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Medical Devices Ordinance **(MedDO)**

of 17 October 2001 (Status as of 1 August 2020)

The Swiss Federal Council,

based on Articles 2 paragraph 2, 4 paragraph 2, 45 paragraph 3, 46 paragraph 2, 47 paragraph 2, 48, 49 paragraph 2, 50 paragraph 1, 51 and 82 of the Therapeutic Products Act of 15 December 2000¹ (TPA),

based on Article 21 number 2 of the Electricity Act of 24 June 1902²,

based on Article 9 paragraph 1 letter b of the Federal Act of 9 June 1977³ on Metrology,

based on Article 4 paragraph 1 of the Federal Act of 12 June 2009⁴ on Products Safety,

based on Article 37 of the Federal Act on Radiological Protection of 22 March 1991⁵ and in implementation the Federal Act of 6 October 1995⁶ on Technical Barriers to Trade,⁷

ordains:

Section 1 General Provisions

Art. 1 Medical Devices

¹ Medical devices are instruments, apparatus, appliances, software, materials, accessories or other medical technology articles, whether used alone or in combination, including the software intended to be used specifically for diagnostic or therapeutic purposes and necessary for the proper application of a medical device:

- a. that are intended for use on human beings;

AS 2001 3487

¹ SR 812.21

² SR 734.0

³ [AS 1977 2394, 1993 3149, 2006 2197 Annex No 134, 2010 5003 Annex No 6. AS 2012 6235 Art. 25]. See now: FA of 17 June 2011 (SR 941.20).

⁴ SR 930.11

⁵ SR 814.50

⁶ SR 946.51

⁷ Amended by No I 7 of the O of 11 June 2010 on the Revision of Sectoral O in the Field of Product Safety, in force since 1 July 2010 (AS 2010 2749).

- 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:
 1. diagnose, prevent, monitor, treat or alleviate diseases,
 2. diagnose, monitor, treat or alleviate injuries or disabilities, or compensate handicaps,
 3. investigate or modify the anatomy, to replace parts thereof, or to investigate, modify or replace a physiological process,
 4. control conception or to make diagnoses in relation to conception.⁸

² Medical devices are divided into:

- a. classical medical devices;
- b. in vitro diagnostic medical devices;
- c. active implantable medical devices.

³ In vitro diagnostic medical devices are medical devices which are used as a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system in accordance with their specified purpose for the in vitro examination of specimens derived from the human body, including blood and tissue donations, and which are used solely or principally for the purpose of providing information:

- a. on physiological or pathological states;
- b. on congenital abnormalities;
- c. to determine safety and compatibility with potential recipients;
- d. to monitor therapeutic measures.

⁴ Active implantable medical devices are medical devices:

- a. which rely for their functioning on a source of electrical energy or any source of power other than that directly generated by the human body or gravity;
- b. which are intended to be totally or partially introduced into the human body by means of a surgical or medical intervention or into a natural orifice by means of a medical intervention; and
- c. which are intended to remain there after the procedure.

⁵ Classical medical devices are medical devices which are neither active implantable medical devices nor in vitro diagnostic medical devices.

Art. 1a⁹ Custom-made devices

¹ Custom-made devices are medical devices made for an individual named patient.

⁸ Amended by No I of the O of 24 Mar. 2010, in force since 1 April 2010 (AS 2010 1215).

⁹ Inserted by No I of the O of 24 Mar. 2010, in force since 1 April 2010 (AS 2010 1215).

² They must be manufactured on written prescription and under the responsibility of a duly qualified professional.

³ The conformity assessment procedure corresponds to that described in Annex 3.

⁴ Mass-produced medical devices which need to be adapted to meet the specific requirement of the professional applying them are not considered to be custom-made devices.

Art. 2 Exceptions from scope

¹ Only Article 6 paragraph 3, 26 and 27 and Section 5 apply to classical and active implantable medical devices derived from devitalised human tissue, or which incorporate such tissue.

² With regard to classical and active implantable medical devices, this Ordinance does not apply to:

- a.¹⁰ human blood, human blood products, human plasma or blood cells of human origin, or products which incorporate at the time of placing on the market such blood, blood products, plasma or cells of human origin, except if this concerns substances which, if used separately, are considered to be a medicinal product constituent or a medicinal product derived from human blood or human blood plasma within the meaning of Article 1 of Directive 2001/83/EC¹¹ of the European Parliament and of the Council of 6 November 2001 on Community code relating to medicinal products for human use, and which are liable to act on the human body in a manner that is ancillary to that of the device;
- b.¹² vital organs, tissues or cells of human origin, or transplant products;
- c. organs, tissues or cells of animal origin, unless a device has been manufactured using devitalised animal tissue or devitalised products derived from animal tissue.

Art. 3 Definitions

¹ In this Ordinance:

- a. *accessory* means articles which are not medical devices in their own right but which are intended specifically by their manufacturer to be used together with a medical device, in accordance with the instructions of the manufacturer of the medical device;
- b.¹³ ...

¹⁰ Amended by No I of the O of 24 Mar. 2010, in force since 1 April 2010 (AS **2010** 1215).

¹¹ OJ L 311 of 28.11.2001, p. 67, last amended by Directive 2009/53/EC, OJ L 168 of 30.6.2009, p. 33. The texts of the Directives and Regulations mentioned in this Ordinance may be consulted and obtained from the Swiss Association for Standardisation, Sulzerallee 70, 8404 Winterthur (www.snv.ch); or at the website: <http://eur-lex.europa.eu>

¹² Amended by No I of the O of 24 Mar. 2010, in force since 1 April 2010 (AS **2010** 1215).

¹³ Repealed by No I of the O of 24 Mar. 2010, with effect since 1 April 2010 (AS **2010** 1215).

- b^{bis}.¹⁴ *medical device manufactured in house* means a medical device that is only intended for use in the manufacturing company or in a partner company included in the quality assurance system of the manufacturing company;
- b^{ter}.¹⁵ *system and procedure pack* means a set of several classical medical devices for which the declarations of conformity are available and which are put together for the use intended by the person first placing the devices on the market;
- c. *performance evaluation* means the provision of proof that under normal operating conditions, an in vitro diagnostic medical device fulfils the performance requirements;
- d. *incident*: means an event associated with a medical device, resulting from a malfunction of the device, a change in significant characteristics, inadequacies in the labelling or instructions for use, and which has led, or could have led, to the death or a serious deterioration in the state of health of patients, users or third parties;
- e.¹⁶ *treaty country* means a state with which Switzerland has concluded an agreement under international law for the mutual recognition of conformity assessments and corresponding procedures for medical devices;
- f.¹⁷ *third country* means a state with which Switzerland has not concluded an agreement under international law for the mutual recognition of conformity assessments and corresponding procedures for medical devices.
- ² The first placing on the market is considered to be when a new device or a device which has been reprocessed or modified in such a way that it no longer serves its intended purpose or produces the intended performance is provided or transferred in Switzerland for the first time, either free of charge or subject to payment. The first placing on the market is also considered to be the use by professionals of a medical device directly imported from a third country or of a medical device produced in house.¹⁸

Section 2 Requirements for Placing on the Market

Art. 4 Requirements for medical devices

¹ The essential requirements in accordance with Article 45 paragraph 2 of the Therapeutic Products Act are specified for:

- a. classical medical devices: in Annex I of Directive 93/42/EEC of the European Council on Medical Devices of 14 June 1993¹⁹ (Directive 93/42/EEC);

¹⁴ Inserted by No I of the O of 24 Mar. 2010, in force since 1 April 2010 (AS **2010** 1215).

¹⁵ Inserted by No I of the O of 24 Mar. 2010, in force since 1 April 2010 (AS **2010** 1215).

¹⁶ Inserted by No I 5 of the O of 18 Aug. 2004, in force since 1 Sept. 2004 (AS **2004** 4037).

¹⁷ Inserted by No I 5 of the O of 18 Aug. 2004, in force since 1 Sept. 2004 (AS **2004** 4037).

¹⁸ Amended by No I of the O of 24 Mar. 2010, in force since 1 April 2010 (AS **2010** 1215).

¹⁹ OJ L 169 of 12.7.1993, p. 1, last amended by Directive 2007/47/EC, OJ L 247 of 21.9.2007, p. 21.

- b.²⁰ in vitro diagnostic medical devices: in Annex I of Directive 98/79/EC²¹;
- c. active implantable medical devices: in Annex 1 of Directive 90/385/EEC of the European Council of 20 June 1990²² on the approximation of the laws of the Member States relating to active implantable medical devices (Directive 90/385/EEC).²³

^l_{bis} Classical and active implantable medical devices which are also machines within the meaning of Directive 2006/42/EU the European Parliament and of the Council of 17 May 2006²⁴ on Machinery and amending Directive 95/16/EU (new version) must comply with the essential health and safety requirements in accordance with Annex 1 of the said Directive if the latter are more specific than the essential requirements in accordance with paragraph 1.²⁵

^l_{ter} Classical medical devices that are intended both for use as medical devices and for use in accordance with the provisions relating to personal protective equipment as stipulated in Directive 89/686/EEC of the European Council of 21 December 1989²⁶ on the approximation of the laws of the Member States relating to personal protective equipment must also comply with the relevant essential health and safety requirements of this Directive.²⁷

² Compliance with the essential requirements covered by technical standards²⁸, common technical specifications²⁹ or prescriptions of the pharmacopoeia³⁰ is presumed if the medical device is in conformity with these standards, specifications or prescriptions.

