Ordinance on In Vitro Diagnostic Medical Devices (IvDO)

of 4 May 2022 (Status as of 1 January 2025)

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 Metrology Act of 17 June 2011[3],
Article 4 paragraph 1 of the Federal Act of 12 June 2009[4] on Product Safety,
Article 37 paragraph 1 of the Radiological Protection Act of 22 March 1991[5] and
in implementation of 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 in vitro diagnostic medical devices and accessories as defined in Article 3 (Devices).

[2] For devices which, when placed on the market or put into service, incorporate as an integral part a medical device in accordance with Article 3 paragraphs 1 and 2 of the Medical Devices Ordinance of 1 July 2020[7] (MedDO), this Ordinance applies only to the in vitro diagnostic medical device part.

Art. 2 Exceptions

This Ordinance does not apply to:

AS **2022** 291

1 SR **812.21**
2 SR **734.0**
3 SR **941.20**
4 SR **930.11**
5 SR **814.50**
6 SR **946.51**
7 SR **812.213**

a. products for general laboratory use or research-use only products, unless such products, in view of their characteristics, are specifically intended by their manufacturer to be used for in vitro diagnostic examination;

b. invasive sampling products or products which are directly applied to the human body for the purpose of obtaining a specimen;

c. internationally certified reference materials;

d. materials used for external quality assessment schemes;

e. devices intended exclusively for veterinary diagnostic purposes.

Section 2 Definitions and References to European Legislation

Art. 3 In vitro diagnostic medical device and its accessories

[1] An *in vitro diagnostic medical device* means any medical device in accordance with Article 3 paragraphs 1 and 2 MedDO[8] which:

a. is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, piece of equipment, software or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body; and

b. solely or principally for the purpose of providing information on one or more of the following:
   1. concerning physiological or pathological processes or states,
   2. concerning congenital physical or mental impairments,
   3. concerning the predisposition to a particular medical condition or a particular disease,
   4. to determine the safety and compatibility with potential recipients,
   5. to predict treatment response or reactions,
   6. to define or monitor therapeutic measures.

[2] Specimen receptacles shall also be deemed to be in vitro diagnostic medical devices.

[3] *Accessory for an in vitro diagnostic medical device* means an article which, whilst not being itself an in vitro diagnostic medical device, is intended by its manufacturer to be used together with one or more particular in vitro diagnostic medical device(s), to:

a. specifically enable the in vitro diagnostic medical device(s) to be used in accordance with its/their intended purpose(s); or to

8 SR **812.213**

b. specifically and directly assist the medical functionality of the in vitro diagnostic medical device or in vitro diagnostic medical devices in terms of its/their intended purpose(s).

Art. 4 Further definitions

[1] In this Ordinance:

a. *making available on the market* means any transfer or cession of a device, other than a device for performance study, 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 a device for performance study, on the Swiss market;

c. *putting into service* means the stage at which a device, other than a device for performance study, 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 preventive 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.[9] *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 set out in Article 16 paragraphs 1 and 2 of Regulation (EU) 2017/746[10] (EU-IVDR);

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

g. *importer* means any natural or legal person domiciled in Switzerland that places a device from abroad on the Swiss market;

h. *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;

i. *economic operator* means a manufacturer, an authorised representative, an importer or a distributor;

9 Amended by No I of the O of 20 Nov. 2024 (Amendment to the Transitional Regulations and Provision of Details on the Authorised Representative), in force since 1 Jan. 2025 (AS **2024** 741).

10 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.

j. *healthcare institution* means an organisation the primary purpose of which is the care or treatment of patients or the promotion of public health;

k. *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;

l. *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;

m. *Provider of information society services* means any natural or legal person who provides a service in accordance with Article 7 paragraph 5.

[2] The definitions set out in Article 2 points 3, 5–19, 24, 30–41, 44–45, 49–56, 60–72 and 74 EU-IVDR also apply.

Art. 5 References to European legislation

[1] The equivalent terms specified in Annex 1 and as used in EU-IVDR[11] and this Ordinance shall apply.

