from this reporting obligation, modalities, periodic summary reports, trend reporting and analyses of serious incidents and field safety corrective action are governed by Articles 27 paragraph 5 and 87–89 EU-MDR.

[2bis] Where an authorised representative is required pursuant to Article 51, this representative is responsible for the reporting obligation in paragraph 1. Furthermore, the authorised representative must submit the trend reports pursuant to paragraph 2 on incidents in Switzerland and abroad to Swissmedic without being requested to do so. Final reports prepared in accordance with Article 89 paragraph 5 EU-MDR should be submitted to Swissmedic. The transfer of these obligations from the manufacturer or from the natural or legal person assembling systems or procedure packs under Article 22 paragraphs 1 and 3 EU-MDR to the authorised representative must be agreed in writing in the mandate.[79]

77 See the footnote to Art. 4 para. 1 let. f.
78 Amended by No I of the O of 19 May 2021, in force since 26 May 2021 (AS **2021** 281).
79 Inserted by No I of the O of 19 May 2021, in force since 26 May 2021 (AS **2021** 281)

3 …[80]

4 Any professional who becomes aware of an incident when using devices must report this to the supplier and Swissmedic. The report may be submitted by a professional association. The timelines for doing so are as set out in Article 87 EU-MDR.

5 Reports must be submitted to Swissmedic electronically and in machine-readable format. Swissmedic publishes information on electronic submission and the forms to be used with content specifications.

Art. 67 Reporting systems in hospitals

1 Hospitals must set up an internal reporting system within the framework of an established quality management system for the purpose of reporting under Article 66 paragraph 4.

2 They must designate a suitable competent person (vigilance contact person) with a medical or technical qualification to assume responsibility for reporting to Swissmedic. They must supply this person's contact details to Swissmedic.

3 Records and all documents created under the vigilance quality management system must be retained for at least 15 years.

Chapter 8 Conduct in relation to Devices

Art. 68 Supply

Devices are supplied in accordance with their intended purpose and the information provided by the manufacturer.

Art. 69 Advertising

1 Claims for products must only contain statements that correspond to the product information.

2 Misleading statements, particularly concerning the intended purpose, safety and performance of a device, are prohibited.

3 Devices intended solely for use by professionals must not be advertised to the public.

Art. 70 Use by professionals

1 Any professional who uses a device from a foreign country without placing it on the market is responsible for the conformity of that device.

2 Device groups intended for use by professionals and which could harm the health of humans in the case of improper use are listed in Annex 6.

80 Repealed by No I of the O of 19 May 2021, with effect from 26 May 2021 (AS **2021** 281).

3 The groups of devices in Annex 6 may only be used in accordance with the professional and operating requirements stated therein.

Art. 71 Maintenance

1 Any person using devices in a professional capacity must ensure that the devices are maintained and tested in accordance with the regulations.

2 Maintenance must be carried out in accordance with the principles of a quality management system, is to be organised appropriately, and must be guided in particular by:

a. the manufacturer's instructions;

b. the particular risk associated with the device and its use.

3 For devices with a measurement function, test procedures may be required in accordance with the Measuring Instruments Ordinance of 15 February 2006[81].

4 Swissmedic can issue and publish requirements for maintenance measures. These requirements will be deemed to constitute the current scientific and technological standards.

Art. 72 Reprocessing

1 Any person using in a professional capacity a device intended for repeated use must ensure on each occasion and prior to use that its functionality has been tested and that it has been processed in accordance with current scientific and technological standards and taking account of the instructions of the manufacturer and the requirements of hygiene.

2 Reprocessing must employ suitable procedures that have been validated in accordance with current scientific and technological standards and whose efficacy has been demonstrated and can be reliably traced and reproduced within a quality management system.

3 Any natural or legal person who processes devices for third parties must:

a. declare that the processed device:
   1. has been processed in accordance with the manufacturer's instructions, or
   2. has been processed using a procedure specific to the processor that is equally safe and effective as the procedure specified by the manufacturer and has been demonstrated to be equally safe and effective by means of a risk analysis and validation process;

b. operate a quality management system that is both suitable and certified to nationally or internationally recognised standards;

81 SR **941.210**

c. provide proof that reprocessing takes place in suitable premises, in accordance with the recognised rules of science and technology and in compliance with hygiene requirements.

d. document that the device has been processed in accordance with letter a.

4 The declaration required under paragraph 3 letter a must identify the device and state the name and address of the establishment that processed it.