³ The Swiss Agency for Therapeutic Products (Agency) establishes which technical standards and common technical specifications appropriately cover the essential requirements for medical devices, and publishes the titles and references thereof in the Federal Gazette.

²⁰ Amended by No I of the O of 25 Oct. 2017, in force since 26 Nov. 2017 (AS **2017** 5935).

²¹ Directive 98/79/EG of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices, OJ L 331 of 7.12.1998, p. 1; last amended by Directive 2011/100/EU, OJ L 341 of 22.12.2011, p. 50.

²² OJ L 189 of 20.7.1990, p. 17, last amended by Directive 2007/47/EC, OJ L 247 of 21.9.2007, p. 21.

²³ Amended by No I of the O of 24 Mar. 2010, in force since 1 April 2010 (AS **2010** 1215).

²⁴ OJ L 157 of 9.6.2006, p. 24, last amended by Commission Regulation (EC) No 596/2009, OJ L 188 of 18.7.2009, p. 14.

²⁵ Inserted by No I of the O of 24 Mar. 2010, in force since 1 April 2010 (AS **2010** 1215).

²⁶ OJ L 399 of 30.12.1989, p. 18, last amended by Commission Regulation (EC) No 596/2009, OJ L 188 of 18.7.2009, p. 14.

²⁷ Inserted by No I of the O of 24 Mar. 2010, in force since 1 April 2010 (AS **2010** 1215).

²⁸ Technical standards (with the exception of electrotechnical standards) can be obtained the Swiss Association for Standardisation, Sulzerallee 70, 8404 Winterthur (www.snv.ch). Electrotechnical standards can be obtained from the Association Electrosuisse, Luppenstrasse 1, 8320 Fehraltendorf, www.electrosuisse.ch.

²⁹ Common technical specifications can be obtained from the SNV.

³⁰ SR **812.211**

⁴ The provisions of the Environmental Protection Act of 7 October 1983³¹ and the Genetic Engineering Act of 21 March 2003³² also apply to the placing on the market of medical devices that are substances or contain organisms.³³

⁵ For the classification, packaging and labelling of in vitro diagnostic medical devices, as well as for classical medical devices which are non-invasive and which do not come into contact with the human body during use, the relevant provisions of Regulation (EC) No 1272/2008³⁴ apply.³⁵

Art. 5³⁶ Classification

¹ Classical medical devices shall be classified as Class I, *Ila*, *Ilb* or III by the person first placing them on the market on the basis of the possible risks they may present when used as intended. This classification must comply with the provisions of Annex IX of Directive 93/42/EEC^{37 38 39}

² A classification already carried out as laid down in paragraph 1 may be used for medical devices imported from a treaty country.

Art. 6 Mandatory notification for the placing of medical devices on the market

¹ The person first placing the following medical devices on the market in Switzerland or in a treaty country and whose place of business is in Switzerland must notify the Agency of the name and address and a description of the devices concerned at the latest by the time they are placed on the market:

- a. class I medical devices;
- b. custom-made classical or active implantable medical devices;
- c. systems and procedure packs.⁴⁰

³¹ SR **814.01**

³² SR **814.91**

³³ Amended by Annex 5 No 2 of the Ordinance on the Handling of Organisms in the Environment of 10 Sept. 2008, in force since 1 Oct. 2008 (AS **2008** 4377).

³⁴ 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 31.12.2008, p. 1; last amended by Regulation (EU) 2016/1179, OJ L 195 of 20.7.2016, p. 11.

³⁵ Inserted by No I 5 of the O of 18 Aug. 2004, (AS **2004** 4037). Amended by No I of the O of 25 Oct. 2017, in force since 26 Nov. 2017 (AS **2017** 5935).

³⁶ Amended by No I 5 of the O of 18 Aug. 2004, in force since 1 Sept. 2004 (AS **2004** 4037).

³⁷ OJ L 169 of 12.7.1993, p. 1, last amended by Directive 2007/47/EC, OJ L 247 of 21.9.2007, p. 21.

³⁸ New classifications which are made within the framework of Directive 93/42/EEC are also applicable to this O.

³⁹ Amended by No I of the O of 24 Mar. 2010, in force since 1 April 2010 (AS **2010** 1215).

⁴⁰ Amended by No I of the O of 24 Mar. 2010, in force since 1 April 2010 (AS **2010** 1215).

² The person first placing in vitro diagnostic medical devices on the market in Switzerland or in a treaty country and whose place of business is in Switzerland must notify the Agency, at the latest by the time they are placed on the market, of:

- a. the name and address;
- b. the devices which are to be placed on the market, including their general technology and application;
- c. for devices in accordance with Annex II of Directive 98/79/EC⁴¹ and for devices for self-testing:⁴²
 1. the name of the devices,
 2. all information which permits the identification of the devices,
 3. the performance characteristics in accordance with Annex I, Section A, Number 3 of Directive 98/79/EC,
 4. the results of the performance evaluation,
 5. the certificates relating to the executed conformity assessment procedures.

^{2bis} For in vitro diagnostic medical devices manufactured in house, a notification need only be submitted for medical devices in accordance with Annex II of Directive 98/79/EC. For medical devices in List A of the said annex, confirmation of accreditation, authorisation or recognition must be included in addition to the documents in paragraph 2 letter c, if:

- a. the manufacturing company is a nationally designated reference laboratory or a laboratory with an equivalent qualification; and
- b. no common technical specifications exist for the medical devices in question.⁴³

³ The person placing medical devices on the market in Switzerland in accordance with Article 2 paragraph 1 must inform the agency, at the latest by the time they are placed on the market, of:

- a. the name and address;
- b. the devices to be placed on the market, including their general technology and application.

⁴ Changes to the information required in paragraphs 1–3 must be reported once a year to the Agency, in consolidated form.

Art. 7 Product information

¹ Product information is subject to the following provisions:

- a. classical medical devices: Annex I Section 13 of Directive 93/42/EEC⁴⁴;

⁴¹ See the footnote to Art. 4 para. 1 let. b.

⁴² Amended by No I of the O of 25 Oct. 2017, in force since 26 Nov. 2017 (AS 2017 5935).

⁴³ Inserted by No I of the O of 24 Mar. 2010, in force since 1 April 2010 (AS 2010 1215).

⁴⁴ OJ L 169 of 12.7.1993, p. 1, last amended by Directive 2007/47/EC, OJ L 247 of 21.9.2007, p. 21.

- b. active implantable medical devices: Annex 1 Sections 14 and 15 of Directive 90/385/EEC⁴⁵;
- c.⁴⁶ in vitro diagnostic medical devices: Annex I Section 8 of Directive 98/79/EC^{47,48}

² The product information must be written in all three official languages of Switzerland. Symbols established by means of harmonised standards may be used to replace written material.

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

- a.⁴⁹ the medical device is supplied exclusively to professionals or is a custom-made device or a medical device manufactured in house;
- b. it is ensured that the user meets the necessary professional and linguistic requirements and qualifications, and agrees to the language restriction;
- c. the protection of patients, users and third parties is nevertheless 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.

Art. 8⁵⁰ Conformity marking and identification number

¹ All medical devices placed on the market in Switzerland must bear the conformity marking in accordance with Annex 1. Foreign conformity marking, as shown in Annex 2, is also accepted.

² No conformity marking is necessary for:

- a. custom-made devices;
- b. products exclusively for demonstration and exhibition purposes;
- c. systems and procedure packs;
- d. devices for clinical trials;
- e. devices for performance evaluation.

⁴⁵ OJ L 189 of 20.7.1990, p. 17, last amended by Directive 2007/47/EC, OJ L 247 of 21.9.2007, p. 21.

⁴⁶ Amended by No I of the O of 25 Oct. 2017, in force since 26 Nov. 2017 (AS 2017 5935).

⁴⁷ See the footnote to Art. 4 para. 1 let. b.

⁴⁸ Amended by No I of the O of 24 Mar. 2010, in force since 1 April 2010 (AS 2010 1215).

⁴⁹ Amended by No I of the O of 24 Mar. 2010, in force since 1 April 2010 (AS 2010 1215).

⁵⁰ Amended by No I of the O of 24 Mar. 2010, in force since 1 April 2010 (AS 2010 1215).

³ For an in vitro diagnostic medical device manufactured in-house, conformity marking is only necessary if the device is a medical device in accordance with Annex II of Directive 98/79/EC⁵¹. No conformity marking is however necessary for a device as laid down in List A of the said Annex if:⁵²

- a. the manufacturing company is a nationally designated reference laboratory or a laboratory with an equivalent qualification; and
- b. no common technical specifications exist for the medical device in question.