[2] Where this Ordinance makes reference to provisions of EU-IVDR which, in turn, refer to other provisions of EU-IVDR or other EU legislative acts, those provisions shall also apply. The version in the footnote to Article 4 paragraph 1 letter e is authoritative for references to EU-IVDR, while the versions of the relevant EU acts set out in Annex 2 point 1 apply to references to other EU acts. This provision excludes onward references to the EU acts listed in Annex 2 number 2; here the Swiss provisions 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 shall meet the general safety and performance requirements set out in Annex I to EU-IVDR[12], taking into account its intended purpose.

[3] If the device complies with the applicable technical standards or common specifications designated by the Swiss Agency for Therapeutic Products (Swissmedic), or relevant sections thereof, or with pharmacopoeial requirements in accordance with the Pharmacopoeia Ordinance of 17 October 2001[13], then the device shall be presumed to comply with those requirements of this Ordinance covered by the applicable

11 See the footnote to Art. 4 para. 1 let. e.
12 See the footnote to Art. 4 para. 1 let. e.
13 SR **812.211**

designated technical standards or common specifications, or relevant sections thereof, or by the pharmacopoeial requirements.

[4] The presumption in paragraph 3 also applies to compliance with the system or process requirements to be fulfilled in accordance with this Ordinance by economic operators, including requirements relating to quality management systems, risk management, post-market surveillance systems, performance studies, clinical evidence or post-market performance follow-up.

[5] Compliance with the common specifications in paragraph 3 is required unless the manufacturer can duly justify that the adopted solutions ensure an equivalent level of safety and performance.

Art. 7 Distance sales

[1] Devices offered in Switzerland by means of information society services – specifically an online service – that fulfil the conditions set out in paragraph 5 must comply with this Ordinance.

[2] Devices offered to users in Switzerland online or via some other form of distance sales are considered to have been made available on the market.

[3] Similarly, devices although not placed on the market, but used in the context of a commercial activity, whether in return for payment or free of charge, for the provision of a diagnostic or therapeutic service offered by means of information society services or by other means of communication shall also comply with this Ordinance.

[4] Upon request by the Swiss Agency for Therapeutic Products (Swissmedic), any natural or legal person offering diagnostic or therapeutic services in accordance with paragraph 1 shall make available a copy of the declaration of conformity.

[5] A device is deemed to be supplied via an information society service if that service:

a. is provided by distance selling, specifically without the contracting parties being physically present at the same time;

b. is provided electronically; and

c. is provided at the individual request of the recipient or the recipient's representative.

Art. 8 Specific requirements

Devices that are also machines within the meaning of Article 1 of the Machine Ordinance of 2 April 2008[14] must satisfy the relevant general safety and health protection requirements of the Machine Ordinance where these requirements are more specific than those of Chapter II of Annex I to EU-IVDR[15].

14 SR **819.14**
15 See the footnote to Art. 4 para. 1 let. e.

Art. 9 Devices manufactured and used in healthcare institutions

[1] Devices manufactured and used solely within healthcare institutions, with the exception of devices for performance studies, are deemed to have been put into service. Such devices are subject to the pertinent general safety and performance requirements of Annex I EU-IVDR[16], but not to any of the other requirements set out in this Ordinance, provided the requirements of Article 5 paragraph 5 letters a–i EU-IVDR are fulfilled.

[2] The documentation specified in Article 5 paragraph 5 letter g EU-IVDR is required for devices of all classes in accordance with Article 14.

[3] Paragraphs 1 and 2 do not apply to devices manufactured on an industrial scale.

Art. 10 Notification of devices manufactured in healthcare institutions

[1] Healthcare institutions that manufacture and use devices as specified in Article 9 shall provide the following information to Swissmedic prior to putting the devices into service:

a. their name and address;

b. the name and intended purpose of the device;

c. the risk class of the device in accordance with Article 14.

[2] Any other relevant information about these devices must be submitted to Swissmedic upon request.

[3] Changes to the information required in paragraph 1 must be reported to Swissmedic within 30 days.

[4] Depending on the risk inherent to a device and its use, Swissmedic may exempt devices manufactured and used in accordance with Article 9 from the reporting obligation.

Art. 11 Parts and components

[1] Any natural or legal person who makes available on the market an item intended to replace an identical or similar integral part or component of a device that is defective or worn in order to maintain or restore the function of the device without changing its performance or safety characteristics or its intended purpose, shall ensure that the item does not adversely affect the safety and performance of the device. Supporting evidence must be kept available for the competent authority.