Art. 73 Single-use devices and their reprocessing

1 Reprocessing and further use of single-use devices is forbidden.

2 Single-use devices reprocessed in a foreign country under Article 17 paragraph 3 EU-MDR[82] must neither be used nor made available on the market.

Art. 74 Cyber security

1 Healthcare institutions must put in place all technical and organisational resources required by the state of the art to ensure that network-compatible products are protected against electronic attack and unauthorised access.

2 Hospitals must identify, evaluate and document the measures taken under paragraph 1 in accordance with the principles of a risk management system. This system forms an integral part of the hospitals' quality management system.

Chapter 9 Market Surveillance

Art. 75 Principle

1 Inspections under the auspices of market surveillance will cover devices made available on the market, conformity assessment procedures, device surveillance, device handling and economic operators' fulfilment of their obligations. They will also cover devices made available in contracting states by natural or legal persons domiciled in Switzerland, the conformity assessment procedures and surveillance activities for such devices and the natural or legal persons' fulfilment of their obligations.

2 The market surveillance activities undertaken by Swissmedic and the Cantons are governed by Articles 93–95, 97 and 98 EU-MDR[83]. Articles 97 paragraph 3 and 98 paragraphs 3 and 4 EU-MDR are excluded.

3 The Cantons will draw up annual plans for their market surveillance activities under paragraph 2. They will provide Swissmedic with an annual summary of the results of their surveillance activities. Swissmedic can determine both the content of the summary and the form in which it is made available.

82 See the footnote to Art. 4 para. 1 let. f.
83 See the footnote to Art. 4 para. 1 let. f.

4 In case of an actual necessity for the protection of public health, Swissmedic will decree the measures under Article 66 TPA in a general ruling.

Art. 76 Responsibilities

1 Swissmedic is responsible for monitoring:

a. devices and device conformity;

b. vigilance;

c. maintenance and reprocessing of devices:

1. in hospitals,

2. that are intended for use in hospitals.

2 Certain aspects of the monitoring activities set out in paragraph 1 remain the responsibility of other federal offices or institutions.

3 The Cantons are responsible for monitoring:

a. the retail trade and dispensing points;

b. the manual production of custom-made devices, of systems and of procedure packs;

c. maintenance and reprocessing of devices by the professionals using them and in healthcare institutions with the exception of hospitals.

Art. 77 Powers

1 For the purposes of verifying conformity, the authorities responsible for monitoring under Article 76 may, without providing compensation:

a. demand the proof and information required;

b. take samples;

c. have the samples tested or submitted to laboratory examination;

d. enter and inspect, during normal working hours and with advance notice or, if necessary, unannounced, the business premises and facilities of natural or legal persons who have an obligation to provide information;

e. consult documents and demand that they, or additional information, be provided in one of the official languages of Switzerland or in English.

2 If a manufacturer or a natural or legal person who assembles systems or procedure packs under Article 22 paragraphs 1 and 3 EU-MDR[84] fails to fulfil their obligations under Article 66, Swissmedic may impose appropriate measures to protect health, up to and including prohibiting the making available on the market or the putting into service of the devices in question.[85]

84 See the footnote to Art. 4 para. 1 let. f.
85 Inserted by No I of the O of 19 May 2021, in force since 26 May 2021 (AS **2021** 281)

Art. 78 Duty to cooperate and provide information

Economic operators that place a device on the market in Switzerland or in a contracting state, and economic operators, professionals and healthcare institutions that make a device available or put it into service in Switzerland or a contracting state have a duty to cooperate on matters of enforcement. In particular, they must provide, free of charge, all necessary information and all necessary proof and documentation to the enforcement bodies.

Chapter 10 Data Processing

Section 1 Data Processing in general

Art. 79 Processing of personal data

Swissmedic and third parties contracted by Swissmedic are empowered to process the personal data that they need to perform the tasks mandated to them by this Ordinance. Specifically, this includes:

a. health data acquired in the course of market surveillance and vigilance;

b. data documenting the reliability and professional qualifications of vigilance contact persons (Art. 67 para. 2) or the individuals responsible for compliance with the regulations (Art. 49 and 52).

Art. 80 Operation of information systems

[1] It is Swissmedic's responsibility to ensure that its information systems operate securely and that data is processed in accordance with legal requirements.

[2] It will draw up a set of processing rules for each information system. These will specify the technical and organisational measures to be taken to ensure that the data is protected and secure.

