Medical Devices Ordinance
(MedDO)

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

The Swiss Federal Council,

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

ordains:

Chapter 1 General Provisions
Section 1 Scope and Exceptions

Art. 1 Scope

[1] This Ordinance applies to:

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

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

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

[3] This Ordinance also applies to:

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

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2 SR **734.0**
3 SR **941.20**
4 SR **930.11**
5 SR **814.50**
6 SR **946.51**

b. devices intended to deliver a medicinal product;

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

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

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

Art. 2 Exceptions

[1] This Ordinance does not apply to:

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

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

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

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

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

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

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

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

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

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

Section 2 Definitions and References to European Legislation

Art. 3 Medical device and accessories

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

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

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

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

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

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

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

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

[2] Medical devices also include:

a. contraceptive or fertility-enhancing products;

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

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

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

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

Art. 4 Further definitions

[1] In this Ordinance:

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

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

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

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

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

f. *manufacturer* means a natural or legal person who manufactures or fully refurbishes a device or has a device designed, manufactured or fully refurbished, and markets that device under its name or trademark; this definition is subject to the clarifying explanations and exceptions in Article 16 paragraphs 1 and 2 of Regulation (EU) 2017/745[7] on medical devices (EU-MDR);

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

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

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

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

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

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

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

7 Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC, OJ L117 of 5.5. 2017, p. 1; last amended by Regulation (EU) 202/561, OJ L 130 of 24.4.2020, p. 18.

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

Art. 5 References to European legislation

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

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

Chapter 2 Making available on the Market and Putting into Service

Section 1 Requirements

Art. 6 General safety and performance requirements

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

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

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

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

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

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