[2] An item that is intended to replace a part or component of a device and that significantly changes the performance or safety characteristics or the intended purpose of the device shall be considered to be a device and shall meet the requirements laid down in this Ordinance.

16 See the footnote to Art. 4 para. 1 let. e.

Art. 12 Conformity marking and identification number

[1] Devices placed on the market in Switzerland or made available on the Swiss market must bear a conformity marking in accordance with Annex 4. The conformity marking presented in Annex V to EU-IVDR[17] is also a permissible conformity marking.

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

a. devices exclusively for demonstration and presentation purposes;

b. devices for performance studies, subject to the provisions of Article 6*a* of the Ordinance of 1 July 2020[18] on Clinical Trials with Medical Devices;

c. devices in accordance with Article 9.

[3] Where the conformity of a device has to be assessed by a conformity assessment body that is designated in accordance with this Ordinance or recognised in connection with an international agreement (designated body), the identification number of this body must be affixed to the conformity marking.

Art. 13 Affixing of conformity markings and identification numbers

[1] The conformity marking and, where necessary, the associated identification number shall be affixed to the device itself or its sterile packaging.

[2] Where this is not possible or practicable owing to the nature of the device, the conformity marking and, where necessary, the associated identification number must be displayed on the packaging.

[3] The conformity marking shall also appear on the instructions for use and on the sales packaging.

[4] The requirements of Article 18 paragraphs 3–6 EU-IVDR[19] and the general principles stated in Article 30 of Regulation (EC) No. 765/2008[20] must also be observed when affixing the conformity marking.

Section 2
Classification, Product Information and Device Identification

Art. 14 Classification

Devices shall be divided into classes A, B, C and D, 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-IVDR[21].

17 See the footnote to Art. 4 para. 1 let. e.
18 SR **810.306**
19 See the footnote to Art. 4 para. 1 let. e.
20 Regulation (EC) No. 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 of the Council, version according to OJ L 218 of 13.8.2008, p. 30.
21 See the footnote to Art. 4 para. 1 let. e.

Art. 15 Product information

[1] Product information comprises the labelling and instructions for use. It is governed by Chapter III of Annex I to EU-IVDR[22].

[2] It must be written in all three official languages of Switzerland. Symbols established by means of technical standards may be used to replace written statements.

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

a. the device is supplied exclusively to healthcare professionals or concerns a device in accordance with Article 9;

b. it is certain that the user meets the necessary professional and linguistic requirements and qualifications, and is in agreement;

c. the protection of patients, users and third parties is ensured; and

d. the efficacy and performance of the medical device are not placed at risk.

[4] If requested, additional information must be provided to users in one of the official languages of Switzerland.

[5] If a product cannot be, or cannot yet be, placed on the market as an in vitro diagnostic medical device, but may be confused with such a device, the claims relating to the said product must indicate clearly and legibly that it is not an in vitro diagnostic medical device and is not suitable for medical purposes.

[6] Devices intended solely for demonstration and presentation purposes must be specifically labelled as such. The information must be clearly visible and comprehensible.

[7] Misleading or contradictory information on a device's intended purpose, safety and performance is forbidden.

[8] For devices for self-testing or for near-patient testing, the information stated in Chapter III of Annex I EU-IVDR should be easily understandable and written in the three official languages.

[9] For devices not intended for self-testing and not placed on the market in accordance with Articles 81 and 82, the details of the authorised representative as specified in Chapter III section 20.2 letter d of Annex I EU-IVDR may be provided in a document accompanying the device.[23]

Art. 16 Unique device identification

[1] The manufacturer shall assign to the device and all superordinate packaging layers a unique device identifier (UDI[24]) prior to placing it on the market.

22 See the footnote to Art. 4 para. 1 let. e.
23 Inserted by No I of the O of 20 Nov. 2024 (Amendment to the Transitional Regulations and Provision of Details on the Authorised Representative), in force since 1 Jan. 2025 (AS **2024** 741).
24 Stands for «unique device identifier».

[2] The manufacturer must state the UDI on the labelling of the device and all higher levels of packaging. Shipping containers are not considered as a higher level of packaging. .

[3] The manufacturer shall maintain a list of all the UDIs he has assigned. This list is part of the technical documentation specified in Annex II to EU-IVDR[25]. It must be kept up-to-date at all times.