Art. 81 Access rights

[1] The following persons and agencies will be given online access to information systems provided this is necessary for the fulfilment of their respective tasks:

a. Swissmedic staff employed in vigilance and market surveillance and third parties mandated to perform tasks in this area;

b. Swissmedic staff employed in administrative penal law;

c. Swissmedic administrators and mandated third parties.

[2] A log of persons and bodies granted access to the information systems will be kept. The data in this log will be stored for two years.

Art. 82 Data archiving and deletion

Personal data will be stored for a period of ten years from the final entry. On the expiry of this period, it will be destroyed.

Section 2 Medical Devices Information System

Art. 83 Responsible authority

Swissmedic is responsible for the medical devices information system required under Article 62*c* TPA (medical devices information system).

Art. 84 Data protection and security

1 Swissmedic shall draw up processing rules in accordance with Article 21 of the Ordinance of 14 June 1993[86] to the Federal Act on Data Protection (OFADP).

2 Articles 20 and 21 OFADP apply to data security.

3 Data processing must be automatically logged.

Art. 85 Content of the medical devices information system

1 This medical devices information system contains the following data:

a. device data;

b. data on economic operators;

c. data on the designated bodies and certificates issued by them;

d. data on clinical trials;

e. vigilance data;

f. market surveillance data;

g. data that can be used to manage and adapt the medical devices information system (system data);

h. authentication data, assigned user roles and basic settings for using the medical devices information system (user data).

2 The medical devices information system only contains personal data where such data is required to record and process information.

Art. 86 Data exchange with other information systems

The medical devices information system can draw the data specified in Article 85 from Eudamed and from cantonal electronic systems; it can also submit data to Eudamed and cantonal systems.

86 SR **235.11**

Art. 87 Access rights

Swissmedic has access to all data recorded in and processed by the medical devices information system.

Art. 88 Data subjects' rights and data rectification

[1] Data subjects' rights, particularly the right to information, rectification and deletion of data, are governed by data protection legislation.

[2] Swissmedic will ensure that data that is incorrect or has been processed unlawfully is corrected in or deleted from the medical devices information system. Correction and deletion will take place as quickly as possible, but no later than 60 days of the data subject making their request.

Art. 89 Data archiving

The personal data specified in Article 85 paragraph 2 must be stored in such a way that it is only possible to identify data subjects for a period of ten years after the last device covered by the declaration of conformity was placed on the market. For implantable devices, this period is extended to 15 years.

Art. 90 Publication of data

Swissmedic may publish the following in the medical devices information system:

a. product data, as specified in accordance Part B of Annex VI to EU-MDR[87];

b. information on economic operators and devices, as specified in Part A of Annex VI to EU-MDR;

c. the general information specified in Article 35 paragraph 7 EU-MDR governing the assessment, designation and notification of conformity assessment bodies and for the monitoring of designated bodies, and on changes that have a significant impact on such tasks;

d. summaries of the annual report on monitoring and on-site assessment activities drawn up in accordance with Article 44 paragraph 12 EU-MDR;

e. summaries of safety and clinical performance in accordance with Article 63;

f. information on certificates issued under Articles 28 and 42–44;

g. field safety notices for users or customers issued in the course of field safety corrective actions in accordance with Article 89 paragraph 8 EU-MDR;

h. summaries of the reports on Swissmedic's activities in monitoring market surveillance;

i. scientific opinions in accordance with Article 106 paragraph 12 EU-MDR;

j. information on market monitoring activities, particularly recalls, on non-conforming devices and preventive health protection measures.

87 See the footnote to Art. 4 para. 1 let. f.

Art. 91 Subsequent use of data

Non-personal data can be used for the independent assessment of long-term device safety or performance or of the traceability of implantable products.

Art. 92 Applicability of the Data Protection Act

All data processing activities carried out in the medical devices information system must comply with the Federal Act of 19 June 1992[88] on Data Protection.

Chapter 11 Final Provisions

Section 1 Enforcement

Art. 93 Amendment of Annexes

[1] The FDHA can amend Annexes 1–3 to this Ordinance in line with international and technical progress.

[2] Where amendments may pose technical barriers to trade, it will effect them by mutual agreement with the Federal Department of Economic Affairs, Education and Research.

Art. 94 Information on directly applicable legal acts of the European Commission

Swissmedic will provide on its website information on legal acts of the European Commission that, according to this Ordinance, are directly applicable in Switzerland in the version binding upon the Member States of the EU and as listed in Annex 4.

Art. 95 Harmonisation of enforcement

[1] When implementing this Ordinance, Swissmedic will respect the implementing acts adopted by the European Commission on the basis of EU-MDR[89].

