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Switzerland

Medical Devices Ordinance (MepV)

812.213

of 17 October 2001 (status at 1 April 2010)

The Swiss Federal Council

having regard to Article 2 Paragraph 2, Article 4 Paragraph 2, Article 45 Paragraph 3, Article 46 Paragraph 2, Article 47 Paragraph 2, Article 48, Article 49 Paragraph 2, Article 50 Paragraph 1, and Articles 51 and 82 of the Law on Therapeutic Products (HMG) of 15 December 2000¹;

to Article 21 Number 2 of the Law on Electricity of 24 June 1902²;

to Article 9 Paragraph 1, Letter b of the Federal Law on Metrology of 9 June 1977³;

to Article 4 of the Federal Law of 19 March 1976 on the Safety of Technical Apparatus and Equipment⁴ and

to Article 37 of the Law on Radiation Protection of 22 March 1991⁵;

and implementing the Federal Law on Technical Barriers to Trade of 6 October 1995^{6,7}

decrees:

Section 1: General Provisions

Article 1 Medical Devices

¹ Medical devices are instruments, apparatus, appliance, software, substances, accessories or other medical technology articles, whether used alone or in combination, including software that is specifically intended for diagnostic or therapeutic purposes and necessary for the proper functioning of a medical device:

- a. that are intended for use on humans;
- b. whose principal intended action in or on the human body is not achieved by pharmacological, immunological or metabolic means, but which action can be assisted by such means; and
- c. that serve to:

AS 2001 3487

¹ SR 812.21

² SR 734.0

³ SR 941.20

⁴ SR 819.1

⁵ SR 814.50

⁶ SR 946.51

⁷ Version according to Number I of the O of 24 March 2010, enforced on 1 April 2010 (AS 2010 1215).

1. Diagnose, prevent, monitor, treat or alleviate diseases;
2. Diagnose, monitor, treat or alleviate injuries or handicap, or compensate handicap
3. Investigate or modify the anatomical structure, to replace parts thereof, or to investigate, modify or replace a physiological process,
4. Control of conception or making diagnoses in relation to conception⁸.

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 according to their intended purpose for the in vitro examination of specimens, including blood and tissue donations, derived from the human body and which are used solely or principally to provide information:

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

⁴ Active implantable medical devices are medical devices:

- a. the functioning of which relies 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 designed to be fully 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;
- c. and which are intended to remain there following the procedure.

⁵ Classical medical devices are medical devices which are neither active implantable medical devices or in vitro diagnostic medical devices.

⁸ Version according to Number I of the O of 24 March 2010, enforced on 1 April 2010 (AS **2010** 1215).

Article 1a⁹ Custom-made devices

¹ Custom-made devices are medical devices manufactured for a specific patient.

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

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

⁴ Mass-produced medical devices that require adjustment based on a specific requirement on the part of the professional applying them are not considered to be custom-made devices.

Article 2 Exceptions from scope

¹ Only Article 6 Paragraph 3, Articles 26 and 27, and Section 5 apply to classical and active implantable medical devices derived from human tissue rendered non-viable, 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 at the time of their being placed on the market incorporate blood, blood products, plasma or cells of human origin, except if it 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 the Directive 2001/83/EC¹¹ of the European Parliament and of the Council of 2 November 2001 on the creation of a Community code for human medicine, and which are liable to act upon the human body in a manner ancillary to that of the device;
- b.¹² vital organs, tissue or cells of human origin, or transplant products;
- c. organs, tissue or cells of animal origin, unless a device is manufactured using animal tissue which is rendered non-viable or non-viable products derived from animal tissue.

⁹ Inserted by Number I of the O of 24 March 2010, enforced on 1 April 2010 (AS **2010** 1215).

¹⁰ Version according to Number I of the O of 24 March 2010, enforced on 1 April 2010 (AS **2010** 1215).

¹¹ OJ L 311 of 28.11.2001, p. 67, last modified 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 are obtainable from the Swiss Information Centre for Technical Standards (switec), Bürglistrasse 29, 8400 Winterthur or at the website: <http://eur-lex.europa.eu/en/treaties/index.htm>

¹² Version according to Number I of the O of 24 March 2010, enforced on 1 April 2010 (AS **2010** 1215).

Article 3 Definitions

1 In this Ordinance the following definitions apply:

- a. *Accessory*: Components, which are not medical devices in themselves, but which are to be used in conjunction with a medical device as intended by the manufacturer according to the instructions of the medical device manufacturer.
- b. ...¹³
- b^{bis}.¹⁴ *Medical device manufactured in-house*: A medical device that is only intended for use in the manufacturing company or in a partner company in which the quality assurance system of the manufacturing company is applied;
- b^{ter}.¹⁵ *System and procedure pack*: A composition of several classical medical devices for which the declarations of conformity are available and which were brought together in line with the intended purpose established by the corresponding person that first placed them on the market.
- c. *Performance evaluation*: The provision of evidence that a medical device for in vitro diagnosis achieves, under normal operating conditions, the requirements for performance.
- d. *Serious adverse incident*: Event associated with a medical device, resulting from a malfunction of the device, change in significant attributes, improper marking or instructions for use, and which has led, or could have led, to the death or a serious deterioration of the state of health of patients, users or third parties.
- e.¹⁶ *Treaty country*: Country with which Switzerland has concluded an agreement for the mutual recognition of conformity assessments and corresponding procedures for medical devices;
- f.¹⁷ *Third country*: Country with which Switzerland has not concluded an agreement 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 product or a product that has been refurbished or altered in such a way that it no longer serves its original purpose or produces the intended effect, is given or transferred in Switzerland, either free or charge or subject to payment. The

¹³ Abolished by Number I of the O of 24 March 2010, enforced on 1 April 2010 (AS 2010 1215).