[4] The obligations and modalities associated with device identification and registration are governed by Articles 24 and 26 and Annex VI to EU--IVDR, taking account of the amendments to this Annex adopted by the European Commission by means of delegated acts[26].

[5] …[27]

Chapter 3 Conformity Assessment, Certificate and Declaration

Section 1 Conformity assessment

Art. 17 Principle

[1] Any natural or legal person who is domiciled in Switzerland and makes devices available on the market in Switzerland or in a contracting state must, upon request, provide the authorities which are responsible for controls in the field of market surveillance, with the declaration of conformity.

[2] A manufacturer domiciled in Switzerland and who places a device on the market in Switzerland or in a contracting state must, prior to placing it on the market, carry out an assessment of the device's conformity in accordance with the applicable conformity assessment procedures. The manufacturer and the importer must be able to prove that such a conformity assessment has been carried out and that the device is compliant.

[3] A manufacturer who puts into service in Switzerland or in a contracting state a device that is not placed on the market, with the exception of devices in accordance with Article 9, and who is domiciled in Switzerland must carry out an assessment of the device's conformity with the relevant conformity assessment procedures before it is put into service. The manufacturer must be able to prove that an according conformity assessment has been carried out and that the device is in compliant.

[4] The demonstration of conformity with the general safety and performance requirements shall also include a performance evaluation in accordance with Article 56 EU-IVDR[28].

25 See the footnote to Art. 4 para. 1 let. e.
26 See Annex 3.
27 Enters into force at a later date (see Art. 91 para. 2).
28 See the footnote to Art. 4 para. 1 let. e.

Art. 18 Exemptions

[1] On a duly justified request, Swissmedic may authorise the placing on the market and putting into service of a specific device the use of which is in the interest of public health, patient safety or health even though:

a. the relevant conformity assessment procedure in accordance with Article 19 has not been carried out; or

b. the language requirements in Article 15 paragraph 2 have not been met.

[2] Individual devices, apart from devices for self-testing, that have not undergone the relevant conformity assessment procedure may be placed on the market and used without authorisation from Swissmedic provided:

a. they are used to test samples with the aim of averting or treating life-threatening conditions or permanent impairments of a body function;

b. no conforming device is available for this specific intended purpose;

c. they are used exclusively in the laboratory to investigate samples from an individual person;

d. the treating healthcare professional has informed the individual person concerned about the non-conformity of the medical device and the related risks; and

e. the individual person concerned has consented to the use of the device.

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

Art. 19 Procedure

The conformity assessment procedure is governed by Article 48 and by Annexes IX–XI to EU-IVDR[29].

Art. 20 Involvement of a designated body

[1] When a designated body is involved, all the information necessary for the conformity assessment must be made available to it.

[2] Manufacturers must not simultaneously apply to more than one designated body in Switzerland or a contracting state to carry out a conformity assessment procedure for the same device.

[3] Any natural or legal person who applies to a designated body must declare whether an application to a different designated body in Switzerland or a contracting state has been withdrawn before a decision was issued or rejected by a different designated body in Switzerland or a contracting state.

29 See the footnote to Art. 4 para. 1 let. e.

[4] If a manufacturer withdraws its application to have a conformity assessment procedure carried out before the designated body has issued its decision on the assessment, the designated body in question shall notify Swissmedic and the other designated bodies.

[5] Where a manufacturer voluntarily changes the designated body, it must comply with the requirements of Article 53 EU-IVDR[30].

Section 2 Certificate of Conformity

Art. 21 Issuing and content

[1] The designated bodies issue certificates of conformity in accordance with Annexes IX–XI to EU-IVDR[31] (Certificates).

[2] The certificates must be issued in one of the three official languages of Switzerland or in English.

[3] They must, as a minimum, include the information required in Annex XII to EU-IVDR, taking account of the amendments to this Annex adopted by the European Commission by means of delegated acts[32].

[4] Certificates issued by bodies designated under EU law and domiciled in a state of the EU or European Economic Area (EEA) but not recognised by an international agreement are deemed equivalent to certificates issued by Swiss bodies if it can be credibly demonstrated that:

a. the conformity assessment procedures applied meet Swiss requirements; and

b. the certificates were issued by a body with an equivalent qualification to that required in Switzerland.

Art. 22 Validity

[1] Certificates are valid for a maximum of five years. The expiry date must be indicated on the certificate.