⁴ Medical devices for which the conformity must be assessed by a conformity assessment body in accordance with Annex 3 must, in addition to the conformity marking, bear the identification number of the conformity assessment body involved. For foreign conformity markings, the Agency may accept, instead of the identification number, other information concerning the conformity assessment body.

⁵ The conformity marking, and where necessary the corresponding identification number, must be placed on the medical device itself or, where this is not possible or appropriate, on the packaging and on the instructions for use and, if possible, on the commercial packaging. The markings must be clearly visible, easy to read and indelible.

⁶ The Agency may publish the identification numbers or the information replacing them as laid down in paragraph 4.

Section 3 Conformity Assessment

Art. 9 Principle

¹ Any person placing medical devices on the market in Switzerland must, on demand, provide the declaration of conformity to the authorities responsible for monitoring within the framework of market surveillance.

² Any person first placing a medical device on the market in Switzerland or in a treaty country and whose place of business is in Switzerland must be able to provide evidence that the device meets the essential requirements and provides the efficacy and/or performance claimed for it.

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

⁴ In response to a justified application, the Agency may authorise the first placing on the market and initial operation of a specific medical 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 has not been carried out; or

⁵¹ See the footnote to Art. 4 para. 1 let. b.

⁵² Amended by No I of the O of 25 Oct. 2017, in force since 26 Nov. 2017 (AS 2017 5935).

- b. the language requirements in Article 7 paragraph 2 have not been met.⁵³

⁵ Individual medical devices that have not undergone the relevant conformity assessment procedure may be placed on the market and used without authorisation from the Agency 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 medical professionals on individual persons;
- d. the medical 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 medical device.⁵⁴

Art. 10 Procedure and Certificate

¹ The procedure for conformity assessment, the necessary certificate and the declaration of conformity are specified in Annex 3.

² When a conformity assessment body is used, all the information necessary for the conformity assessment must be made available to it.

³ A certificate which has been modified, suspended or withdrawn by a conformity assessment body may not be used further in its original form.

Section 4 Conformity Assessment Bodies

Art. 11 Prerequisites

¹ The conformity assessment bodies must:

- a.⁵⁵ be accredited by the Swiss Accreditation Service in accordance with the Accreditation and Designation Ordinance of 17 June 1996⁵⁶ (AccDO) and be designated by the Agency as such; or
- b.⁵⁷ ...
- c. be recognised by Switzerland within the framework of an international treaty.

^{1bis} The Agency shall only designate conformity assessment bodies which meet the conditions of Annex 3a number 1 in addition to the requirements of AccDO. For this

⁵³ Amended by No I of the O of 1 July 2020, in force since 1 Aug. 2020 (AS 2020 2975).

⁵⁴ Inserted by No I of the O of 1 July 2020, in force since 1 Aug. 2020 (AS 2020 2975).

⁵⁵ Amended by No I of the O of 25 Oct. 2017, in force since 26 Nov. 2017 (AS 2017 5935).

⁵⁶ SR 946.512

⁵⁷ Repealed by No I of the O of 1 April 2015, with effect since 15 April 2015 (AS 2015 999).

purpose, it shall thoroughly assess the conformity assessment body concerned; this assessment shall include an on-site assessment.⁵⁸

² Foreign assessment bodies which are not recognised under paragraph 1 may be used if it can be demonstrated to the satisfaction of the Agency that:

- a. the examination or conformity assessment procedures used meet Swiss requirements; and
- b. the foreign assessment body has a qualification that is equivalent to that required in Switzerland.

³ The State Secretariat for Economic Affairs may, in agreement with the Agency, order that assessment bodies under paragraph 2 or the certificates issued by them are not recognised if appropriate Swiss assessment bodies or the certificates issued by them are not recognised by the State in which the foreign assessment body is located. In such cases, in addition to interests related to health policy, interests related to the Swiss national economy and to foreign economic relations shall also be taken into account.

Art. 11a⁵⁹ Duration, renewal and extension of designation

¹ The designation shall be granted for a fixed term and shall be limited to a maximum of five years.

² It may be renewed for a maximum of five years at a time. An application therefor shall be made before the end of the validity period.

³ The Agency may extend the scope of the designation on request.

⁴ Both to renew the designation and to extend its scope, the Agency shall conduct the same assessments, including an on-site assessment, as for the designation. To renew the designation, it may also observe an audit conducted by the conformity assessment body at the premises of one of its clients.

Art. 11b⁶⁰ Cooperation with the European Commission and the Member States of the European Union

Where prescribed by international agreement, the Agency shall cooperate with the European Commission and the Member States of the European Union (EU) in the procedure for designation, or for the renewal or extension thereof. Cooperation is regulated by Annex 3b number 1.

⁵⁸ Inserted by No I of the O of 1 April 2015 (AS 2015 999). Amended by No I of the O of 25 Oct. 2017, in force since 26 Nov. 2017 (AS 2017 5935)

⁵⁹ Inserted by No I of the O of 1 April 2015, in force since 15 April 2015 (AS 2015 999).

⁶⁰ Inserted by No I of the O of 1 April 2015 (AS 2015 999). Amended by No I of the O of 25 Oct. 2017, in force since 26 Nov. 2017 (AS 2017 5935).

Art. 12⁶¹ Validity of the certificates

¹ Decisions and certificates in accordance with the procedure laid down in Annexes II, III, V and VI of Directives 93/42/EEC⁶² and 90/385/EEC⁶³ and Annexes 2, 3 and 5 of Directive 90/385/EEC and Annexes III, IV, V and VII of Directive 98/79/EC⁶⁴ may be taken or issued by conformity assessment bodies and may have a maximum validity of five years. On application, the certificates may be extended for a maximum of five years at a time.

² Conformity assessment bodies must suspend, withdraw or restrict a certificate they have issued when the prerequisites for its issue are no longer met.

Art. 12a⁶⁵ Validity of the certificates on the cessation of activities by the conformity assessment body

¹ Where a conformity assessment body completely or partially ceases its activities, the Agency may on request allow the manufacturer of the medical devices concerned or the person who first places the medical devices concerned on the market a period of no more than twelve months or set such a period *ex officio* within which to have the conformity of the medical devices certified by another conformity assessment body.

² It may extend the period under paragraph 1 by a maximum of twelve months.

³ Within the period set by the Agency, the certificates may continue to be used in their original form. The manufacturer or the person who first places the medical device on the market remains responsible for the safety, effectiveness and performance of the medical device.

⁴ The Agency determines the requirements that the manufacturer of the medical device concerned or the person who first places the medical device on the market must meet within the period set by the Agency.

Art. 13⁶⁶ Reporting and information obligations

¹ The conformity assessment bodies shall report all certificates that they issue, modify, supplement, suspend, restrict, withdraw, or refuse to the Agency, stating the devices affected.

² The conformity assessment bodies shall notify the other conformity assessment bodies of any certificate that they suspend, withdraw, or refuse, stating the devices affected. On request, they also inform them of certificates that they have issued, modified or supplemented, and make additional relevant information available.

⁶¹ Amended by No I of the O of 24 Mar. 2010, in force since 1 April 2010 (AS **2010** 1215).

⁶² OJ L 169 of 12.7.1993, p. 1, last amended by Directive 2007/47/EC, OJ L 247 of 21.9.2007, p. 21.

⁶³ OJ L 189 of 20.7.1990, p. 17, last amended by Directive 2007/47/EC, OJ L 247 of 21.9.2007, p. 21.

⁶⁴ OJ L 331 of 7.12.1998, p. 1, last amended by Regulation (EC) No 596/2009, OJ L 188 of 18.7.2009, p. 14.

⁶⁵ Inserted by No I of the O of 25 Oct. 2017, in force since 26 Nov. 2017 (AS **2017** 5935).

⁶⁶ Amended by No I of the O of 24 Mar. 2010, in force since 1 April 2010 (AS **2010** 1215).

Art. 13a⁶⁷ Subsequent surveillance of conformity assessment bodies

¹ The Agency shall monitor the conformity assessment bodies in accordance with Article 32 AccDO and Annex 3c number 1.⁶⁸

² It may at any time:

- a. conduct announced or unannounced on-site assessments;
- b. observe audits conducted by the conformity assessment body at the premises of its clients.

Section 4a⁶⁹**Conformity Assessment Bodies in terms of the Regulation of the European Parliament and of the Council of 5 April 2017 on Medical Devices and the Regulation of the European Parliament and of the Council of 5 April 2017 on In Vitro Diagnostic Medical Devices****Art. 13b** Requirements

Conformity assessment bodies that wish to carry out conformity assessment activities in accordance with Regulation (EU) 2017/745⁷⁰ on medical devices (MDR) and Regulation (EU) 2017/746⁷¹ on in vitro diagnostic medical devices (IVDR) must:

- a. meet the requirements of Article 11 paragraph 1 and Annex 3a section 2;
- b. be capable of carrying out the conformity assessment activities in accordance with the MDR and the IVDR; and
- c. have undergone an assessment procedure in accordance with Article 13d.