¹⁴ Inserted by Number I of the O of 24 March 2010, enforced on 1 April 2010 (AS 2010 1215).

¹⁵ Inserted by Number I of the O of 24 March 2010, enforced on 1 April 2010 (AS 2010 1215).

¹⁶ Inserted by Number I 5 of the O of 18 August 2004, (AS 2004 4037).

¹⁷ Inserted by Number I 5 of the O of 18 August 2004, (AS 2004 4037).

first placing on the market is also considered to be the use, by a professional, of a medical device directly imported from a third country or of a medical device produced in house¹⁸.

Section 2: Pre-requisites for placing on the market

Article 4 Requirements for medical devices

¹ The essential requirements according to Article 45 Paragraph 2 of the Law on Therapeutic Products are specified as follows:

- a. classical medical devices: in Annex I of Directive of the European Council 93/42/EEC on Medical Devices of 14 June 1993¹⁹ (Directive 93/42/EEC);
- b. medical devices for in vitro diagnosis: in Annex I of Directive of the European Parliament and of the Council 98/79/EC of 27 October 1998²⁰ on in vitro diagnosis (Directive 98/79/EC);
- c. active implantable medical devices: in Annex 1 of Directive of the European Council 90/385/EEC of 20 June 1990²¹ on the approximation of the laws of the Member States relating to active implantable medical devices (Directive 90/385/EEC)²².

^{1bis} Classical and active implantable medical devices that are also machines in accordance with the Directive of the European Parliament and of the Council 2006/42/EU of 17 May 2006²³ regarding machinery and in modification of Directive 95/16/EU (new version), must comply with the essential health and safety requirement in accordance with Annex 1 of the said Directive as long as the said specifications are more specific than the essential requirements in accordance with paragraph 1.²⁴

^{1ter} 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 the Directive of the European Council 89/686/EEC of 21 December 1989²⁵ on the approximation of the laws of the Member States relating to personal protective

¹⁸ Version according to Number I of the O of 24 March 2010, enforced on 1 April 2010 (AS **2010** 1215).

¹⁹ OJ L 169 of 12 July 1993, page 1, last modified by Directive 2007/47/EC, OJ L 247 of 21 September 2007, page 21.

²⁰ OJ L 331 of 7 December 1998, page 1, last modified by Regulation (EC) No. 596/2009, OJ L 188 of 18 July 2009, page 14.

²¹ OJ L 189 of 20 July 1990, page 17, last modified by Directive 2007/47/EC, OJ L 247 of 21 September 2007, page 21.

²² Version according to Number I of the O of 24 March 2010, enforced on 1 April 2010 (AS **2010** 1215).

²³ OJ L 157 of 9 June 2006, page 24, last modified by Commission Regulation (EC) No. 596/2009, OJ L 188 of 18 July 2009, page 14.

²⁴ Inserted according to Number I of the O of 24 March 2010, enforced on 1 April 2010 (AS **2010** 1215).

²⁵ OJ L 399 of 30 December 1989, page 18, last modified by Commission Regulation (EC) No. 596/2009, OJ L 188 of 18 July 2009, page 14.

equipment must also correspond to the relevant essential health and safety requirements of this guideline.²⁶

² Compliance with the essential requirements, as specified by technical standards²⁷, common technical specifications²⁸ or by the regulations of the pharmacopoeia²⁹ is presumed where the medical device complies with these standards, specifications or regulations.

³ The Swiss Agency for Therapeutic Products (Agency) establishes the technical standards and common technical specifications which are appropriate to specify the essential requirements for medical devices and publishes the titles and references thereof in the Federal Official Journal.

⁴ The regulations of the Law on Environmental Protection of 7 October 1983³⁰ and the Law on genetic engineering of 21 March 2003³¹ also apply to the placing on the market of medical devices that are substances or contain organisms.

⁵ For the classification, packaging and identification of medical devices for in-vitro diagnosis, as well as for 'classical' medical devices which are not invasive and which do not come into contact with the human body during use, the relevant requirements of the Directive of the European Parliament and of the Council 99/45/EC of 31 May 1999³² concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations apply.³⁴

Article 5³⁵ Classification

¹ Classical medical devices are to be classified as Class I, IIa, IIb or III by the person first placing them on the market on the basis of the possible risks they may

²⁶ Inserted according to Number I of the O of 24 March 2010, enforced on 1 April 2010 (AS **2010** 1215).

²⁷ Technical standards (with the exception of electrotechnical ones) are obtainable from the Swiss Information Centre for Technical Standards (switec), Bürglistrasse 29, 8400 Winterthur; phone 052 224 54 54; www.snv.ch. For electrotechnical standards: Swiss Electrical Association (SEV), Normen und Drucksachen, Luppmenstrasse 1, 8320 Fehraltorf; phone 0244 956 11 65; www.electrosuisse.ch.

²⁸ Common technical specifications are obtainable from the Swiss Information Centre for Technical Standards (switec), Bürglistrasse 29, 8400 Winterthur.

²⁹ SR 812.211

³⁰ SR **814.01**

³¹ SR **814.91**

³² Version according to Annex 5 Number 2 of the Ordinance on release of 10 September 2008, enacted on 1 October 2008 (AS **2008**, 4377).

³³ OJ L 200 of 30 Junly 1999, page 1, last modified by Regulation (EC) nr. 1272/2008, OJ L 353 of 31 December 2008, page 1.

³⁴ Inserted by Number I 5 of the O of 18 August 2004, (AS **2004** 4037). Version according to Number I of the O of 24 March 2010, enforced on 1 April 2010 (AS **2010** 1215).