[2] Regulations (EU) No 207/2012[90] and No 722/2012[91] will remain in force until such time as they are repealed in the EU by implementing acts adopted by the European Commission on the basis of EU-MDR.

88 SR **235.1**
89 See the footnote to Art. 4 para. 1 let. f.
90 Commission Regulation (EU) No 207/2012 of 9 March 2012 on electronic instructions for use of medical devices, version according to OJ L 72 of 10.3.2012, p. 28.
91 Commission Regulation (EU) No 722/2012 of 8 August 2012 concerning particular requirements as regards the requirements laid down in Council Directives 90/385/EEC and 93/42/EEC with respect to active implantable medical devices and medical devices manufactured utilising tissues of animal origin, version according to OJ L 212 of 9.8.2012, p. 3.

Art. 96 Cooperation with the European Commission and authorities of the contracting states

[1] Where provided for by international agreements, Swissmedic, the designated bodies and economic operators will cooperate with the European Commission and the authorities of the contracting states.

[2] Swissmedic can appoint experts who are qualified to evaluate conformity assessment bodies in the field of medical devices.

[3] The Agency may appoint experts to participate in expert groups of the European Commission and the authorities of the contracting states.

Art. 97 Collaboration with the customs authorities

[1] The customs authorities provide Swissmedic with information on the import, export and transit of devices.

[2] Swissmedic can mandate the customs authorities to detain devices for further inspection and to obtain samples.

Art. 98 Expert laboratories in Switzerland

[1] Laboratories that wish to be designated an expert laboratory by the European Commission in accordance with Article 106 paragraph 7 EU-MDR[92] may apply to Swissmedic for designation.

[2] They must demonstrate to Swissmedic in particular that they:

a. meet the criteria set out in Article 106 paragraph 8 EU-MDR; and

b. are able to assume the tasks under Article 106 paragraph 10 EU-MDR, taking account of the amendments to this provision adopted by the European Commission by means of delegated acts[93], in accordance with the requirements in each case.

[3] They must operate in one of the following fields:

a. physico-chemical characterisation;

b. microbiological, mechanical, electrical, electronic or non-clinical biological and toxicological testing or biocompatibility testing.

[4] If the requirements are met, Swissmedic will propose to the EU Commission that the laboratory be designated an expert laboratory.

92 See the footnote to Art. 4 para. 1 let. f.
93 See Annex 4.

Section 2
Repeal of other Legislation and Transitional Provisions

Art. 99 Repeal of other legislation

The following ordinances are repealed:

1. the Medical Devices Ordinance of 17 October 2001[94];
2. Ordinance of 22 June 2006[95] on the List of Prescription Medical Devices.

Art. 100 Validity of certificates issued under the old legislation

[1] Certificates issued under the old legislation prior to 25 May 2017 will retain their validity until the expiry date stated therein, but no longer than 26 May 2022.

[2] Certificates issued under the old legislation since 25 May 2017 will retain their validity until the expiry date stipulated in them, but no longer than 26 May 2024.

Art. 101 Placing on the market of products that comply with the old legislation

[1] Provided they continue to comply with the old legislation from 26 May 2021 and have not undergone any significant changes in their design or intended purpose, the following medical devices may be placed on the market or put into service until 26 May 2024:

a. devices classified as class I under the old legislation for which a declaration of conformity was issued before 26 May 2021 and for which the conformity assessment procedure under this Ordinance necessitates the involvement of a designated body;

b. devices with a certificate valid under Article 100.

[2] The post-market surveillance and market monitoring of these devices, vigilance, and registration of economic operators and of the devices themselves are subject to the provisions of this Ordinance.

[3] Devices legally placed on the market prior to 26 May 2021 under the old legislation and devices placed on the market from 26 May 2021 under paragraph 1 can continue to be placed on the market or put into service until 26 May 2025. The above is subject to Article 103.

Art. 102 Exemptions for non-compliant medical devices

Exemptions issued by Swissmedic under Article 9 paragraph 4 of the Medical Devices Ordinance of 17 October 2001[96] shall retain their validity.

94 [AS **2001** 3487; **2004** 4037 no I 5, II para. 2; **2008** 4377 Annex 5 no 2; **2010** 1215, 2749 no I 7; **2015** 999; **2017** 5935; **2019** 999 Art. 28 para. 2; **2020** 2975]
95 [AS **2006** 3679]
96 See the footnote to Art. 99 no 1.

