Schweizerische Eidgenossenschaft
Confédération suisse
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This text is a provisional version, which only contains the amendments. The final version will be published on www.fedlex.admin.ch when the amendments come into force.

Medical Devices Ordinance
(MedDO)

Amendment of «$$SmartDocumentDate»

The Swiss Federal Council ordains:

I

The Medical Devices Ordinance of 1 July 2020[1] is to be amended as follows:

Art. 4 para. 1 let. f footnote

[1] In this Ordinance:

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[2] on medical devices (EU-MDR);

Art. 8 para. 1 and 2

[1] and [2] only concern the Italian text.

Art. 13 para. 2 let. d

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

d. Investigational devices, subject to the provisions of Article 6 of the Ordinance of 1 July 2020[3] on Clinical Trials with Medical Devices (ClinO-MD);

1 SR **812.213**
2 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) 2023/607, OJ L 80 of 20.3.2023, p. 24.
3 SR **810.306**

Art. 15 Classification

Devices shall be divided into classes I, IIa, IIb and III, taking into account the intended purpose of the devices and their inherent risks. This classification must comply with the provisions of Annex VIII to EU-MDR[4], taking into account the implementing acts of the European Commission listed in Annex 5*a*.

Art. 21 para. 4

[4] The demonstration of compliance with the general safety and performance requirements must also include a performance evaluation in accordance with Article 61 EU-MDR.[5]

Art. 93 para. 1

The FDHA may adapt Annexes 1-3 and 5-6 to this Ordinance to reflect international or technical developments.

Art. 100 para. 2 and 3

[2] Certificates issued under the old legislation since 25 May 2017 and that were still valid on 26 May 2021 and that have not subsequently been withdrawn shall retain their validity until the date set out under Article 101 paragraph 1 letter b for the relevant risk category of the devices.

[3] Certificates issued under the old legislation since 25 May 2017 and that were still valid on 26 May 2021 and that expired before 20 March 2023 shall retain their validity until the date set out under Article 101 paragraph 1 letter b for the relevant risk category of the devices, provided one of the following requirements is fulfilled:

a. before the date of expiry of the certificates, the manufacturer and a body designated in accordance with Chapter 5, or a notified body in accordance with the EU-MDR[6] that is based in an EU or EEA country, have signed a written agreement in accordance with Section 4.3, second paragraph of Annex VII to the Regulation for the conformity assessment in respect of the devices covered by the expired certificate or in respect of devices intended to substitute those devices;

b. Swissmedic has granted a derogation from the applicable conformity assessment procedure in accordance with Article 22 paragraph 1 letter a, or a competent authority of an EU or EEA member state has granted a derogation from the applicable conformity assessment procedure in accordance with Article 120 paragraph 2 subparagraph 2 letter b EU-MDR;

4 See footnote to Art. 4 para. 1 let. f.
5 See footnote to Art. 4 para. 1 let. f.
6 See footnote to Art. 4 para. 1 let. f.

c. The competent authority has required the manufacturer to carry out the applicable conformity assessment procedure as part of its market surveillance activities, in accordance with Article 75 paragraph 2 of this Ordinance, or in accordance with Article 97 paragraph 1 EU-MDR.

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

1 The following devices may be placed on the market or put into service until the stated dates:

a. Devices for which the conformity assessment procedure under the old legislation did not require the involvement of a designated body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Ordinance required the involvement of a notified body: until 31 December 2028;

b. Devices with a valid certificate as set out under Article 100:

1. Class III devices and class IIb implantable devices except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors: until 31 December 2027,

2. Class IIb devices other than those covered under number 1, for class IIa devices, and for class I devices placed on the market in sterile condition or class I devices with a measuring function: until 31 December 2028.

1bis The placing on the market or putting into service of devices under paragraph 1 is only permitted if the following requirements are fulfilled:

a. The devices continue to comply with the old legislation.

b. They have not undergone any significant changes in their design or intended purpose.

c. The devices do not represent an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health.

d. By no later than 26 May 2024, the manufacturer has put in place a quality management system in accordance with Article 10 paragraph 9 EU-MDR[7].

e. By no later than 26 May 2024, the manufacturer or authorised representative has lodged a formal application for conformity assessment in accordance with Annex VII paragraph 4.3 subparagraph 1 EU -MDR, in respect of devices listed in paragraph 1 or in respect of devices that are intended to substitute such devices. The application must be directed to a designated body in accordance with Chapter 5 or a notified body in accordance with the EU-MDR based in an EU or EEA country.

f. The manufacturer and the designated or notified body in accordance with letter e must have signed a written agreement by no later than 26 September 2024 in accordance with Annex VII paragraph 4.3 subparagraph 2 EU-MDR.