³⁵ Version according to Number I 5 of the O of 18 August 2004, (AS **2004** 4037).

present when used as intended. Classification shall be done in accordance with Annex IX of the Directive 93/42/EEC^{36, 37, 38}.

² For those medical devices which are imported from a treaty country, an existing classification according to Para. 1 can be adopted.

Article 6 Registration duty for placing 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 having its place of business in Switzerland must notify the name, address and a description of the applicable devices to the Agency at the latest by the time point at which they are placed on the market:

- a. Class I medical devices;
- b. custom-made devices;
- c. systems and procedure packs.³⁹

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

- a. name and address;
- b. the devices which are to be placed on the market, including their general technology and application;
- c. for devices according to Annex II of the Directive 98/79/EC⁴⁰ and for devices for self-testing:⁴¹
 1. name of the devices,
 2. all details which permit identification of these devices,
 3. the performance characteristics according to Annex I, Section A, Number 3 of the Directive 98/79/EC,
 4. the results of the performance evaluation,
 5. the certificates relating to the conformity assessment procedure.

³⁶ OJ L 169 of 12 July 1993, page 1, last modified by Directive 2007/47/EC, OJ L 247 of 21 September 2007, page 21.

³⁷ New classifications which are made within the framework of Directive 93/42/EEC are also applicable to this Ordinance.

³⁸ Version according to Number I of the O of 24 March 2010, enforced on 1 April 2010 (AS 2010 1215).

³⁹ Version according to Number I of the O of 24 March 2010, enforced on 1 April 2010 (AS 2010 1215).³⁸ N

⁴⁰ OJ L 331 of 7 December 1998, page 1, last modified by Regulation (EC) No. 596/2009, OJ L 188 of 18 July 2009, page 14.

⁴¹ Version according to Number I of the O of 24 March 2010, enforced on 1 April 2010 (AS 2010 1215).

^{2bis} For medical devices manufactured in-house for in vitro diagnostics, only a notification must be submitted to the Agency in the case that the devices are listed in Annex II of Directive 98/79/EC. For medical devices classified as List A in the said annex, the notification must, in accordance with paragraph 2, letter 2, also include confirmation of accreditation, licence or recognition 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 device in question.

³ Whosoever places medical devices according to Article 2 Paragraph 1 on the market in Switzerland shall, before placing them on the market, notify to the Agency:

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

⁴ Changes in the information in Paragraphs 1 - 3 shall be sent once per year to the Agency in consolidated form.

Article 7 Product information

¹ Product information shall be in accordance with:

- a. Classical medical devices: Annex I, Section 13 of the Directive 93/42/EEC⁴³;
- b. Active implantable medical devices: Annex 1, Sections 14 and 15 of the Directive 90/385/EEC⁴⁴;
- c. Medical devices for in vitro diagnosis: Annex I, Section 8 of the Directive 98/79/EC⁴⁵.⁴⁶

² The product information must be written in all three official languages. Symbols which are contained in harmonized standards can replace wording.

³ Product information can be restricted to less than the three official languages, or be in English, provided:

⁴² Inserted by Number I of the O of 24 March 2010, enforced on 1 April 2010 (AS 2010 1215).

⁴³ OJ L 169 of 12 July 1993, page 1, last modified by Directive 2007/47/EC, OJ L 247 of 21 September 2007, page 21.

⁴⁴ OJ L 189 of 20 July 1990, page 17, last modified by Directive 2007/47/EC, OJ L 247 of 21 September 2007, page 21.

⁴⁵ OJ L 331 of 7 December 1998, page 1, last modified by Regulation (EC) No. 596/2009, OJ L 188 of 18 July 2009, page 14.

⁴⁶ Version according to Number I of the O of 24 March 2010, enforced on 1 April 2010 (AS 2010 1215).

- a.⁴⁷ the medical device is supplied exclusively to professionals or where the medical device is a custom-made device or a medical device manufactured in-house;
- b. there is assurance that the user has the necessary professional and linguistic qualifications, and agrees with the language restriction;
- c. the protection of patients, users and third parties is nevertheless ensured; and
- d. effective and intended use is not jeopardized.

⁴ If requested, additional information shall be given to users in one of the official languages.

⁵ If a product that is not, or not yet, permitted to be placed on the market as a medical device can be confused with one that is, the claims of the former must clearly and legibly indicate that it is not a medical device and is not suitable for medical purposes.

Article 8⁴⁸ Conformity marking and identification number

¹ All medical devices placed on the market in Switzerland must bear the conformity marking according to Annex 1. A foreign conformity marking shown in Annex 2 is also accepted as a conformity marking.

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 investigation;
- e. devices for performance evaluation.

³ For a medical device for in vitro diagnosis manufactured in-house, a conformity marking is only necessary if it is a medical device according to Annex II of Directive 98/79/EC⁴⁹. No conformity marking is however necessary for a product according to List A of the said Annex if:

- a. the manufacturing company has a nationally designated reference laboratory or a laboratory with an equivalent qualification; and
- b. no common technical specifications exist for it.

⁴⁷ Version according to Number I of the O of 24 March 2010, enforced on 1 April 2010 (AS 2010 1215).

⁴⁸ Version according to Number I of the O of 24 March 2010, enforced on 1 April 2010 (AS 2010 1215).

⁴⁹ OJ L 331 of 7 December 1998, page 1, last modified by Regulation (EC) No. 596/2009, OJ L 188 of 18 July 2009, page 14.

⁴ Medical devices for which the conformity must be assessed by a conformity assessment body according to 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 are to be applied to 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 sales packaging. The markings must be clearly visible, easy to read and indelible.