[2] At the manufacturer's request, the validity of the certificate may be extended by a maximum of five years following a re- assessment carried out in accordance with the applicable conformity assessment procedure. Certificates may be extended more than once.

[3] Any supplement to a certificate is valid for the same period as the certificate to which it belongs.

30 See the footnote to Art. 4 para. 1 let. e.
31 See the footnote to Art. 4 para. 1 let. e.
32 See Annex 3.

Art. 23 Suspension, restriction and revocation

[1] If a designated body finds that a manufacturer no longer fulfils the requirements of this Ordinance, it shall impose on that manufacturer a suitable deadline for restoring compliance.

[2] If this deadline passes without the manufacturer taking suitable corrective action, the designated body shall suspend, revoke or restrict the certificate in question.

[3] A certificate that has been amended, suspended or revoked by a designated body must no longer be used in its original form.

Art. 24 Documentation requirements

[1] The designated body shall provide Swissmedic and the other designated bodies with:

a. all information on certificates it has issued and any amendments or supplements to such certificates;

b. information on suspended, reinstated or revoked certificates;

c. information on certificates it has refused;

d. information on restrictions imposed on certificates.

[2] Notifications of certificates for Class D devices, with the exception of applications to supplement or renew existing certificates, must include the documents specified in Article 50 paragraph 1 EU-IVDR[33].

Section 3 Declaration of Conformity

Art. 25

[1] If the applicable conformity assessment procedure has demonstrated that the requirements of this Ordinance have been fulfilled, the manufacturer of devices, apart from devices used for performance studies, issues a declaration of conformity. The manufacturer shall continuously update this declaration.

[2] The declaration of conformity shall include the information required in Annex IV to EU-IVDR[34], taking account of the amendments to this Annex adopted by the European Commission by means of delegated acts[35]. It must be written in one of the three official languages of Switzerland or English or translated into one of these languages.

[3] If a device also requires a manufacturer's declaration of conformity for aspects not covered by this Ordinance but nevertheless required by other legislation in order to demonstrate compliance with that legislation, a single declaration of conformity shall be drawn up.

33 See the footnote to Art. 4 para. 1 let. e.
34 See the footnote to Art. 4 para. 1 let. e.
35 See Annex 3.

[4] By drawing up the declaration of conformity, the manufacturer assumes responsibility for compliance with the requirements of this Ordinance and all other legislation applicable to the device.

Chapter 4 Designated Bodies

Section 1 Designation

Art. 26 Requirements and application

[1] Swissmedic shall only designate conformity assessment bodies which are domiciled in Switzerland, have completed an assessment procedure in accordance with Article 27 and which comply with the requirements set out in Annex VII to EU-IVDR[36].

[2] Applications for designation must be submitted to Swissmedic. They must in particular include:

a. details of the activities and the types of devices for which designation is sought;

b. proof that the requirements of Annex VII to EU-IVDR are met.

[3] Swissmedic shall, within thirty days, check that the application for designation is complete, and shall request the applicant to provide any missing information.

[4] It shall review the application and accompanying documents and draw up a preliminary assessment report.

Art. 27 Assessment

[1] Swissmedic shall conduct an on-site assessment of the conformity assessment body and, if relevant, of all sub-contractors and subsidiaries.

[2] If Swissmedic identifies non-compliances in the course of its assessment, it shall draw up a list of non-compliances for the applicant. Swissmedic shall set a deadline for the conformity assessment body by which the latter shall submit to Swissmedic a corrective action plan to address the non-compliances and a preventive action plan.

[3] The plans shall indicate the root cause of the identified non-compliances and shall include a timeframe for implementation of the actions therein.

[4] Swissmedic shall decide whether the proposed action is suitable and whether the timeframe for implementation is appropriate.

Art. 28 Assessment report

[1] If Swissmedic approves the plans required under Article 27 paragraph 2, it shall prepare an assessment report.

[2] This shall comprise the following:

36 See the footnote to Art. 4 para. 1 let. e.

a. the result of the assessment;

b. confirmation that suitable corrective and preventive actions have been appropriately addressed and, where necessary, implemented;

c. the scope of the designation.

Art. 29 Issuance and extension of designation

[1] Swissmedic shall issue the designation if the conformity assessment body meets the requirements.

[2] The extension of designations is subject to the requirements and procedures laid out in Articles 26–28.