Art. 103 Devices incorporating devitalised tissue or cells of human origin

[1] Devices incorporating devitalised tissue or cells of human origin or their derivatives as specified in Article 1 paragraph 3 letter c no. 2 and d that were lawfully placed on the market or put into service prior to 26 May 2021 may still be placed on the market or put into service until 26 May 2025. Art. 101 paragraph 2 applies mutatis mutandis.

[2] Until such time as a corresponding special Ordinance is issued, devices covered by Article 2*a* paragraph 2 TPA are subject to the Medical Devices Ordinance of 17 October 2001[97]. Devices covered by Article 2*a* paragraph 2 TPA that were lawfully placed on the market prior to 26 May 2021 may still be placed on the market or put into service until such time as a corresponding special Ordinance is issued.

Art. 104 Affixing the UDI

The UDI required by Article 17 paragraph 2 must be affixed:

a. for implantable and class III devices: from 26 May 2021;

b. for class IIa and IIb devices: from 26 May 2023;

c. for class I devices: from 26 May 2025*;*

d. for reusable devices where the UDI has to be affixed to the product itself: two years after the dates given in letters a–c for the relevant product class.

Art. 104*a*[98] Appointment of authorised representatives

[1] If the manufacturer is domiciled in an EU or EEA state, or if the manufacturer has designated an authorised representative domiciled in an EU or EEA state, that manufacturer must designate an authorised representative in accordance with Article 51 paragraph 1 within the following time periods:

a. for class III devices, class IIb implantable devices and active implantable devices: by 31 December 2021;

b. for non-implantable class IIb devices and class IIa devices: by 31 March 2022;

c. for class I devices: by 31 July 2022.

[2] For systems and procedure packs, an authorised representative in accordance with Article 51 paragraph 5 must be appointed by 31 July 2022.

Art. 104*b*[99] Registration by economic operators

Economic operators that have placed devices on the market prior to 26 May 2021 in accordance with Article 22*a* of the Medical Devices Ordinance of 17 October

97 See the footnote to Art. 99 no 1.
98 Inserted by No I of the O of 19 May 2021, in force since 26 May 2021 (AS **2021** 281)
99 Inserted by No I of the O of 19 May 2021, in force since 26 May 2021 (AS **2021** 281)

2001[100] must register the information required under Article 55 paragraphs 1 and 5 by 26 November 2021.

Art. 105[101] In vitro diagnostic medical devices

[1] Until such time as a corresponding special Ordinance is issued, in vitro diagnostic medical devices are subject to the Medical Devices Ordinance of 17 October 2001[102], subject to paragraphs 2 and 3.

[2] In vitro diagnostic medical devices must not carry the name and address of the natural or legal person who first places them on the Swiss market on their labelling, outer packaging or instructions for use if they carry the name and address of the natural or legal person who places them on the market in an EU or EEA state.

[3] In vitro diagnostic medical devices that have been notified to the competent authority of an EU or EEA state in accordance with Article 6 paragraph 2 of the Medical Devices Ordinance of 17 October 2001 do not have to be additionally notified to Swissmedic.

Art. 106 Devices without an intended medical purpose

Unless Swissmedic has designated common specifications in accordance with Article 8 paragraph 1 for devices without an intended medical purpose in accordance with Annex 1, these devices are subject to the old legislation.

Art. 107 Conformity assessment bodies

[1] Conformity assessment body designations issued under Section 4 of the Medical Devices Ordinance of 17 October 2001[103] will become void.

[2] The conformity assessment body that issued the certificates under the old legislation will remain responsible for adequately monitoring these devices. It will be subject to supervision by Swissmedic.

[3] Conformity assessment body designations issued under Section 4*a* of the Medical Devices Ordinance of 17 October 2001 will retain their validity.

[4] Until a special Ordinance for in vitro diagnostic medical devices enters into force, the conformity assessment bodies for these devices will continue to be designated in accordance with Section 4 and 4*a* of the Medical Devices Ordinance of 17 October 2001.