⁶ The Agency may make public the identification numbers or the information replacing them according to Paragraph 4.

Section 3: Conformity Assessment

Article 9 Principle

¹ The person placing medical devices on the market in Switzerland must, on demand, provide the Declaration of Conformity to the Authorities responsible for inspections within the framework of market surveillance.

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

³ For medical devices placed on the market exclusively within the armed forces or within the framework of its special assignments, the Federal Department of Home Affairs (Department) can, after reaching agreement with the Federal Department of Defense, Civil Protection and Sports, grant exemptions.

⁴ The Agency can grant exemptions for the placing on the market of individual non-conforming medical devices when:

- a. they serve the purpose of rectification of life-threatening conditions or elimination of permanent impairment of a bodily function;
- b. no conforming device is available for this indication;
- c. usage will be on individual persons only.

Article 10 Procedure and Certificates

¹ The procedure for conformity assessment, the necessary certificate and the Declaration of Conformity must comply with Annex 3.

² Where 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 changed, suspended, or revoked by a conformity assessment body shall not be used further in its original form.

Section 4: Conformity Assessment Bodies

Article 11 Prerequisites

¹ Conformity assessment bodies must:

- a. be accredited according to the Ordinance on Accreditation and Notification of 17 June 1996⁵⁰;
- b. be authorized by other Federal regulations; or
- c. be recognized by Switzerland within the framework of an international agreement.

² Foreign assessment bodies which are not recognized according to Paragraph 1 can be used where the Agency can be satisfied that:

- a. the examination or conformity assessment procedures used meet Swiss requirements; and
- b. the foreign assessment body is qualified to the same extent as is required in Switzerland.

³ The State Secretariat for Economic Affairs can decree, after reaching agreement with the Agency, that assessment bodies referred to in Paragraph 2 or the certificates issued by them not be recognized when appropriate Swiss assessment bodies or the certificates issued by them are not recognized 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 foreign economic relations shall also be taken into account.

Article 12⁵¹ Validity of certificates

¹ Decisions and certificates according to the procedure in Annexes II, II, V and VI of the Directives 93/42/EEC⁵² and 90/385/EEC⁵³ and the Annexes 2, 3 and 5 of Directive 90/385EEC and Annexes III, IV, V and VII of Directive 98/79/EC⁵⁴ may be issued by conformity assessment bodies with a maximum validity of five years. On application, the certificates may be renewed for a maximum of five years at a time.

⁵⁰ SR 946.512

⁵¹ Version according to Number I of the O of 24 March 2010, enforced on 1 April 2010 (AS 2010 1215).

⁵² OJ L 169 of 12 July 1993, page 1, last modified by Directive 2007/47/EC, OJ L 247 of 21 September 2007, page 21.

⁵³ OJ L 189 of 20 July 1990, page 17, last modified by Directive 2007/47/EC, OJ L 247 of 21 September 2007, page 21.

⁵⁴ OJ L 331 of 7 December 1998, page 1, last modified by Regulation (EC) No. 596/2009, OJ L 188 of 18 July 2009, page 14.

² Conformity assessment bodies must suspend, revoke or limit a certificate issued by them when the prerequisites for issue are no longer met.

Article 13⁵⁵ Duty to Notify and Inform

¹ Conformity assessment bodies must notify the Agency about any certificate that they issue, modify, complete, suspend, limit, revoke, or refuse, giving information concerning the devices affected.

² Conformity assessment bodies must notify the other conformity assessment bodies about any certificate which they suspend, revoke, or refuse giving information concerning the devices affected. Upon request they must also inform on certificates which they have issued, modified or completed, providing other relevant information.

Section 5: Product surveillance

Article 14 Selfcontrols

¹ The person who first places the device on the market in Switzerland or in a treaty country must establish a system for product surveillance.⁵⁶ This system must contain device specific information as follows:

- a. complaints;
- b. relevant experience concerning use and effectiveness;
- c. reports from specialised literature;
- d. results of own investigations;
- e. corrective actions.

² Every person who places the device further on the market must collect complaints and relevant experience concerning use and effectiveness and deliver these to the product surveillance system.

Article 15⁵⁷ Reporting serious adverse incidents

¹ The person who first places the device on the market and who becomes aware of serious adverse incidents in Switzerland must notify these to the Agency. If this person becomes aware of serious adverse incidents in a treaty country, the report must be sent to the competent authority in the affected treaty country.

⁵⁵ Version according to Number I of the O of 24 March 2010, enforced on 1 April 2010 (AS 2010 1215).

⁵⁶ Version according to Number I 5 of the O of 18 August 2004, (AS 2004 4037).

⁵⁷ Version according to Number I of the O of 24 March 2010, enforced on 1 April 2010 (AS 2010 1215).

² Any professional person who determines a serious adverse 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 drawn up:

- a. For an incident that clearly represents a direct threat to the life or health of a considerable number of persons or has the potential to do so: immediately, but in all cases within two calendar days after awareness about the event;
- b. For an incident that has led to a death or an unexpected serious deterioration in the state of a patient's health: immediately, but in all cases within ten calendar days after awareness;
- c. In other cases: immediately, but in all cases within 30 days after awareness.

⁴ Hospitals must establish an internal reporting system according to the principles of quality assurance, designate a suitable, knowledgeable person with medical or technical training who is responsible for the duty to inform the Agency, and notify the Agency of the person designated.

Article 15a⁵⁸ Summary reports

On application, the Agency may authorise the person who first places a medical device on the market to submit the reports periodically, in summarised form, in the case that the cause of the defect is known or if, following recalls and other security measures in accordance with Article 15c, defective products are still in circulation.