7 See footnote to Art. 4 para. 1 let. f.

1ter Class III custom-made implantable devices may be placed on the market or put into service until 26 May 2026 without a certificate issued by a designated body in accordance with Chapter 5 or a notified body in accordance with the EU-MDR based in an EU or EEA country. following a conformity assessment procedure in accordance with Article 10 paragraph 2, provided the following requirements are fulfilled:

a. The manufacturer or its authorised representative has lodged a formal application in accordance with Annex VII paragraph 4.3 subparagraph 1 EU-MDR with a designated body in accordance with Chapter 5 or a notified body in accordance with the EU-MDR based in an EU or EEA country for conformity assessment of the custom-made devices by no later than 26 May 2024.

b. The manufacturer and a designated body in accordance with Chapter 5, or a notified body based in an EU or EEA country in accordance with the EU-MDR have signed a written agreement in accordance with Annex VII paragraph 4.3 subparagraph 2 EU-MDR by no later than 26 September 2024.

2 For the post-market surveillance of devices set out under paragraph 1, their market surveillance, vigilance, and registration of economic operators and of the devices themselves are subject to the provisions of this Ordinance.

3 Devices legally placed on the market prior to 26 May 2021 under the old legislation and devices placed on the market from 26 May 2021 in accordance with paragraphs 1 and 1ter may continue to be made available on the market or put into service. Article 103 remains reserved.

Art. 106 Groups of products without an intended medical purpose

1 As long as Swissmedic has not designated common specifications for groups of products without an intended medical purpose in accordance with Article 8 paragraph 1, the old legislation applies for these devices.

2Devices that fall under the groups of products defined under Annex 1 and for which the manufacturer is conducting or intends to conduct a clinical investigation in order to generate clinical data for the clinical evaluation to confirm their conformity with the relevant basic safety and performance requirements in accordance with Article 6 paragraph 2, and with the common specifications under Article 8 paragraph 1, and for which the conformity assessment procedure requires the involvement of a designated body in accordance with Chapter 5 or a notified body in accordance with the EU-MDR[8] based in an EU or EEA country, may be placed on the market or put into service until 31 December 2029, if the following requirements are fulfilled:

a. The devices were already legally marketed prior to 1 May 2024, and they still meet the requirements that applied to the device prior to 1 May 2024.

b. There are no significant changes to the design and intended purpose of the devices.

8 See footnote to Art. 4 para. 1 let. f.

[3] The placing on the market or putting into service in accordance with paragraph 2 is only permitted during the following periods if the following requirements are also fulfilled:

a. From 1 November 2024 to 1 May 2025: the sponsor in accordance with Article 2 letter d ClinO-MD[9] or in accordance with Article 2 no. 49 EU-MDR has received a notification from the competent body confirming that the application for a clinical investigation of the devices is complete.;.

b. From 2 May 2025 to 31 December 2027: the sponsor has initiated the clinical investigation.

c. From 1 January 2028 to 31 December 2029: the manufacturer and a designated body in accordance with Chapter 5 or a notified body in accordance with the EU-MDR based in an EU or EEA country have signed a written agreement on the performance of the conformity assessment.

[4] Devices that fall under the groups of products under Annex 1 and for which the manufacturer does not intend to conduct a clinical investigation but for which the conformity assessment procedure requires the involvement of a designated body in accordance with Chapter 5 or a notified body in accordance with the EU-MDR based in an EU or EEA country may be placed on the market or put into service until 31 December 2028 provided the following requirements are fulfilled:

a. The devices were already legally marketed prior to 1 May 2024 and continue to comply with the requirements that applied to the devices prior to 1 May 2024.

b. There are no significant changes to the design and intended purpose of the devices.

[5]Placing on the market or putting into service in accordance with paragraph 4 from 1 January 2027 to 31 December 2028 is only permitted if a written agreement on the performance of a conformity assessment has also been signed by the manufacturer and a designated body in accordance with Chapter 5 or a notified body in accordance with the EU-MDR based in an EU or EEA country.

[6] Devices that fall under the groups of products listed under Annex 1 that have certificates issued under the old legislation that were valid on 26 May 2021 and expired prior to 20 March 2023, but which did not fulfil the conditions under Article 100 paragraph 3 letters a, b or c, may continue to be placed on the market or put into service until the deadlines stipulated under Article 101 paragraph 1 letter b, provided the requirements in accordance with Article 101 paragraph 1bis are fulfilled. Article 101 paragraph 2 and Article 107 paragraphs 2-2ter are applicable.

Art. 107 para. 2–2^{quater}

[2] The conformity assessment body that is no longer designated in accordance with paragraph 1 and that issued the certificates under the old legislation shall remain responsible for appropriate surveillance in respect of the applicable requirements to the

9 SR **810.306**

devices it has certified, unless the manufacturer has agreed with a designated body in accordance with Chapter 5 or a notified body in accordance with the EU-MDR[10] based in an EU or EEA country that it will perform such surveillance.

[2bis] The designated body in accordance with Article 101 paragraph 1[bis] letter f shall bear responsibility for the surveillance in respect of the devices covered by the written agreement by no later than 26 September 2024. Where the written agreement concerns devices that are intended to substitute other devices for which a certificate was issued under the old legislation, the surveillance shall be conducted in respect of the devices that are being substituted.

[2ter] The arrangements for the transfer of surveillance from the designated body that issued the certificate to a designated body in accordance with Chapter 5 or a notified body in accordance with the EU-MDR based in an EU or EEA country shall be defined in an agreement between the manufacturer and the body performing the surveillance, and where practicable, the body that issued the certificate. The designated body in accordance with Chapter 5 shall not be responsible for conformity assessment activities carried out by the designated body that issued the certificate.