Art. 108[104] Reporting devices, systems and procedure packs

[1] Until Article 17 paragraph 5 comes into force, the following reporting obligations will continue to apply to natural or legal persons domiciled in Switzerland:

100 See the footnote to Art. 99 no 1.
101 Amended by No I of the O of 19 May 2021, in force since 26 May 2021 (AS **2021** 281).
102 See the footnote to Art. 99 no 1.
103 See the footnote to Art. 99 no 1.
104 Amended by No I of the O of 19 May 2021, in force since 26 May 2021 (AS **2021** 281).

a. for manufacturers and natural or legal persons who assemble systems or procedure packs under Article 22 paragraphs 1 and 3 EU-MDR[105]: the reporting obligations set out in Article 6 paragraphs 1 and 4 of the Medical Devices Ordinance of 17 October 2001[106]:

b. for natural or legal persons who place medical devices on the market under Article 2 paragraph 1 of the Medical Devices Ordinance of 17 October 2001: the reporting obligations set out in Article 6 paragraphs 3 and 4 of the Medical Devices Ordinance of 17 October 2001.

2 …[107]

Art. 109[108]

Art. 110 Commencement

1 Subject to the exceptions in paragraph 2, this Ordinance comes into force on 26 May 2021.

2 Articles 17 paragraph 5 and 108 paragraph 2 will come into force at a later date.[109]

105 See the footnote to Art. 4 para. 1 let. f.
106 See the footnote to Art. 99 no 1.
107 To enter into force in due course (Art. 110 para. 2).
108 Repealed by No I of the O of 19 May 2021, with effect from 26 May 2021 (AS **2021** 281).
109 Amended by No I of the O of 19 May 2021, in force since 26 May 2021 (AS **2021** 281).

Annex 1
(Art. 1 para. 1 letter b)

Product groups without an intended medical purpose

1. Contact lenses or other items intended to be introduced into or onto the eye.
2. Products intended to be totally or partially introduced into the human body through surgically invasive means for the purpose of modifying the anatomy or fixation of body parts with the exception of products used in tattooing or body piercing.
3. Substances, combinations of substances, or items intended to be used for facial or other dermal or mucous membrane filling by subcutaneous, submucous or intradermal injection or other introduction, excluding those for tattooing.
4. Equipment intended to be used to reduce, remove or destroy adipose tissue, such as equipment for liposuction, lipolysis or lipoplasty.
5. High intensity electromagnetic radiation (e.g. infra-red, visible light and ultra-violet) emitting equipment intended for use on the human body, including coherent and non-coherent sources, monochromatic and broad spectrum, such as lasers and intense pulsed light equipment, for skin resurfacing, tattoo or hair removal or other skin treatment.
6. Equipment intended for brain stimulation that applies electrical currents or magnetic or electromagnetic fields that penetrate the cranium to modify neuronal activity in the brain.

Annex 2
(Art. 5 para. 1)

Equivalent terms

The terms listed below and used in EU-MDR[110] and this Ordinance are equivalent as follows:

EU	Switzerland
a. English terms	
Union	Switzerland
Member State	Switzerland
Third country	Other state
Union market	Swiss market
Union legislation / Union harmonisation legislation	Legislation
Harmonised standard	Designated standard
State of the art	Scientific and technological standards
EU declaration of conformity	Declaration of conformity
Official Journal of the European Union	Federal Gazette (*Bundesblatt*)
Established outside / within the Union	Domiciled in / outside Switzerland
Authority	Competent authority under Swiss law
Healthcare professional	Professional
Suspension	Suspension
Withdrawal	Revocation
Transplants	Organs
b. German terms	
Union	Schweiz
Mitgliedstaat	Schweiz
Drittstaat / Drittland	anderer Staat
Unionsmarkt	Schweizer Markt
Rechtsvorschriften der Union / Harmonisierungsrechtssvorschriften der Union	Rechtsvorschriften
Harmonisierte Norm	Bezeichnete Norm

110 See the footnote to Art. 4 para. 1 let. f.

EU	Switzerland
Stand der Technik	Stand von Wissenschaft und Technik
EU-Konformitätserklärung	Konformitätserklärung
Amtsblatt der Europäischen Union	Bundesblatt
Ausserhalb / In der Union ansässig	Sitz ausserhalb / in der Schweiz
Behörde	Nach schweizerischem Recht zuständige Behörde
Angehörige der Gesundheitsberufe	Fachpersonen
Aussetzung	Suspendierung
Zurückziehung	Widerruf
Transplantate	Organe
Union	Suisse
c. French terms	
État membre	Suisse
État tiers / pays tiers	autre État
marché de l'Union	marché suisse
législation (actes législatifs) de l'Union / législation d'harmonisation de l'Union	législations
norme harmonisée	norme désignée
état de l'art	état de la science et de la technique
déclaration de conformité UE	déclaration de conformité
investigation clinique	essai clinique
dispositif faisant l'objet d'une investigation	dispositif faisant l'objet d'un essai clinique
Journal officiel de l'Union européenne	Feuille fédérale
situé hors de l'Union / établi dans l'Union	sis à l'étranger / en Suisse
notice d'utilisation	mode d'emploi
conditionnement	emballage
notification des incidents graves	déclaration des incidents graves
autorités	autorités compétentes en vertu du droit suisse
professionnels de la santé	professionnels
retrait	révocation