Article 15b⁵⁹ Trend reports

If the person who first places a medical device on the market observes a clear increase in the number of incidents within the framework of monitoring the product, he must notify the Agency thereof, and of any measures undertaken in that respect.

Article 15c⁶⁰ Measures taken with respect to serious adverse incidents

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

⁵⁸ Inserted by Number I of the O of 24 March 2010, enforced on 1 April 2010 (AS 2010 1215).

⁵⁹ Inserted by Number I of the O of 24 March 2010, enforced on 1 April 2010 (AS 2010 1215).

⁶⁰ Inserted by Number I of the O of 24 March 2010, enforced on 1 April 2010 (AS 2010 1215).

² This person immediately reports the recall of a product or other safety measures regarding the products on the market to the Agency if the product was manufactured in Switzerland or is on the Swiss market. If the product 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.

³ This person must send the Agency, within a reasonable time, a final report on the measures taken and their effects.

Article 15d⁶¹ Duty to disseminate information on recalls and other security measures

Persons retailing or distributing a medical device must forward information regarding recalls or other safety measures regarding products on the market, in an appropriate manner, to affected users and if applicable to patients.

Article 15e⁶² Collection and evaluation of the reports

¹ The Agency will ensure that reports are systematically collected, evaluated and, where necessary, forwarded.

² Where necessary, it informs the cantons and the competent authorities in treaty countries concerning serious adverse incidents. In all cases, it informs them of recalls and other security measures relating to products that are on the market.

³ Where necessary, the Agency publishes the recalls and the other safety measures relating to products that are on the market, in an appropriate form.

Section 6: Particular requirements for activities associated with medical devices

Article 16 Prescription requirement

¹ Medical devices for self- use which even with correct use could endanger the health of human beings, or which contain medicinal substances subject to prescription, may only be delivered when prescribed by a physician.

² The Agency will list those device groups which may only be delivered when prescribed by a physician, in an Ordinance.

⁶¹ Inserted by Number I of the O of 24 March 2010, enforced on 1 April 2010 (AS **2010** 1215).

⁶² Inserted by Number I of the O of 24 March 2010, enforced on 1 April 2010 (AS **2010** 1215).

Article 17 Delivery for use

¹ The delivery of medical devices for use is governed by the intended purpose and by the information from the person who first places them on the market.

² Medical devices which may only be delivered when prescribed by a physician, which may be obtained by self-service for own use and which do not belong in Class I, as well as medical devices for in vitro diagnosis for self- testing, may only be delivered for use when the delivering entity can ensure there is professional consultation available and when the operational prerequisites are met.

³ The delivery for use to the general public of in vitro diagnostic medical devices for the diagnosis of transmissible diseases in humans is forbidden. The Agency can grant exemptions in the interests of public health.

⁴ The delivery of medical products manufactured in-house for in vitro diagnosis is forbidden.⁶³

Article 18⁶⁴ Use

¹ Annex 6 lists those medical devices which are intended for use by professionals and which, by careless use, can endanger the health of human beings.

² The product groups identified in Annex 6 may only be used under the prescribed conditions for personal qualifications and operating conditions.

³ The Department is authorised to adapt Annex 6 to technological developments and to add product groups to it which are intended for use by professionals and which, by careless use, can endanger the health of human beings.

Article 19⁶⁵ Refurbishment

¹ When a professional reuses a medical device that is intended for use several times, this person must ensure that its functionality is checked and that it is correctly refurbished before each re-use.

² Refurbishment is 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 Records must be made of the process and validation data for sterilisation.

⁶³ Inserted by Number I of the O of 24 March 2010, enforced on 1 April 2010 (AS 2010 1215).

⁶⁴ Version according to Number I 5 of the O of 18 August 2004, (AS 2004 4037).

⁶⁵ Version according to Number I of the O of 24 March 2010, enforced on 1 April 2010 (AS 2010 1215).

⁴ Whosoever refurbishes 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 successfully carried out.

Article 20 Maintenance

¹ Whosoever uses medical devices as a professional must ensure the maintenance and associated inspections are carried out in accordance with the specifications.

² Maintenance must be carried out according to the principles of quality assurance, is to be appropriately planned internally and must take special account of:

- a. the instructions of the person who first placed the device on the market.
- b. the particular risk associated with the device and its use.

³ The results of maintenance and the associated inspections, of the defects and faults found, and actions taken are to be recorded for:

- a. active medical devices;
- b. devices with a measuring function which can be calibrated

⁴ Inspection procedures according to the Ordinance on Calibration of 17 December 1984⁶⁶ can be foreseen for medical devices with a measuring function.

Article 20a⁶⁷ Alteration

Whosoever changes medical devices or has them changed, or who refurbishes them or has them refurbished, in such a manner that they no longer serve their intended purpose or provide the intended performance must fulfil the requirements for the first placing on the market.

Article 21 Advertising

¹ The claims made for medical devices which are for direct delivery to the general public or which are for direct use by the general public may contain only such statements concerning use, performance capability and effectiveness as correspond with the product information.

² Misleading statements concerning effectiveness and/or performance capability of a medical device are prohibited.

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

- a. may only be delivered when prescribed by a physician;
- b. are placed on the market for use only by a professional.

⁶⁶ See today: Ordinance on Calibration of 15 February 2006 (SR **941.210**).

⁶³ Inserted by Number I of the O of 24 March 2010, enforced on 1 April 2010 (AS **2010** 1215).

Article 22 Import and export

¹ For the export of medical devices to a third country, the Agency can, upon the presentation of the appropriate evidence, issue an export certificate according to Article 50 Paragraph 2 of the Law on Therapeutic Products.