Art. 13c Application

¹ The application for designation as a conformity assessment body under Article 13b must be submitted to the Agency. It 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 3a section 2 have been met.

⁶⁷ Inserted by No I of the O of 1 April 2015, in force since 15 April 2015 (AS 2015 999)

⁶⁸ Amended by No I of the O of 25 Oct. 2017, in force since 26 Nov. 2017 (AS 2017 5935).

⁶⁹ Inserted by No I of the O of 25 Oct. 2017, in force since 26 Nov. 2017 (AS 2017 5935).

⁷⁰ 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; amended by OJ L 117 of 5.5.2017, p. 1.

⁷¹ 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; amended by OJ L 117 of 5.5.2017, p. 176.

² The Agency shall check within thirty days whether the application for designation is complete, and if necessary request the applicant to submit any information that is missing.

³ It shall check the application and the accompanying documents and issue a preliminary assessment report.

Art. 13d Assessment

¹ The Agency shall conduct an on-site assessment of the conformity assessment body and if applicable of all sub-contractors and subsidiaries. It shall provide the applicant conformity assessment body with a list of the non-compliances identified in the assessment.

² The conformity assessment body shall submit a plan with corrective measures to eliminate the deficiencies and a plan with preventive measures to the Agency within the timeframe allowed. The plan shall indicate the root cause of the identified non-compliances and shall include a timeframe for implementing the measures.

³ The Agency shall decide whether the measures proposed by the conformity assessment body to eliminate the non-compliances identified in the assessment are suitable and the planned timeframe is appropriate.

⁴ If the Agency agrees to the proposal mentioned in paragraph 2, it shall draw up a final assessment report including 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. 13e Granting the designation

¹ The Agency shall grant the designation if the conformity assessment body meets the requirements. In doing so, it shall take account of the following provisions in particular:

- a. scope and definitions: Articles 1 and 2 MDR⁷² and Articles 1 and 2 IVDR⁷³ respectively;
- b. declaration of conformity and marking: Articles 19 and 20 as well as Annexes IV and V MDR and Articles 17 and 18 as well as Annexes IV and V IVDR respectively;
- c. classification: Article 51 and Annex VIII MDR and Article 47 and Annex VIII IVDR respectively;
- d. conformity assessment procedure and certificates of conformity: Articles 52–59 and Annexes IX–XIII MDR, and Articles 48–54 and Annexes IX–XII IVDR respectively.

⁷² See the footnote to Art. 13b.

⁷³ See the footnote to Art. 13b.

² In addition, it shall take account of the following provisions, insofar as they impose obligations on the conformity assessment body:

- a. provisions relating to the review of the quality management system for the provision of information and changes to the outer packaging in accordance with Articles 16 MDR and 16 IVDR;
- b. provisions relating to the review of clinical valuations under Article 61 MDR or relating to the performance evaluation and clinical evidence under Article 56 IVDR;
- c. provisions relating to the review of the report on the safety of products under Articles 86 MDR and 81 IVDR.

Art. 13f Expanding the designation

The requirements and procedures in Articles 13c–13e apply to expanding a designation.

Art. 13g Sub-contractors and subsidiaries

¹ Conformity assessment 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 under the sub-contract or by the subsidiary.

² They shall ensure that the sub-contractor or the subsidiary meets the applicable requirements of Annex 3a section 2. They must be able to prove to the Agency that the sub-contractor or the subsidiary is capable of carrying out the tasks assigned to it.

³ They shall notify the Agency within 15 days if they delegate work in terms of paragraph 1.

⁴ They shall publish a list of their subsidiaries.

Art. 13h Cessation of conformity assessment activities

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

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

³ The conformity assessment body assuming responsibility in terms of 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.

Art. 13i Suspension, restriction and withdrawal of the designation

¹ The designation shall be suspended, restricted or withdrawn if the conformity assessment body:

- a. no longer or only partly meets the requirements; or
- b. fails to carry out corrective measures ordered by the Agency.

² A suspension is imposed for a maximum of twelve months. It may be extended by a maximum of a further twelve months.

³ If its designation is suspended, restricted or withdrawn, the conformity assessment body must notify all the manufacturers concerned or all persons placing the medical devices concerned on the market for the first time within ten days.

Art. 13j Unduly issued certificates

¹ In the event of any restriction, suspension or of a withdrawal of a designation, the conformity assessment body shall suspend or withdraw any certificates which were unduly issued.

² If the conformity assessment body fails to fulfil this obligation, the Agency shall order it to suspend or withdraw the certificates. It shall allow an appropriate period for doing so.

Art. 13k Validity of the certificates in the event of the suspension or restriction of the designation

¹ If the Agency suspends or restricts the designation of a conformity assessment body, the certificates concerned remain valid provided the Agency:

- a. confirms within a month that there is no safety issue with the products concerned; and
- b. outlines a timeline and measures to remedy the suspension or restriction.

² The certificates also remain valid if the Agency:

- a. confirms that during the suspension or restriction, no certificates relevant to the suspension will be issued, amended or re-issued; and
- b. states whether the conformity assessment body is able to continue to monitor and remain responsible for existing certificates during the suspension or restriction.

³ The conformity assessment body shall notify the manufacturers concerned or the persons placing the medical devices concerned on the market for the first time.

⁴ If the Agency determines that the conformity assessment body is unable to support existing certificates, these certificates remain valid provided the manufacturer of the product concerned or the person placing the product concerned on the market for the first time confirms in writing to the Agency or, if he or she is based in a contracting state, to the authority responsible for medical devices there within three months following suspension or restriction of the designation that another qualified con-

formity assessment body is temporarily assuming the task of monitoring and will remain responsible for the certificates during the suspension or restriction.

Art. 13/ Validity of the certificates in the case of withdrawal the designation

¹ If the Agency withdraws the designation of a conformity assessment body, the certificates affected remain valid for nine months provided:

- a. the Agency or the competent authority for medical devices in the contracting state where the manufacturers concerned or the person placing the medical devices concerned on the market for the first time have their place of business confirms that there is no safety issue associated with the devices in question; and
- b. another conformity assessment 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 the withdrawal of the designation.

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

Art. 13m Duty of involvement, to report and to provide information

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

² The conformity assessment bodies shall notify the Agency within 15 days of any change that affects their ability to meet the requirements of Annex 3a number 2 or to carry out conformity assessments.

³ In relation to certificates, the duty to report and to provide information is governed by Article 13.

Art. 13n Monitoring and re-assessment of the conformity assessment bodies

¹ The Agency shall monitor the conformity assessment bodies and their subsidiaries and sub-contractors and carry out re-assessments. Monitoring and re-assessments are carried out in accordance with Annex 3c number 2.

² At least once a year, the Agency shall review whether the conformity assessment bodies and if applicable their subsidiaries and sub-contractors meet the requirements and obligations of Annex 3a number 2.

³ For this purpose, it may at any time:

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

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

⁴ The Agency may publish the summary of the annual report on monitoring activities and on-site assessments in terms of Article 44 paragraph 12 MDR⁷⁴ or Article 40 paragraph 12 IVDR⁷⁵.

Art. 13o Tariffs

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

Art. 13p Cooperation with the European Commission and the member states the EU

¹ The Agency shall cooperate with the European Commission and the EU member states in particular in relation to designation and its amendment or extension and in the monitoring and re-assessment of a conformity assessment body, insofar as this is provided for by an international agreement. Cooperation is governed by Annex 3b number 2.

² The Agency shall appoint experts who are qualified to assess conformity assessment bodies in the field of medical devices.

³ Where an international agreement permits enquiries from the European Commission or an EU member state in connection with a conformity assessment carried out by a conformity assessment body, the conformity assessment body shall answer these immediately, and within 15 days at the latest. It shall inform the Agency that it has received such enquiries and provide it with copies of the enquiries and of the answers.

Section 5 Product Surveillance

Art. 14⁷⁶ Post-market surveillance

¹ The person first placing the device on the market in Switzerland or in a treaty country must take appropriate measures in order to be in a position, during the lifecycle of a device, to:

- a. recognise the risks that could be caused by the device;
- b. prevent possible risks;
- c. ensure the traceability of the device.

⁷⁴ See the footnote to Art. 13b.

⁷⁵ See the footnote to Art. 13b.

⁷⁶ Amended by No I 7 of the O of 11 June 2010 on the Revision of Sectoral O in the Field of Product Safety, in force since 1 July 2010 (AS 2010 2749).

² For this purpose, the said person must operate a product surveillance system and compile the following product-specific information:

- a. complaints;
- b. relevant experience concerning use and efficacy;
- c. reports from the specialised press;
- d. results of own investigations;
- e. corrective measures.

³ The said person must examine complaints relating to the safety of the device with due care, and if necessary carry out random sampling and take the appropriate corrective measures.

⁴ Every person who subsequently places the device on the market must contribute to fulfilling the safety requirements and participate in the surveillance of the safety of the devices that are placed on the market. For that purpose, they shall collect complaints and relevant experience concerning use and efficacy and deliver these to the product surveillance system.