EU	Switzerland
d. Italian terms	
Unione	Svizzera
Stato Membro	Svizzera
paese terzo	altro Stato
mercato dell'Unione	mercato svizzero
legislativo dell'Unione / normativa di armonizzazione dell'Unione	legislazioni
norma armonizzata	norma designata
stato dell'arte	stato della scienza e della tecnica
dichiarazione di conformità UE	dichiarazione di conformità
marcatura CE di conformità	marchio di conformità
Gazzetta ufficiale dell'Unione europea	Foglio federale
avente sede fuori dall'Unione,/ stabilito nell'Unione	avente sede all'estero/ in Svizzera
autorità	autorità competente secondo il diritto svizzero
operatori sanitari	specialisti
controllata	società controllata
ritiro	revoca
immissione sul mercato	immissione in commercio
segnalazione di incidenti gravi	notifica di incidenti gravi
indagini cliniche	sperimentazioni cliniche
dispositivo oggetto di indagine	dispositivo oggetto di sperimentazione clinica
confezionamento	imballaggio

Annex 3
(Art. 5 para. 2)

Applicable law

1 EU law

Where this Ordinance makes reference to provisions of EU-MDR[111] that in turn make reference to EU law, the versions below are applicable:

1.1 Regulation (EC) 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006, (OJ L 353 of 31.12.2080, p. 1).

1.2 Commission Regulation (EU) No 207/2012 of 9 March 2012 on electronic instructions for use of medical devices (OJ L 72 of 10.3.2012, p. 28).

1.3 Commission Regulation (EU) No 722/2012 of 8 August 2012 concerning particular requirements as regards the requirements laid down in Council Directives 90/385/EEC and 93/42/EEC with respect to active implantable medical devices and medical devices manufactured utilising tissues of animal origin(OJ L 212 of 9.8.2012, p. 3).

111 See the footnote to Art. 4 para. 1 let. f.

2 Swiss law

Where this Ordinance makes reference to provisions of EU-MDR[112] that in turn make reference to EU law, the Swiss law below is applicable in place of the EU law:

EU law	Swiss legislation
1. Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, OJ L 311 of 28.1.2001, p. 67.	Therapeutic Products Act of 15 December 2000[113]
2. Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, OJ L 136 of 30.4.2004, p. 1.	Therapeutic Products Act of 15 December 2000
3. Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004, OJ L 324 of 10.12.2017, p. 121.	Therapeutic Products Act of 15 December 2000
4. 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 of 5.5.2017, p. 176.	Therapeutic Products Act of 15 December 2000
5. Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products, OJ L 210 of 7.8.1985, p. 29.	Product Liability Act of 18 June 1993[114]

112 See the footnote to Art. 4 para. 1 let. f.
113 SR **812.21**
114 SR **221.112.944**

EU law	Swiss legislation
6. Directive 2014/30/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to electromagnetic compatibility, OJ L 96 of 29.3.2001, p. 79.	Ordinance of 25 November 2015[115] on Electromagnetic Compatibility
7. Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC, OJ L 157 of 09.06.2006, p. 24.	Machine Ordinance of 2 April 2008[116]
8. Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products, OJ L 324 of 22.12.2009, p. 59.	FDHA Ordinance of 16 December 2016[117] on Cosmetics
9. Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells, OJ L 102 of 7.4.2004, p. 48.	Therapeutic Products Act of 15 December 2000 and Transplantation Act of 8 October 2004[118]
10. Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC, OJ L 33 of 8.2.2003, p. 30.	Therapeutic Products Act of 15 December 2000 and Transplantation Act of 8 October 2004

115 SR **734.5**
116 SR **819.14**
117 SR **817.023.31**
118 SR **810.21**

EU law	Swiss legislation
11. Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety OJ L 31 of 1.2.2002, p. 1.	Foodstuffs Act of 20 June 2014[119]
12. Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council, OJ L 316 of 14.11.2021, p. 12.	Therapeutic Products Act of 15 December 2000 and Federal Act of 6 October 1995[120] on Technical Barriers to Trade
13. Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data, OJ L 8 of 12.1.2001, p. 1.	Federal Act of 19 June 1992[121] on Data Protection
14. Regulation (EC) No. 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93, OJ L 218 of 13.8.2008, p. 30.	Federal Act of 6 October 1995 on Technical Barriers to Trade and Product Safety Act of 12 June 2009[122]