² For the importation of medical devices, the Agency can, upon presentation of the appropriate documentation, issue an import certificate where a third country demands evidence of the legality of the medical device to be placed on the market.

³ If there is reason, the Agency can set special conditions for the issue of a certificate.

⁴ It revokes a certificate if:

- a. it was issued on the basis of incorrect documentation;
- b. the devices noted in it are no longer covered by the necessary Declarations of Conformity and the associated certificates, or are subject to import or export prohibitions;
- c. the medical devices represent a danger to the health of users, patients or third parties.

Section 7: Enforcement in the framework of compliance monitoring**Article 23** Principle

¹ Enforcement in the framework of market surveillance (compliance monitoring) will ensure that the medical devices placed on the market, the procedures for placing them on the market, product surveillance and activities associated with medical devices comply with the regulations contained in this Ordinance. Compliance monitoring also concerns medical devices which are placed on the market in treaty countries by persons resident in Switzerland, as well as the procedures for placing them on the market, and product surveillance.⁶⁸

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

Article 24 Authorities

¹ The Agency is responsible for the compliance monitoring of medical devices. Certain aspects remain within the jurisdiction of other Federal offices or agencies.

² The cantons carry out the compliance monitoring:

⁶⁸ Version according to Number I 5 of the O of 18 August 2004, (AS 2004 4037).

- a. of the retail trade and points of issue;
- b. of the workmanlike manufacture of custom- made devices, of systems and of procedure packs.
- c. of the maintenance and refurbishment of medical devices by professionals using them, with the exception of hospitals.⁶⁹

Article 25 Co-ordination body

¹ The Agency can appoint a co-ordination body. This:

- a. co-ordinates the compliance monitoring and, where applicable, the inspection of the measuring accuracy of medical devices, and also the initiation of injunctions by various authorities;
- b. acts as a single contact point for questions and reporting in connection with medical devices;
- c. informs the relevant responsible authorities for compliance monitoring about notifications received in accordance with Article 6.

² The enforcement authorities in the field of medical devices are represented in the co-ordination body. The Agency chairs the co-ordination body and has the secretariat.

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

Article 26 Authority

For their review of the conformity of medical devices, the bodies responsible for compliance monitoring may, free of charge:

- a. demand the evidence and information necessary;
- b. take samples;
- c. initiate tests;
- d.⁷⁰ enter and inspect during normal working hours the business premises and facilities of persons who are required to provide information;
- e.⁷¹ inspect documents and demand that they, or additional information, be provided in one of the official languages or in English.

⁶⁹ Version according to Number I of the O of 24 March 2010, enforced on 1 April 2010 (AS **2010** 1215).

⁷⁰ Version according to Number I of the O of 24 March 2010, enforced on 1 April 2010 (AS **2010** 1215).

⁷¹ Version according to Number I of the O of 24 March 2010, enforced on 1 April 2010 (AS **2010** 1215).

Article 26a⁷² Use of personal data

¹ The bodies responsible for enforcement of this Ordinance are authorised to use such personal data as they need in order to fulfil all their duties according to this Ordinance. This also includes data relating to health condition obtained in the context of market surveillance (Art. 58 and 59 of the Law on Therapeutic Products).

² All usage is subject to the Federal Law of 19 June 1992⁷³ on data protection.

Article 27 Administrative measures

¹ If a medical device does not comply with the regulations, the competent authority informs the person who placed it on the market about the result of the compliance monitoring procedure and gives that person the opportunity to respond. The authority can order measures to be taken. It provides a reasonable time for compliance with the ordered measures.

² If there is justified suspicion that a medical device, even when it complies with the regulations, poses an immediate and serious threat to the health or safety of patients, users or third parties, the relevant enforcement authorities will take immediate steps to remove the medical device from the market, to prohibit its being placed on the market or to seize it. The Agency will then initiate the necessary measures.

Section 8: Final provisions**Article 28** Repeal of existing law

The following enactments are repealed:

- a. the Medical Devices Ordinance of 24 January 1996⁷⁴;
- b. the In vitro Diagnostic Ordinance of 24 February 1993⁷⁵.

Article 29⁷⁶ Transition provisions relating to the modification of 24 March 2010

¹ The hospitals shall establish the internal reporting system in accordance with the principles of quality assurance by 1 July 2011.

² The compliance control by the cantons for the maintenance and refurbishment of medical devices for professionals using them shall be implemented as of 1 July 2011.

⁷² Inserted by Number I 5 of the O of 18 August 2004, (AS **2004** 4037).

⁷³ SR **235.1**

⁷⁴ [AS **1996** 987, 1868, **1998** 1496]

⁷⁵ [AS **1993** 967, **1996** 2348]

⁷⁶ Version according to Number I of the O of 24 March 2010, enforced on 1 April 2010 (AS **2010** 1215).

Article 30 Coming into force
This Ordinance comes into force on 1 January 2002.

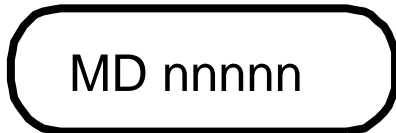
Annex 1
(Art. 8 Para. 1)

Conformity marking:

The conformity marking is to be represented as follows:



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



*Annex 2*⁷⁷
(Art. 8 Para. 1)

The following conformity marking is defined in Directives 93/42/EEC⁷⁸ Annex XII, 98/79/EC⁷⁹ Annex X and 90/385/EEC⁸⁰ Annex 9. The illustration is for information purposes only.



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



⁷⁷ Version according to Number I of the O of 24 March 2010, enforced on 1 April 2010 (AS **2010** 1215).