Art. 15⁷⁷ Reporting of incidents

¹ If the person first placing the device on the market becomes aware of incidents in Switzerland, that person must report these to the Agency. If this person becomes aware of incidents in a treaty country, the report must be sent to the competent authority in the treaty country concerned.

² Any professional person who becomes aware of an incident when using medical devices must report this to the Agency. The report may be submitted by a professional association.

³ The report must be made:

- a. for an event that represents or might represent, clearly and directly, a serious threat to the life or health of a considerable number of persons: without delay, but in all cases not later than two calendar days following the date of awareness of the event;
- b. for an event that has led to a death or an unexpected, serious deterioration in the state of a patient's health: without delay, but in all cases not later than ten calendar days following the date of awareness of the event;
- c. in other cases: without delay, but in all cases not later than 30 days following the date of awareness of the event.

⁴ Hospitals must establish an internal reporting system based on the principles of quality assurance, designate an appropriate, competent person with medical or technical training to carry out the mandatory reporting to the Agency, and notify the Agency of the person designated.

⁷⁷ Amended by No I of the O of 24 Mar. 2010, in force since 1 April 2010 (AS 2010 1215).

Art. 15a⁷⁸ Periodic summary reports

On application, the Agency may authorise the person first placing a medical device on the market to submit the reports periodically, in summarised form, if the root cause is known or if defective devices are still on the market following recalls and other field safety corrective actions as laid down in Article 15c.

Art. 15b⁷⁹ Trend report

If the person first placing a medical device on the market observes a clear increase in the number of events in the course of device monitoring, he must notify the Agency accordingly, and of any measures undertaken, in the form of a trend report.

Art. 15c⁸⁰ Measures taken relating to incidents

¹ The person who first places a medical device on the market and who becomes aware of incidents with this device must take the necessary internal measures and safety measures to reduce the risk associated with the device that is on the market, such as recall, exchange, modification, or destruction of the device, or sending a safety warning regarding its use.

² This person shall report the recall of a device or other field safety corrective actions regarding the devices on the market to the Agency immediately if the device was manufactured in Switzerland or is on the Swiss market. If the device was manufactured in a treaty country or is marketed there, the report must also be sent to the competent authority of the treaty country in question.

^{2bis} The report includes, in particular, the following information:

- a. all information that permits the identification of the device;
- b. a comprehensive description of the danger that can be caused by the device,
- c. all available information regarding the persons who have procured the device and, unless it has been provided directly to the users, regarding the persons to whom it has been delivered.⁸¹

³ This person must send the Agency, in a timely manner, a final report on the measures taken and their effects.

Art. 15d⁸² Mandatory further dissemination of information on recalls and other field safety corrective actions

It is mandatory for every person who places the medical device subsequently on the market to forward information, in an appropriate manner, to the affected users and if

⁷⁸ Inserted by No 1 of the O of 24 Mar. 2010, in force since 1 April 2010 (AS **2010** 1215).

⁷⁹ Inserted by No 1 of the O of 24 Mar. 2010, in force since 1 April 2010 (AS **2010** 1215).

⁸⁰ Inserted by No 1 of the O of 24 Mar. 2010, in force since 1 April 2010 (AS **2010** 1215).

⁸¹ Inserted by No 17 of the O of 11 June 2010 on the Revision of Sectoral O in the Field of Product Safety, in force since 1 July 2010 (AS **2010** 2749).

⁸² Inserted by No 1 of the O of 24 Mar. 2010, in force since 1 April 2010 (AS **2010** 1215).

applicable to the patients in the case of recalls or other field safety corrective actions related to devices that are on the market.

Art. 15^{e83} Collection and evaluation of the reports

¹ The Agency ensures that the reports are systematically compiled, evaluated and, where necessary, forwarded.

² Where necessary, it informs the cantons and the competent authorities in treaty countries of incidents. In all cases, it informs them of recalls and other field safety corrective measures relating to devices that are on the market.

³ Where necessary, the Agency publishes the recalls and the other field safety corrective actions relating to devices that are on the market, in an appropriate form.

Section 6 Special Provisions for the Handling of Medical Devices

Art. 16 Mandatory prescription

¹ Medical devices for personal use which could endanger human health even when used correctly or which contain medicinal products for which prescription is mandatory may only be dispensed on medical prescription.

² The Agency lists the product groups that may be dispensed on prescription only, in the form of an Ordinance.

Art. 17 Dispensing

¹ The dispensing of medical devices is regulated according to their intended purpose and to the information provided by the person first placing them on the market.

² Medical devices for which medical prescription is mandatory, medical devices obtained over the counter for personal use and which are not in Class I, and in vitro diagnostic medical devices for self-testing, may only be dispensed if the dispensing point can guarantee that professional advice is available and satisfies operational requirements.

³ The dispensing to the general public of in vitro diagnostic medical devices for the diagnosis of transmissible human diseases is prohibited. The Agency may grant exemptions in the interests of public health.

⁴ The dispensing of medical devices manufactured in house for in vitro diagnosis is prohibited.⁸⁴

⁸³ Inserted by No I of the O of 24 Mar. 2010, in force since 1 April 2010 (AS **2010** 1215).

⁸⁴ Inserted by No I of the O of 24 Mar. 2010, in force since 1 April 2010 (AS **2010** 1215).

Art. 18⁸⁵ Use

¹ Medical devices intended for use by professionals and which could harm the health of humans in the case of improper use are listed in Annex 6.

² The product groups listed in Annex 6 may only be used in accordance with the professional and operating requirements stated therein.

³ The Department is authorised to adapt Annex 6 to technological developments and to add product groups intended for use by professionals and which could harm the health of humans in the case of improper use.

Art. 19⁸⁶ Reprocessing

¹ A professional who makes repeated use of a medical device that is intended for such use must ensure, before each new use, that its functionality is checked and that it has been correctly reprocessed.

² Reprocessing is considered to be any maintenance measure that is necessary in order to prepare a used or new medical device for its intended use, notably activities such as cleaning, disinfection and sterilisation.

³ Data on the sterilisation process and validation must be recorded.

⁴ Any person who reprocesses medical devices for third parties must be able to demonstrate that a conformity assessment procedure in accordance with Annex 3 for the preparation and sterilisation of medical devices has been completed successfully.

Art. 20 Maintenance

¹ Any person using medical devices in a professional capacity must ensure that the maintenance of the devices and the associated tests are carried out according to regulations.

² Maintenance must be carried out in accordance with the principles of quality assurance, is to be appropriately planned and organised internally, and must notably address:

- a. the maintenance instructions drawn up by the person first placing the device on the market.
- b. the particular risk associated with the device and its use.

³ The results of the maintenance and of the associated tests, the deficiencies and faults identified, and the actions taken, are to be recorded for:

- a. active medical devices;
- b. calibratable medical devices with a measuring function.

⁸⁵ Amended by No 15 of the O of 18 Aug. 2004, in force since 1 Sept. 2004 (AS 2004 4037).

⁸⁶ Amended by No 1 of the O of 24 Mar. 2010, in force since 1 April 2010 (AS 2010 1215).

⁴ For medical devices with a measurement function, test procedures may be required in accordance with the Measuring Instruments Ordinance of 15 February 2006^{87,88}

Art. 20^a Modification

Any person modifying or reprocessing medical devices or who has them modified or reprocessed in such a way that they no longer serve their intended use or achieve their intended performance must fulfil the requirements for first-time placing on the market.

Art. 21 Advertising

¹ The claims with regard to the use, performance and efficacy of medical devices for direct dispensing to the general public or for direct use by the general public must be restricted to those contained in the product information only.

² Misleading statements concerning the efficacy and performance of a medical device are prohibited.

³ Advertising to the general public is prohibited for medical devices:

- a. that may be dispensed on medical prescription only;
- b. that are placed on the market for exclusive use by professionals.

Art. 22 Import and export

¹ For the export of medical devices to a third country, the Agency may, on presentation of the appropriate justification documents, issue an export certificate in accordance with Article 50 paragraph 2 of the Therapeutic Products Act.

² For the import of medical devices, the Agency may, on presentation of the appropriate documentation, issue an import certificate if a third country requires proof of the marketability of the medical device.

³ In justified cases, the Agency may impose certain conditions with regard to issuing a certificate.

⁴ It shall withdraw a certificate if:

- a. it was issued on the basis of false documentation;
- b. the devices stated thereon are no longer covered by the necessary declarations of conformity and the corresponding certificates, or if they are subject to import or export embargoes;
- c. the medical devices represent a danger to the health of users, patients or third parties.

⁸⁷ SR **941.210**

⁸⁸ Amended by No I of the O of 1 April 2015, in force since 15 April 2015 (AS **2015** 999).

⁸⁹ Inserted by No I of the O of 24 Mar. 2010, in force since 1 April 2010 (AS **2010** 1215).

Section 6a⁹⁰**Placing Products on the Market in accordance with the MDR or the IVDR****Art. 22a**

Products that meet the requirements of the MDR⁹¹ or the IVDR⁹² may be placed on the market in Switzerland.