[2quater] The conformity assessment body that is no longer designated in accordance with paragraph 1 and that remains responsible for surveillance in accordance with paragraph 2, shall be subject to supervision by Swissmedic.

II

[1] Annex 1 is amended according to the enclosure.

[2] A new Annex 5*a* is added to this Ordinance, as per enclosure.

III

The amendment of other legislation is set out in the Annex.

IV

This Ordinance enters into force on 1 November 2023.

«$$SmartDocumentDate»

On behalf of the Swiss Federal Council

President of the Swiss Confederation: Alain Berset
Federal Chancellor: Walter Thurnherr

[10] See footnote to Art. 4 para. 1 let. f.

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

Groups of products without an intended medical purpose

Title
Only concerns the Italian text.

Annex 5a
(Art. 15)

Implementing acts of the European Commission considered in the classification of devices

For the classification of devices, the following implementing acts of the European Commission are taken into consideration:

1. Commission Implementing Regulation (EU) 2022/2347 of 1 December 2022 laying down rules for the application of Regulation (EU) 2017/745 of the European Parliament and of the Council as regards reclassification of groups of certain active products without an intended medical purpose (OJ. L 311 of 2.12.2022, p. 94)

Annex
(No. III)

Amendment of other legislation

The following enactments are amended as follows:

1. Ordinance of 1 July 2020[11] on Clinical Trials with Medical Devices

Art. 2a para. 3 footnote

[3] The conduct of non-interventional performance studies in which only already sampled anonymised biological material or already collected anonymised health-related personal data are further used, is governed by Articles 3 and 4 of the Ordinance of 20 September 2013[12] on Clinical Trials (ClinO), Article 25 HRO and Article 57 of Regulation (EU) 2017/746[13] (EU-IVDR).

Art. 4 para. 1 letter a footnote

[1] The sponsor and the investigator must meet the following requirements:

a. for clinical investigations: the requirements in accordance with Article 72 and Annex XV Chapters I and III of Regulation (EU) 2017/745[14] (EU-MDR);

2. Ordinance of 4 May 2022[15] on In Vitro Diagnostic Medical Devices

Art. 4 para. 1 let. e footnote

[1] In this Ordinance:

e. *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

11 SR **810.306**
12 SR **810.305**
13 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, OJ L 117 of 5.5.2017, p. 176; last amended by Regulation (EU) 2023/607, OJ. L 80 of 20.3.2023, p. 24.
14 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) 178/2002 and Regulation (EC) 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC, OJ. L 117 of 5.5.2017, p. 1; last amended by Regulation (EU) 2023/607, OJ. L 80 of 20.3.2023, p. 24.
15 SR **812.219**

to the clarifying explanations and exceptions set out in Article 16 paragraphs 1 and 2 of Regulation (EU) 2017/746[16] (EU-IVDR);

Art. 61 para. 2

[2] Devices for self-testing may be supplied only if the dispensing point can guarantee that professional advice is available and that the operational requirements are satisfied. Article 13 of the Federal Act of 15 June 2018[17] on Human Genetic Testing remains reserved.

Art. 82 para. 3 and 4

[3] Devices that were lawfully placed on the market prior to 26 May 2022 in accordance with the old legislation and those that were placed on the market after 26 May 2022 in accordance with paragraph 1 may continue to be made available on the market or put into service.

[4] *Repealed*

3. Ordinance of 16 December 2016 on Foodstuffs and Utility Articles[18]

There is no English translation for the full ordinance. For completeness, the German text is translated in this document.

Art. 63

Repealed

Art. 95b Transitional provision on the amendment of 29 September 2023

As long as afocal cosmetic contact lenses may be marketed without a certificate of conformity in accordance with Article 106 of the Medical Devices Ordinance of 1 July 2020[19], the requirements stipulated by the FDHA pursuant to the former Article 63 of this Ordinance shall continue to apply. Compliance with these requirements is verified by the enforcement authorities in accordance with the federal legislation on foodstuffs and utility articles.

16 Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU, OJ L 117 of 5.5.2017, p. 176; last amended by Regulation (EU) 2023/607, OJ L 80 of 20.3.2023, p. 24.
17 SR **810.12**
18 SR **817.02**
19 SR **812.213**

4. Ordinance of 23 November 2005[20] on Items intended for Human Contact

Art. 1 let. a no. 4

Repealed

Chapter 2, Section 3: (Art. 10-12)

Repealed

Art. 28b Transitional provision on the amendment of 29 September 2023

As long as afocal cosmetic contact lenses may be marketed without a certificate of conformity in accordance with Article 106of the Medical Devices Ordinance of 1 July 2020[21], the requirements set out under the previous Chapter 2, Section 3 of this Ordinance shall apply. Compliance with these requirements is verified by the enforcement authorities in accordance with the federal legislation on foodstuffs and utility articles.

Annex 3

Repealed

20 SR **817.023.41**
21 SR **812.213**