119 SR **817.0**
120 SR **946.51**
121 SR **235.1**
122 SR **930.11**

EU law	Swiss legislation
15. Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, OJ L 396, 30.12.2006, p. 1.	Chemicals Act of 15 December 2000[123]
16. Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products, OJ L 167 of 27.6.2012, p. 1.	Ordinance on Biocidal Products of 18 May 2005[124]
17. Council Directive 80/181/EEC of 20 December 1979 on the approximation of the laws of the Member States relating to units of measurement and on the repeal of Directive 71/354/EEC, OJ L 39 of 15.2.1980, p. 40.	Metrology Act of 17 June 2011[125]
18. Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom, OJ L 13 of 17.1.2014, p. 1.	Radiological Protection Act of 22 March 1991[126]

123 SR **813.1**
124 SR **813.12**
125 SR **941.20**
126 SR **814.50**

EU law	Swiss legislation
19. Directive 2004/10/EC of the European Parliament and of the Council of 11 February 2004 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances, OJ L 50 of 20.2.2004, p. 44.	Ordinance of 18 May 2005[127] on Good Laboratory Practice
20. Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices, OJ L 189 of 20.7.1990, p. 17.	Medical Devices Ordinance of 17 October 2001
21. Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, OJ L 169 of 12.7.1993, p. 1.	Medical Devices Ordinance of 17 October 2001

127 SR **813.112.1**

Annex 4[128]
(Art. 4 para. 2, 17 para. 4, 19 para. 1 let. c, 20 para. 1, 23, 25 para. 3, 29 para. 2, 45 para. 2, 46 para. 3, 47 para. 1 and 98 para. 2 let. b)

Delegated acts of the European Commission based on EU-MDR[129]

For the purposes of implementing this Ordinance, the legal acts adopted on the basis of the provisions of EU-MDR set out below will apply in Switzerland in the binding version applicable to the EU Member States:

Subject matter	Passed by the European Commission based on the EU-MDR
Art. 4 para. 2 MedDO	Delegated act in accordance with Art. 3 EU-MDR
Art. 17 para. 4 MedDO	Delegated act in accordance with Art. 27 para. 10 EU-MDR
Art. 19, para. 1 let. c MedDO	Implementing act in accordance with Article 42 paragraph 13 EU-MDR
Art. 20 para. 1 MedDO	Delegated act in accordance with Art. 18 para. 3 EU-MDR
Art. 23 MedDO	Delegated act in accordance with Art. 52 para. 5 EU-MDR
Art. 25 para. 3 MedDO	Delegated act in accordance with Art. 56 para. 6 EU-MDR
Art. 29 para. 2 MedDO	Delegated act in accordance with Art. 19 para. 4 EU-MDR
Art. 45 para. 2 MedDO	Delegated act in accordance with Art. 44 para. 11 EU-MDR
Art. 46 para. 3 MedDO	Delegated act in accordance with Art. 61 para. 8 EU-MDR
Art. 47 para. 1 MedDO	Delegated act in accordance with Art. 10 para. 4 EU-MDR
Art. 98 para. 2 letter b MedDO	Delegated act in accordance with Art. 106 para. 15 EU-MDR

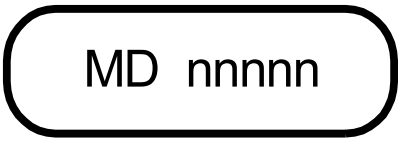
128 Revised by rectification of 4 May 2021 (AS **2021** 260).
129 See the footnote to Art. 4 para. 1 let. f.

Annex 5
(Art. 13 para. 1)

Conformity marking

The conformity marking is as follows:

Where a designated body has to be involved, its identification number is to be placed beside its conformity marking.



Annex 6
(Art. 70, paras 2 and 3)

Product groups intended for use by professionals, qualifications and circumstances of use

1. Product groups

Devices for injection intended to remain in the human body for longer than 30 days (long-term injectable devices) must only be used by a doctor or by a professional with the qualifications set out in number 2 under the direct supervision of a doctor, who will be deemed accountable.

2. Qualifications

Long-term injectable devices may be used by qualified healthcare professionals with appropriate training in the injection of long-term implantable devices.