Section 7 Monitoring within the Framework of Market Surveillance**Art. 23 Principle**

¹ Monitoring within the framework of market surveillance (compliance monitoring) ensures that the medical devices placed on the market, the procedure for placing them on the market, product surveillance, and the handling of medical devices comply with the regulations contained in this Ordinance. Compliance monitoring also extends to medical devices which are placed on the market in treaty countries by persons with a place of business in Switzerland and also to the procedures for placing them on the market and product surveillance.⁹³

² Compliance monitoring is carried out in the form of random sampling or as a consequence of incidents.

Art. 24 Institutions

¹ The Agency is responsible for the compliance monitoring of medical devices. Certain aspects remain the responsibility of other federal offices or institutions.

² The cantons are responsible for compliance monitoring:

- a. of the retail trade and dispensing points;
- b. of the manual production of custom-made devices, of systems and of procedure packs;
- c. of the maintenance and reprocessing of medical devices by the professionals using them, with the exception of hospitals.⁹⁴

³ The Agency is also responsible for the retrospective control of products in terms of Article 22a. Control and market surveillance are governed by Articles 23–27.⁹⁵

⁹⁰ Inserted by No I of the O of 25 Oct. 2017, in force since 26 Nov. 2017 (AS 2017 5935).

⁹¹ See the footnote to Art. 13b.

⁹² See the footnote to Art. 13b.

⁹³ Amended by No I 5 of the O of 18 Aug. 2004, in force since 1 Sept. 2004 (AS 2004 4037).

⁹⁴ Amended by No I of the O of 24 Mar. 2010, in force since 1 April 2010 (AS 2010 1215).

⁹⁵ Inserted by No I of the O of 25 Oct. 2017, in force since 26 Nov. 2017 (AS 2017 5935).

Art. 25 Coordination body

¹ The Agency may appoint a coordination body. This:

- a. coordinates the compliance monitoring and, where applicable, the testing of the measuring functions of medical devices, and also the notification of official decisions taken by various authorities;
- b. acts as a single point of contact for questions and reports in connection with medical devices;
- c. informs the relevant institutions responsible for compliance monitoring about reports received as laid down in Article 6.

² The authorities responsible for enforcement in the field of medical devices are represented in the coordination body. The Agency chairs the coordination body and acts as the secretariat.

³ The other enforcement authorities inform the Agency of their activities related to the compliance monitoring of medical devices.

Art. 26 Powers

The institutions responsible for compliance monitoring may, in order to examine the conformity of medical devices, and free of charge:

- a. demand the proof and information required;
- b. take samples;
- c. order that tests be carried out;
- d.⁹⁶ enter and inspect, during normal working hours, the business premises and facilities of persons who have an obligation to provide information;
- e.⁹⁷ consult documents and demand that they, or additional information, be provided in one of the official languages of Switzerland or in English.

Art. 26a⁹⁸ Processing of personal data

¹ The institutions responsible for enforcement are authorised to use personal data that is needed in order to fulfil all the tasks with which they are mandated by means of the present Ordinance. This also includes data relating to health that is obtained within the context of governmental market surveillance (Arts. 58 and 59 of the Therapeutic Products Act).

² All of the processing is subject to the Federal Act of 19 June 1992⁹⁹ on Data Protection.

⁹⁶ Amended by No I of the O of 24 Mar. 2010, in force since 1 April 2010 (AS **2010** 1215).

⁹⁷ Amended by No I of the O of 24 Mar. 2010, in force since 1 April 2010 (AS **2010** 1215).

⁹⁸ Inserted by No I 5 of the O of 18 Aug. 2004, in force since 1 Sept. 2004 (AS **2004** 4037).

⁹⁹ SR **235.1**

Art. 26b¹⁰⁰ Mandatory cooperation and provision of information

It is mandatory for the person first placing a medical device on the market in Switzerland or in a treaty country and for any person who places the device subsequently on the market to provide cooperation, where necessary, with regard to enforcement. These persons must notably provide, free of charge, all information and all proof and documentation required to the enforcement bodies.

Art. 27 Administrative measures

¹ If a medical device does not comply with the legal provisions, the competent authority shall inform the person who placed it on the market of the result of the compliance monitoring procedure and give that person the opportunity to respond. The authority may impose measures. It shall allow a reasonable period of time within which the measures imposed are to be taken.

² If there is justified suspicion that a medical device, even when it complies with the legal provisions, poses an immediate and serious threat to the health or safety of patients, users or third parties, the relevant enforcement bodies shall take immediate measures to withdraw the medical device from the market, to prohibit its being placed on the market or to seize it. The Agency will subsequently initiate the necessary measures according to Article 66 of the Therapeutic Products Act. In case of an actual necessity for the protection of public health, the Agency shall decree the measures in a general ruling.¹⁰¹

Section 7a Implementation¹⁰²**Art. 27a¹⁰³** Amendment of Annexes

¹ The Federal Department of Home Affairs may amend the annexes to this Ordinance in line with international or technical developments.

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

¹⁰⁰ Inserted by No 17 of the O of 11 June 2010 on the Revision of Sectoral O in the Field of Product Safety, in force since 1 July 2010 (AS 2010 2749).

¹⁰¹ Amended by No 17 of the O of 11 June 2010 on the Revision of Sectoral O in the Field of Product Safety, in force since 1 July 2010 (AS 2010 2749).

¹⁰² Inserted by No 1 of the O of 25 Oct. 2017, in force since 26 Nov. 2017 (AS 2017 5935).

¹⁰³ Inserted by No 1 of the O of 1. April 2015, in force since 15 April 2015 (AS 2015 999).

Art. 27b¹⁰⁴ Harmonisation of implementation

The Agency shall implement Section 4a and shall in doing so respect the implementing acts in accordance with Annex 7 issued by the European Commission based on the MDR¹⁰⁵ or the IVDR¹⁰⁶.

Art. 27c¹⁰⁷ Participation in European expert groups

The Agency may appoint experts to participate in expert groups of the EU Commission and the EU member states.

Art. 27d¹⁰⁸ Expert and reference laboratories in Switzerland

¹ Any laboratory that wishes to operate as an expert laboratory designated by the European Commission under Article 106 paragraph 7 MDR¹⁰⁹ or as a reference laboratory designated under Article 100 IVDR¹¹⁰ may submit an application to the Agency.

² It must demonstrate to the Agency in particular that it:

- a. meets the criteria under Article 106 paragraph 8 MDR or Article 100 paragraph 4 IVDR; and
- b. is able to assume responsibility for the tasks mentioned in Article 106 paragraph 10 MDR or Article 100 paragraph 2 IVDR.

³ An expert laboratory must operate in one of the following fields:

- a. physico-chemical characterisation;
- b. microbiological, biocompatibility, mechanical, electrical, electronic or non-clinical biological and toxicological testing.

⁴ If the requirements are met, the Agency shall propose to the EU Commission that the laboratory be designated an expert or reference laboratory.

¹⁰⁴ Inserted by No I of the O of 25 Oct. 2017, in force since 26 Nov. 2017 (AS 2017 5935).

¹⁰⁵ See the footnote to Art. 13b.

¹⁰⁶ See the footnote to Art. 13b.

¹⁰⁷ Inserted by No I of the O of 25 Oct. 2017, in force since 26 Nov. 2017 (AS 2017 5935).

¹⁰⁸ Inserted by No I of the O of 25 Oct. 2017, in force since 26 Nov. 2017 (AS 2017 5935).

¹⁰⁹ See the footnote to Art. 13b.

¹¹⁰ See the footnote to Art. 13b.

Section 8 Final Provisions**Art. 28** Repeal of current legislation

The following enactments are repealed:

- a. the Medical Devices Ordinance of 24 January 1996¹¹¹;
- b. the In vitro Diagnostic Ordinance of 24 February 1993¹¹².

Art. 29¹¹³ Transitional provisions relating to the amendment of 25 October 2017

¹ Certificates in accordance with Article 12 paragraph 1 for in vitro diagnostic medical devices may be issued until 25 May 2022. All certificates in accordance with Article 12 paragraph 1 cease to be valid by 27 May 2024 at the latest.¹¹⁴

² Conformity assessment bodies that have been designated in accordance with Section 4a, may carry out conformity assessment procedures under the MDR¹¹⁵ and the IVDR¹¹⁶ and issue related certificates from 26 November 2017.

Art. 30 Commencement

This Ordinance comes into force on 1 January 2002.

¹¹¹ [AS 1996 987 1868, 1998 1496]

¹¹² [AS 1993 967, 1996 2348]

¹¹³ Amended by No I of the O of 25 Oct. 2017, in force since 26 Nov. 2017 (AS 2017 5935).

¹¹⁴ Amended by No I of the O of 1 July 2020, in force since 1 Aug. 2020 (AS 2020 2975).

¹¹⁵ See the footnote to Art. 13b

¹¹⁶ See the footnote to Art. 13b.