⁷⁸ OJ L 169 of 12 July 1993, page 1, last modified by Directive 2007/47/EC, OJ L 247 of 21 September 2007, page 21.

⁷⁹ OJ L 331 of 7 December 1998, page 1, last modified by Regulation (EC) No. 596/2009, OJ L 188 of 18 July 2009, page 14.

⁸⁰ OJ L 189 of 20 July 1990, page 17, last modified by Directive 2007/47/EC, OJ L 247 of 12 September 2007, page 21.

Annex 3
(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 to be found:

- a. for active implantable medical devices, in the Annexes 2-5 of the Directive 90/385/EEC⁸²;
- b. for classical medical devices, in the Annexes II-X of the Directive 93/42/EEC⁸³;
- c. for medical devices for in vitro diagnosis, in the Annexes II-VIII of the Directive 98/79/EC⁸⁴.

2. A conformity assessment body is to be used:

- a. for active implantable medical devices according to the Directive 90/385/EEC;
- b. for classical medical devices in Class IIa, IIb and III according to the Directive 93/42/EEC;
- c. for medical devices for in vitro diagnosis for self-testing;
- c1. for medical devices for in vitro diagnosis according to Annex II of the Directive 98/79/EC, even if manufactured in-house (except for products according to Section 3, letter b);
- d. for classical medical devices in Class I which are sterilized or have a measuring function.

3. A conformity assessment body does not have to be used for:

- a. the other classical medical devices in Class I (not sterile, not having a measuring function);
- b. medical devices manufactured in house for in vitro diagnosis according to Annex II of the Directive 98/79/EC if:
 1. the manufacturer is a nationally designated reference laboratory or a laboratory with an equivalent qualification; and
 2. no common technical specifications exist for them.

⁸¹ Corrected according to Number III Para. 1 of the O of 24 March 2010, enforced on 1 April 2010 (AS 2010 1215).

⁸² OJ L 189 of 20 July 1990, page 17, last modified by Directive 2007/47/EC, OJ L 247 of 21 September 2007, page 21

⁸³ OJ L 169 of 12 July 1993, page 1, last modified by Directive 2007/27/EC, OJ L 247 of 21 September 2007, page 21.

⁸⁴ OJ L 331 of 7 December 1998, page 1, last modified by Regulation (EC) No. 596/2009, OJ L 188 of 18 July 2009, page 14.

- b^{bis}. For other medical devices for in vitro diagnosis for which section 2 does not apply.
- c. all medical devices which are intended to be subjected to 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 according to the instructions of the person who placed them on the market has been tested and is present;
 - b. the system or procedure pack is accompanied by useful user instructions, including those of 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 is to be carried out according to Annex VII of the Directive 93/42/EEC. The required Declaration of Conformity is to be prepared before placing the devices on the market for the first time.
6. Conformity assessment for classical medical devices in Class IIa:
- The conformity assessment is to be carried out according to one of the following procedures according to the Directive 93/42/EEC:
- a. the procedure for EC Conformity Assessment according to Annex VII of this Directive in conjunction with one of the following procedures:
 1. EC Verification according to Annex IV;
 2. EC Conformity Assessment (Production quality assurance) according to Annex V;
 3. EC Conformity Assessment (Product quality assurance) according to Annex VI.
 - b. the procedure for an EC Conformity assessment according to Annex II of this Directive (Full quality assurance system). In this case, Annex II, Section 4 does not apply.
- The required Declaration of Conformity is to be prepared before placing the devices on the market for the first time.
7. Conformity assessment for classical medical devices in Class IIb
- The conformity assessment is to be carried out according to one of the following procedures according to the Directive 93/42/EEC:
- a. the procedure for an EC Conformity assessment according to Annex II of this Directive (Full quality assurance system). In this case, Annex II, Section 4 does not apply;

- b. the procedure for EC Type Examination according to Annex III of this Directive in conjunction with one of the following procedures:
 1. EC Verification according to Annex IV;
 2. EC Conformity Assessment (Production quality assurance) according to Annex V; or
 3. EC Conformity Assessment (Product quality assurance) according to Annex VI.

The required Declaration of Conformity is to be prepared before placing the devices on the market for the first time.

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

The conformity assessment is to be carried out according to one of the following procedures according to the Directive 93/42/EEC:

- a. the procedure for an EC Conformity Assessment according to Annex II of this Directive (Full quality assurance system);
- b. the procedure for EC Type Examination according to Annex III of this Directive in conjunction with one of the following procedures:
 1. EC Verification according to Annex IV;
 2. EC Conformity Assessment according to Annex V.

The required Declaration of Conformity is to be prepared before placing the devices on the market for the first time.

9. Conformity assessment for active implantable medical devices:

The conformity assessment is to be carried out according to one of the following procedures according to the Directive 90/385/EEC:

- a. the procedure for an EC Conformity Assessment according to Annex 2 of this Directive (Full quality assurance system).
- b. the procedure for EC Type Examination according to Annex 3 of this Directive in conjunction with one of the following procedures:
 1. EC Verification according to Annex 4; or
 2. EC Conformity Assessment to Type according to Annex 5.

The required Declaration of Conformity is to be prepared before placing the devices on the market for the first time.

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

The conformity assessment is to be carried out according to Annex VIII of the Directive 93/42/EEC or for active implantable medical devices according to Annex 6 of the Directive 90/385/EEC.

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

The conformity assessment is to be carried out according to Annex III of the Directive 98/79/EC. The required Declaration of Conformity is to be prepared before placing the devices on the market for the first time.

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

The conformity assessment is to be carried out according to one of the following procedures:

- a. According to Annex III of the Directive 98/79/EC;
- b. According to Section 13;
- c. According to Section 14.