Art. 30 Sub-contractors and subsidiaries

[1] Designated bodies that delegate part of the work to sub-contractors or to subsidiaries bear full responsibility for the work carried out on their behalf by sub-contractors or by the subsidiaries.

[2] They shall verify that the sub-contractor or the subsidiary meets the applicable requirements of Annex VII to EU-IVDR[37].

[3] They must notify Swissmedic if they delegate work under the terms of paragraph 1. They must be able to demonstrate to Swissmedic that the sub-contractor or the subsidiary is capable of carrying out the tasks assigned to it.

[4] Conformity assessment activities may only be delegated if the designated body has informed the legal or natural person that applied for conformity assessment accordingly.

[5] The designated bodies shall make publicly available a list of their subsidiaries.

Art. 31 Duty of cooperation and notification requirement

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

[2] The designated bodies shall notify Swissmedic within 15 days of any change which may affect their compliance with the requirements of Annex VII to EU-IVDR[38] or their ability to conduct conformity assessments.

Art. 32 Tariffs

The designated bodies shall issue lists of the standard fees charged for their activities and make these lists publicly available.

37 See the footnote to Art. 4 para. 1 let. e.
38 See the footnote to Art. 4 para. 1 let. e.

Section 2 Cessation of Conformity Assessment Activities

Art. 33

[1] If a designated body ceases to carry out its conformity assessment activities, it shall inform Swissmedic and the manufacturers concerned as soon as possible. In the case of a planned cessation of activities, notice must be given one year before the activities cease. Swissmedic shall revoke the designation at the time of cessation of activities.

[2] The certificates remain valid for a maximum of nine months following the cessation of activities, provided another designated body assumes responsibility for the devices covered by those certificates and confirms this in writing.

[3] The designated body assuming responsibility in accordance with paragraph 2 shall conduct a full assessment of the devices concerned before the nine-month period expires and before issuing new certificates for those devices.

Section 3 Suspension, Restriction or Revocation of Designation

Art. 34 Principle

[1] Designation shall be suspended, restricted or revoked if the designated body:

a. no longer or only partly meets the requirements; or

b. fails to carry out corrective actions ordered by Swissmedic.

[2] Suspensions shall be imposed for a maximum of twelve months. They may be extended by a maximum of a further twelve months.

[3] If its designation is suspended, restricted or revoked, the designated body must inform the manufacturers concerned within ten days.

Art. 35 Unduly issued certificates

[1] In the event of its designation being restricted, suspended or revoked, the designated body shall suspend or revoke any certificates which were unduly issued.

[2] If the designated body fails to fulfil this requirement, Swissmedic shall instruct it to suspend or revoke the certificates and set an appropriate deadline for doing so.

Art. 36 Validity of certificates in the event of suspension or restriction of designation

[1] If Swissmedic suspends or restricts the designation of a designated body, the certificates concerned remain valid provided Swissmedic:

a. confirms within a month that no safety issue exists in relation to the certificates concerned; and

b. outlines a timeline and measures to remedy the suspension or restriction.

[2] The certificates also remain valid if Swissmedic:

a. confirms that during the suspension or restriction, no certificates relevant to the suspension shall be issued, amended or re-issued; and

b. states that the designated body is able to continue to monitor and retain responsibility for existing certificates during the suspension or restriction.

[3] The designated body shall inform the manufacturers concerned or the persons or entities placing the devices concerned on the market.

[4] Should Swissmedic ascertain that the designated body does not have the capability to support existing certificates issued, these certificates retain their validity if the manufacturer of the device in question confirms to Swissmedic or, if it is domiciled in a contracting state, to the competent authority there, in writing and within three months of designation being suspended or restricted that:

a. another qualified designated body is temporarily assuming the monitoring functions; and that

b. this designated body is responsible for the certificates during the period of suspension or restriction.

Art. 37 Validity of certificates in the event of designation being revoked

[1] If Swissmedic revokes the designation of a designated body, the certificates affected remain valid for nine months provided:

a. Swissmedic or, if the manufacturer is domiciled in a contracting state, the competent authority there confirms that there is no safety issue associated with the devices in question, and

b. another designated body confirms in writing that it is assuming immediate responsibility for the certificates for these devices and can complete the assessment of the devices within twelve months of designation being revoked.