Annex 1
(Art. 8 para. 1)

Conformity marking

The conformity marking is as follows:



Where a conformity assessment body must be used, its identification number is placed beside its conformity marking.



*Annex 2*¹¹⁷
(Art. 8 para. 1)

The following conformity marking is defined in Directives 93/42/EEC¹¹⁸ Annex XII, 98/79/EC¹¹⁹ Annex X and 90/385/EEC¹²⁰ Annex 9. The illustration is for information purposes only.



Where a conformity assessment body must be used, its identification number is to be placed beside its conformity marking.



¹¹⁷ Amended by No III para. 2 of the O of 24 Mar. 2010 (AS **2010** 1215). Revised by No II para. 3 of the O of 25 Oct. 2017, in force since 26 Nov. 2017 (AS **2017** 5935).

¹¹⁸ See the footnote to Art. 4 para. 1 let. a.

¹¹⁹ See the footnote to Art. 4 para. 1 let. b.

¹²⁰ See the footnote to Art. 4 para. 1 let. c.

*Annex 3*¹²¹
(Art. 10 para. 1)

Conformity assessment procedures

1. The person first placing a device on the market is responsible for the conformity assessment procedure and for the preparation of the declaration of conformity. The definitions and procedures to be used are found:
 - a. for active implantable medical devices, in Annexes 2–5 of Directive 90/385/EEC¹²²;
 - b. for classical medical devices, in Annexes II–X of Directive 93/42/EEC¹²³;
 - c. for in vitro diagnostic medical devices, in Annexes II–VIII of Directive 98/79/EC¹²⁴.
2. A conformity assessment body is used:
 - a. for active implantable medical devices as laid down in Directive 90/385/EEC;
 - b. for classical medical devices in Class IIa, IIb and III as laid down in Directive 93/42/EEC;
 - c. for in vitro diagnostic medical devices for self-testing;
 - c^{bis}. for in vitro diagnostic medical devices as laid down in Annex II of Directive 98/79/EC, even if manufactured in house (except for products in accordance with Section 3, letter b);
 - d. for classical medical devices in Class I which are sterilised or have a measuring function.
3. A conformity assessment body need not be used for:
 - a. the other classical medical devices in Class I (not sterile, not having a measuring function);
 - b. in vitro diagnostic medical devices manufactured in house as laid down in Annex II of Directive 98/79/EC if:
 1. the manufacturing company is a nationally designated reference laboratory or a laboratory with an equivalent qualification, and
 2. no common technical specifications exist for the medical devices in question.

¹²¹ Revised by No III para. 1 of the O of 24 Mar. 2010 (AS **2010** 1215) and No II para. 4 of the O of 25 Oct. 2017, in force since 26 Nov. 2017 (AS **2017** 5935).

¹²² OJ L 189 of 20.7.1990, p. 17, last amended by Directive 2007/47/EC, OJ L 247 of 21.9.2007, p. 21

¹²³ OJ L 169 of 12.7.1993, p. 1, last amended by Directive 2007/27/EC, OJ L 247 of 21.9.2007, p. 21.

¹²⁴ See the footnote to Art. 4 para. 1 let. b.

- b^{bis}. the other in vitro diagnostic medical devices to which section 2 does not apply;
 - c. all medical devices which are to be subjected to a clinical investigation or a performance evaluation;
 - d. custom-made devices.
4. Any supplier who assembles a system or procedure pack must declare that:
- a. the mutual compatibility of the components in accordance with the instructions drawn up by the person who placed them on the market has been tested and is established;
 - b. the system or procedure pack is accompanied by relevant user instructions, including those from the person who placed them on the market; and
 - c. all activities are monitored internally in a suitable manner.

5. Conformity assessment for classical medical devices in Class I:

The conformity assessment shall be carried out as laid down in Annex VII of Directive 93/42/EEC. The required declaration of conformity shall be drawn up before placing the devices on the market for the first time.

6. Conformity assessment for classical medical devices in Class IIa:

The conformity assessment shall be carried out as laid down in one of the following procedures in accordance with Directive 93/42/EEC:

- a. the procedure for EC declaration of conformity in accordance with Annex VII of this Directive in conjunction with the procedure:
 - 1. for EC verification in accordance with Annex IV,
 - 2. for EC declaration of conformity (Production quality assurance) in accordance with Annex V,
 - 3. for EC declaration of conformity (Product quality assurance) in accordance with Annex VI;
- b. the procedure for the full quality assurance system (EC declaration of conformity in accordance with Annex II of this Directive); in this case, Annex II, Section 4 does not apply.

The required declaration of conformity shall be drawn up before placing the devices on the market for the first time.

7. Conformity assessment for classical medical devices in Class IIb

The conformity assessment shall be carried out as laid down in one of the following procedures in accordance with Directive 93/42/EEC:

- a. the procedure for the full quality assurance system (EC declaration of conformity in accordance with Annex II of this Directive); in this case, Annex II, Section 4 does not apply;
- b. the procedure for the EC type-examination in accordance with Annex III of this Directive in conjunction with the procedure:
 - 1. for EC verification in accordance with Annex IV,

2. for EC declaration of conformity (Production quality assurance) in accordance with Annex V, or
3. for EC declaration of conformity (Product quality assurance) in accordance with Annex VI.

The required declaration of conformity shall be drawn up before placing the devices on the market for the first time.

8. Conformity assessment for classical medical devices in Class III:

The conformity assessment shall be carried out as laid down in one of the following procedures in accordance with Directive 93/42/EEC:

- a. the procedure for the full quality assurance system (EC declaration of conformity in accordance with Annex II of this Directive);
- b. the procedure for the EC type-examination in accordance with Annex III of this Directive in conjunction with the procedure:
 1. for EC verification in accordance with Annex IV,
 2. for EC declaration of conformity in accordance with Annex V.

The required conformity declaration shall be drawn up before placing the devices on the market for the first time.

9. Conformity assessment for active implantable medical devices:

The conformity assessment shall be carried out as laid down in one of the following procedures in accordance with Directive 90/385/EEC:

- a. the procedure for the full quality assurance system (EC declaration of conformity in accordance with Annex 2 of this Directive).
- b. the procedure for the EC type-examination in accordance with Annex 3 of this Directive in conjunction with one of the following procedures:
 1. for EC verification in accordance with Annex 4, or
 2. for EC declaration of conformity in accordance with Annex 5.

The required conformity declaration shall be drawn up before placing the devices on the market for the first time.

10. Conformity assessment for custom-made devices and medical devices for clinical investigation in all classes:

The conformity assessment shall be carried out as laid down in Annex VIII of Directive 93/42/EEC or for active implantable medical devices as laid down in Annex 6 of Directive 90/385/EEC.

11. Conformity assessment for all in vitro diagnostic medical devices with the exception of those mentioned in Annex II of Directive 98/79/EC, those intended for self-testing and those intended for performance evaluation:

The conformity assessment shall be carried out as laid down in Annex III of Directive 98/79/EC. The required declaration of conformity shall be established before placing the devices on the market for the first time.

12. Conformity assessment for in vitro diagnostic medical devices for self-testing:

The conformity assessment shall be carried out as laid down in one of the following procedures:

- a. in accordance with Annex III of Directive 98/79/EC;
- b. in accordance with Section 13;
- c. in accordance with Section 14.

If the procedure is carried out as laid down in Annex III of Directive 98/79/EC, the development of the products in accordance with Section 6 of this Annex must be confirmed by a conformity assessment body with an EC design-examination certificate and the required declaration of conformity must be drawn up before placing the devices on the market for the first time.

13. Conformity assessment for in vitro diagnostic medical devices as laid down in Annex II, List B of Directive 98/79/EC:

The conformity assessment shall be carried out as laid down in one of the following procedures in accordance with Directive 98/79/EC:

- a. the procedure for the full quality assurance system (EC declaration of conformity in accordance with Annex IV of this Directive);
- b. the procedure for the EC type-examination in accordance with Annex V of this Directive in conjunction with one of the following procedures:
 1. for EC verification in accordance with Annex VI, or
 2. for EC declaration of conformity in accordance with Annex VII.

The required conformity declaration shall be drawn up before placing the devices on the market for the first time.

14. Conformity assessment for in vitro diagnostic medical devices as laid down in Annex II, List A of Directive 98/79/EC:

The conformity assessment shall be carried out as laid down in one of the following procedures in accordance with Directive 98/79/EC:

- a. the procedure for the full quality assurance system (EC declaration of conformity in accordance with Annex IV of this Directive);
- b. the procedure for the EC type-examination in accordance with Annex V of this Directive in conjunction with the procedure for production quality assurance in accordance with Annex VII.

The required conformity declaration shall be drawn up before placing the devices on the market for the first time.

15. Conformity assessment for in vitro diagnostic medical devices, for performance evaluation:

The conformity assessment shall be carried out as laid down in Annex VIII of Directive 98/79/EC. A statement as laid down in Annex VIII of Directive 98/79/EC shall be drawn up before the performance evaluation.

