Medical Devices Ordinance
(MedDO)

Amendment dated 1 April 2015

The Swiss Federal Council
decrees:

I

The Medical Devices Ordinance of 17 October 2001[1] is hereby amended as follows:

Article 11.1. a and b and 1bis

[1] The conformity assessment bodies shall:

a. be accredited by the Swiss Accreditation Service in accordance with the Accreditation and Designation Ordinance of 17 June 1996[2] (AccDO) and, where prescribed by international agreement, be designated by the Agency as such; or

b. *repealed*

[1bis] The Agency shall only designate conformity assessment bodies, which meet the conditions of Annex 3*a*, in addition to the requirements of AccDO. For this purpose, it shall thoroughly assess the conformity assessment body concerned; such assessment shall include an on-site assessment.

Article 11a 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.

1 SR **812.213**
2 SR **946.512**

Article 11b Cooperation with the European Commission and the Member States of the European Union

In accordance with Annex 3*b*, and where prescribed by international agreement, the Agency shall cooperate with the European Commission and the Member States of the European Union in the procedure for designation, or for renewal or extension thereof.

Article 13a Subsequent surveillance of conformity assessment bodies

1 The Agency shall monitor the conformity assessment bodies in accordance with AccDO[3] Article 32 and Annex 3*c*.

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.

Article 20.4

4 For medical devices with a measurement function, test procedures may be required in accordance with the Measuring Instruments Ordinance of 15 February 2006.[4]

Article 27a Amendment of Annexes

1 The Swiss 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.

II

This Ordinance shall have new Annexes numbered 3*a*, 3*b* and 3*c*, as attached.

III

This Ordinance shall come into force on 15 April 2015.

1 April 2015 In the name of the Swiss Federal Council

Federal President: Simonetta Sommaruga
Federal Chancellor: Corina Casanova

3 SR **946.512**
4 SR **941.210**

Annex 3a
(Article 11.1bis)

Conditions for the designation of conformity assessment bodies

Only conformity assessment bodies which meet the conditions of Annex I of Implementing Regulation (EU) No. 920/2013[5] shall be designated.

5 Commission Implementing Regulation (EU) No 920/2013 of 24 September 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 ECOJ L 253 of 25 September 2013, p. 8.

Annex 3b
(Article 11*b*)

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

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.

Annex 3c
(Article 13*a*)

Subsequent surveillance of the conformity assessment bodies

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 18 months: all other conformity assessment bodies.