If the procedure carried out is that according to Annex III of Directive 98/79/EC, the development of the products according to 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 prepared before placing the devices on the market for the first time.

13. Conformity assessment for in vitro diagnostic medical devices according to Annex II, List B of the Directive 98/79/EC:

The conformity assessment is to be carried out according to one of the following procedures according to the Directive 98/79/EC:

- a. the procedure for an EC Conformity Assessment according to Annex IV of this Directive (Full quality assurance system);
- b. the procedure for EC Type Examination according to Annex V of this Directive in conjunction with one of the following procedures:
 1. EC Verification according to Annex VI; or
 2. EC Conformity Assessment according to Annex VII.

The required Declaration of Conformity is to be prepared before placing the devices on the market for the first time.

14. Conformity assessment for medical devices for in vitro diagnosis according to Annex II, List A of the Directive 98/79/EC:

The conformity assessment is to be carried out according to one of the following procedures according to the Directive 98/79/EC:

- a. the procedure for an EC Conformity Assessment according to Annex IV of this Directive (Full quality assurance system).
- b. the procedure for EC Type Testing according to Annex V of this Directive in conjunction with the procedure for Production quality assurance according to Annex VII.

The required Declaration of Conformity is to be prepared before placing the devices on the market for the first time.

15. Conformity assessment for medical devices for in vitro diagnosis for performance evaluation:
The conformity assessment is to be carried out according to Annex VIII of the Directive 98/79/EC.
A declaration according to Annex VIII is to be prepared before the performance evaluation.

16. Conformity assessment for medical devices for in vitro diagnosis manufactured in house:
A declaration must be prepared for the product that includes the following information:

- a. Identification of the product;
- b. Name and address of the manufacturing establishment;
- c. Declaration that the product corresponds to the essential requirements.

The manufacturing establishment must have an appropriate quality assurance system according to recognised national or international standards (e.g. Good Practice in microbiological and serological laboratories in accordance with the Ordinance of 26 June 1996⁸⁵, the 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 according to Annex I of the Directive 98/79/EC and to its claimed performance.

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

- a. The manufacturing establishment is a nationally designated reference laboratory or a laboratory with an equivalent qualification;
- b. The product is classified as a List A one according to the said annex; and
- c. There are no common technical specifications for it.

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

- a. A declaration must be drawn up with the following information:
 1. Identification of the product,
 2. Name and address of the company carrying out the refurbishment,
 3. Declaration confirming that the product has been refurbished according to the instructions of the person who first placed it on the market, or declaration that a risk analysis and a validation procedure has demonstrated that an own refurbishment carried out is equally safe and effective.
- b. The company carrying out the refurbishment must have an appropriate quality assurance system according to nationally or internationally recognised standards.
- c. The documentation relating to the refurbishment must demonstrate that the product has been refurbished accordant to letter a, section 3.

Annex 4

Comparison of terms used in the EC Directives 90/385/EEC⁸⁷, 93/42/EEC⁸⁸ and 98/79/EC⁸⁹ and in the MepV

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 MepV
Notified body	Conformity assessment body
Directive 80/181/EEC ⁴⁴	Ordinance on legal units of 23 November 1994 ⁹¹
EC declaration of conformity (Annex 2, full quality assurance system)	Declaration of Conformity for a full quality assurance system
Responsible person according to 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 testing certificate

⁸⁶ Version according to Number III Para. 2 of the O of 24 March 2010, enforced on 1 April 2010 (AS **2010** 1215).

⁸⁷ OJ L 189 of 20 July 1990, page 17, last modified by Directive 2007/47/EC, OJ L 247 of 21 September 2007, page 21.

⁸⁸ OJ L 169 of 12 July 1993, page 1, last modified by Directive 2007/47/EC, OJ L 247 of 21 September 2007, page 21.

⁸⁹ OJ L 331 of 7 December 1998, page 1, last modified by EC Regulation No. 596/2009, OJ L 188 of 18 July 2009, page 14.

⁹⁰ OJ L No. L 39 of 15 February 1980, page 4.

⁹¹ SR **941.202**

*Annex 5*⁹²

⁹² Abrogated by Number III Para. 1 of the O of 24 March 2010, enforced on 1 April 2010 (AS **2010** 1215).

*Annex 6*⁹³

(Art. 18)

1 Product groups

The following product groups may only be used by a medical doctor, or by a professional trained in order to meet the requirements of this Annex and under the control and responsibility of a medical doctor:

- a. Products for injection which are intended to remain within the human body for longer than 30 days (long-term implantable devices);
- b. Class 4 laser devices according to the European Standard EN 60825- 1:1994⁹⁴ and Revisions A1:2002 and A2:2001 (high energy lasers).
- c. High energy pulsed non-coherent light sources such as high energy flash lamps.

2 Requirements for training:

- a. Long-term implantable devices may be used by a specialized nurse with a diploma and appropriate further training in the area of injection of long term implantable devices, or by persons with equivalent basic and further training.
- b. High energy laser devices and high energy pulsed non-coherent light sources may be used by cosmeticians with a Federal or equivalent specialist qualification, or by persons with equivalent basic and further training, provided they have been sufficiently trained in the use of the equipment.
- c. Patients who are treated with high energy laser devices or high energy pulsed non-coherent light sources must be attended to by a medical doctor before and after the treatment.

⁹³ Abrogated by Section II Para. 2 of the O of 18 August 2004 (AS **2004** 4037). Corrected according to Number III Para. 1 of the O of 24 March 2010, enforced on 1 April 2010 (AS **2010** 1215).

⁹⁴ This standard can be obtained from the Swiss Information Centre for Technical Standards, Bürglistrasse 29, 8400 Winterthur.