16. Conformity assessment for in vitro diagnostic medical devices manufactured in house:

A declaration must be drawn up for the product, which includes the following information:

- a. identification of the product;
- b. name and address of the manufacturing company;
- c. declaration that the product corresponds to the essential requirements.

The manufacturing company must have an appropriate quality assurance system as laid down in recognised national or international standards (e.g. good practice in microbiological and serological laboratories in accordance with the Ordinance of 26 June 1996¹²⁵ on Microbiological and Serological Laboratories, European standard ISO/IEC 17025 2000 [General requirements for the competence of testing and calibration laboratories] or EA-04/10 2002 [Accreditation for Microbiological Laboratories]).

The documentation relating to the product must prove that the product corresponds to the essential requirements in accordance with Annex I of Directive 98/79/EC and to its claimed performance.

For medical devices in accordance with Annex II of Directive 98/79/EC, such a procedure may only be applied if:

- a. the manufacturing company is a nationally designated reference laboratory or a laboratory with an equivalent qualification;
- b. the product is classified as laid down in List A of this annex; and
- c. no common technical specifications exist for the medical devices in question.

17. Conformity assessment for the reprocessing of medical devices by third parties:

- a. A declaration must be drawn up for the product to be reprocessed, with the following information:
 1. identification of the product,
 2. name and address of the company carrying out the reprocessing,
 3. declaration confirming that the product has been reprocessed as laid down in the instructions drawn up by the person who first placed it on the market, or declaration that a risk analysis and a validation procedure has provided proof that own reprocessing procedures are applied in an equally safe and effective manner.
- b. The company carrying out the reprocessing must have an appropriate quality assurance system as laid down in nationally or internationally recognised standards.

¹²⁵ [AS 1996 2324, 2001 3294 No II 11, 2003 4835, 2004 4037 No II. AS 2015 1497 Art. 26]. See now: the O of 29 April 2015 on Microbiology Laboratories (SR 818.101.32).

- c. The documentation relating to the reprocessing must prove that the product has been reprocessed in accordance with letter a number 3.

*Annex 3a*¹²⁶
(Art. 11.1^{bis} und 13*b*)

Conditions for the designation of conformity assessment bodies

1. Designation in accordance with Section 4

Conformity assessment bodies must meet the requirements of Annex I of Implementing Regulation (EU) No 920/2013¹²⁷.

2. Designation in accordance with Section 4a

Conformity assessment bodies must meet the requirements of Annex VII MDR¹²⁸ or IVDR¹²⁹.

¹²⁶ Inserted by No II of the O of 1 April 2015 (AS 2015 999). Amended by No II para. 1 of the O of 25 Oct. 2017, in force since 26 Nov. 2017 (AS 2017 5935).

¹²⁷ Commission Implementing Regulation (EU) No 920/2013 of 24 Sept. 2013 on the designation and the supervision of notified bodies under Council Directive 90/385/EEC on active implantable medical devices and Council Directive 93/42/EEC on medical devices, version as per OJ L 253 of 25.9.2013, p. 8.

¹²⁸ See the footnote to Art. 13*b*.

¹²⁹ See the footnote to Art. 13*b*.

*Annex 3b*¹³⁰
(Art. 11*b* and 13*p*)

Cooperation with the European Commission and the Member States of the European Union

1. Cooperation in accordance with Section 4

A representative of the European Commission and representatives of the designating authorities of two Member States of the European Union may participate in the assessments of conformity assessment bodies conducted by the Agency, including on-site assessments. They shall receive access to the documents necessary to assess the conformity assessment bodies.

2. Cooperation in accordance with Section 4*a*

Cooperation is governed by the following provisions:

- a. Assessment of the application (Art. 39 MDR¹³¹ and Art. 35 IVDR¹³² respectively);
- b. Monitoring and re-assessment (Art. 44 MDR and Art. 40 IVDR respectively);
- c. Changes to the designation (Art. 46 MDR and Art. 42 IVDR respectively);
- d. Peer review and exchange of experience (Art. 48 MDR and Art. 44 IVDR respectively).

¹³⁰ Inserted by No II of the O of 1 April 2015 (AS 2015 999). Amended by No II para. 1 of the O of 25 Oct. 2017, in force since 26 Nov. 2017 (AS 2017 5935).

¹³¹ See the footnote to Art. 13*b*.

¹³² See the footnote to Art. 13*b*.

*Annex 3c*¹³³
(Art. 13a and 13n)

Subsequent surveillance, monitoring and re-assessment of the conformity assessment bodies

1. Subsequent surveillance in accordance with Section 4

The Agency shall assess the reviews conducted by the conformity assessment bodies, conduct on-site assessments and observe audits as follows:

- a. at least every 12 months: conformity assessment bodies with more than 100 clients;
- b. at least every months: all other conformity assessment bodies

2. Monitoring and re-assessment in accordance with Section 4a

¹ When monitoring or re-assessing conformity assessment bodies, the Agency shall take account of the requirements and procedures set out in Articles 44 and 45 MDR¹³⁴ and Articles 40 and 41 IVDR¹³⁵ respectively.

² Three years after the designation of a conformity assessment body and thereafter either every four years or as determined by the European Commission in a delegated act the Agency shall determine whether the conformity assessment bodies still meet the requirements of Article 13b and Annex 3a section 2.

¹³³ Inserted by No II of the O of 1 April 2015 (AS 2015 999). Amended by No II para. 1 of the O of 25 Oct. 2017, in force since 26 Nov. 2017 (AS 2017 5935).

¹³⁴ See the footnote to Art. 13b.

¹³⁵ See the footnote to Art. 13b.

Comparison of terms used in the EC Directives 90/385/EEC¹³⁷, 93/42/EEC¹³⁸ and 98/79/EC¹³⁹ and in the MedDO

To correctly interpret the Annexes of the EC Directives to which this Ordinance refers, the following equivalent terms apply:

EC term	Equivalent term in the MedDO
Notified body Directive 80/181/EEC ¹⁴⁰	Conformity assessment body Ordinance on Units of 23 November 1994 ¹⁴¹
EC declaration of conformity (Annex 2 or II, respectively, complete or full quality assurance system, respectively)	Declaration of conformity for a full quality assurance system
Responsible person in accordance with Art. 14 Para. 2 of Directive 93/42/EEC	Person first placing (a medical device) on the market
Authorised representative	Person first placing (a medical device) on the market
Competent authority	Swiss Agency for Therapeutic Products, Bern
Design (of products)	Development (of products)
EC type-examination certificate	Type-examination certificate

¹³⁶ Amended by No III para. 2 of the O of 24 Mar. 2010 (AS **2010** 1215). Revised by No II para. 5 of the O of 25 Oct. 2017, in force since 26 Nov. 2017 (AS **2017** 5935).

¹³⁷ See the footnote to Art. 4 para. 1 let. c.

¹³⁸ See the footnote to Art. 4 para. 1 let. a.

¹³⁹ See the footnote to Art. 4 para. 1 let. b.

¹⁴⁰ OJ L 39 of 15 2.1980, p. 4.

¹⁴¹ SR **941.202**

*Annex 5*¹⁴²

¹⁴² Repealed by No III para. 3 of the O of 24 Mar. 2010, with effect since 1 April 2010 (AS **2010** 1215).

*Annex 6*¹⁴³
(Art. 18)

1. Product groups

The following product groups may only be used by a physician, or by a professional trained in accordance with the provisions of this Annex, under the monitoring and responsibility of a physician:

- a. Products for injection which are intended to remain within the human body for longer than 30 days (long-term injectable devices);
- b. and c. ...

2. Requirements for training

- a. Long-term injectable devices may be used by qualified healthcare professionals with appropriate training in the injection of long-term implantable devices, or by persons with equivalent training;
- b. and c. ...

¹⁴³ Inserted by No II para. 2 of the O of 18 Aug. 2004 (AS **2004** 4037). Revised by No III para. 1 of the O of 24 March 2010 (AS **2010** 1215) and by Art. 28 para. 2 of the O of 27 Feb. 2019 to the FA on Protection against Non-Ionising Radiation and Sound, in force since 1 June 2019 (AS **2019** 999).

*Annex 7¹⁴⁴
(Art. 27b)*

Relevant legislation of the European Commission

The implementing acts issued by the European Commission based on the MDR¹⁴⁵ or the IVDR¹⁴⁶:

- a. on guaranteeing the standard application of the requirements in accordance with Annex VII MDR or Annex VII IVDR;
- b. on determining procedures and reports for applying for designation and assessing the application;
- c. on the list of codes and the corresponding types of devices for specifying the scope of the designation of conformity assessment bodies;
- d. on determining implementing rules and the documents for the monitoring the assessment of the technical documentation and the documentation on the clinical evaluations and their coordination;
- e. on determining implementing rules and the documents for the peer review mechanism as well as training and qualification.

¹⁴⁴ Inserted by No II para. 2 of the O of 25 Oct. 2017, in force since 26 Nov. 2017 (AS 2017 5935).

¹⁴⁵ See the footnote to Art. 13b.

¹⁴⁶ See the footnote to Art. 13b.