[2] Swissmedic may, within the limits of its competence, extend the provisional validity of the certificates for further periods of three months, which altogether must not exceed twelve months.

Section 4 Monitoring and Re-assessment of Designated Bodies

Art. 38

[1] Swissmedic shall monitor the designated bodies and their subsidiaries and sub-contractors and carry out re-assessments. In the course of monitoring and re-assessing designated bodies and reviewing their assessments, Swissmedic shall take account of the requirements and procedures set out in Articles 40 and 41 EU-IVDR[39].

[2] It shall verify whether designated bodies still satisfy the requirements of Article 32 paragraph 1 and Annex VII to EU-IVDR three years after designation, and then every four years, in the course of a full re-assessment. This provision is subject to changes

[39] See the footnote to Art. 4 para. 1 let. e.

in assessment intervals resulting from delegated acts[40] issued by the European Commission.

[3] Swissmedic shall carry out an on-site audit at least once a year to ascertain whether the designated bodies and, where necessary, their subsidiaries and sub-contractors fulfil the requirements and obligations of Annex VII to EU-IVDR.

[4] For this purpose, it may at any time:

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

b. carry out audits of the personnel of the designated body and its subsidiaries or sub-contractors or observe audits that the designated body carries out on manufacturers' premises.

Chapter 5 Requirements for Economic Operators

Section 1 Manufacturers

Art. 39 Affixing the conformity marking and performance evaluation

[1] Manufacturers guarantee that their devices have been designed and manufactured in accordance with the requirements of this Ordinance when placing them on the market or putting them into service.

[2] They must affix the conformity marking to their devices.

[3] They must conduct a performance evaluation in accordance with Article 56 and Annex XIII to EU-IVDR[41]. They must update this performance evaluation based on the results of the post-market performance follow-up.

Art. 40 Technical documentation

[1] Manufacturers must specify in the technical documentation the information required in Annexes II and III to EU-IVDR[42], taking account of the amendments to these Annexes made by the European Commission by means of delegated acts[43].

[2] Manufacturers must submit either the complete technical documentation or a summary thereof when requested to do so by the competent authority.

Art. 41 Document retention requirements

Manufacturers must ensure that the following documents are available to the competent authority for at least ten years after the last device covered by the declaration of conformity has been placed on the market:

a. the complete technical documentation;

40 See Annex 3.
41 See the footnote to Art. 4 para. 1 let. e.
42 See the footnote to Art. 4 para. 1 let. e.
43 See Annex 3.

b. the declaration of conformity;

c. a copy of the certificates issued, including any amendments and supplements.

Art. 42 Person responsible for regulatory compliance

[1] Manufacturers must have available within their organisation at least one person responsible for regulatory compliance who possesses the requisite expertise in the field of in vitro diagnostic medical devices.

[2] Proof of the requisite expertise the person responsible for regulatory compliance possesses, the responsibilities of this person, exceptions and further modalities are governed by Article 15 EU-IVDR[44].

[3] The person responsible for regulatory compliance must have a deputy. If a number of persons are jointly responsible for regulatory compliance, their respective areas of responsibility shall be stipulated in writing.

[4] The person responsible for regulatory compliance must suffer no disadvantage within the manufacturer's organisation in relation to the proper fulfilment of his or her duties, regardless of whether or not they are employees of the organisation.

Art. 43 Further obligations

The further obligations incumbent on manufacturers, particularly the requirements regarding their quality and risk management systems, are governed by Article 10 EU-IVDR[45].

Section 2 Authorised Representative

Art. 44 Obligations

[1] Where the manufacturer of a device is not domiciled in Switzerland, the device may only be placed on the market if the manufacturer designates an authorised representative domiciled in Switzerland by means of a written mandate.

[2] The authorised representative is responsible for the formal and safety-related aspects of placing the device on the market.

[3] The authorised representative's rights and obligations and the scope of its mandate are governed by Article 11 EU-IVDR[46].

[4] The manufacturer and authorised representative may contractually agree that, instead of the authorised representative keeping available a copy of the technical documentation, the manufacturer shall, on request, submit the documentation straight to

44 See the footnote to Art. 4 para. 1 let. e.
45 See the footnote to Art. 4 para. 1 let. e.
46 See the footnote to Art. 4 para. 1 let. e.

Swissmedic. The authorised representative must ensure that the documentation is submitted within seven days.

[5] Changes in authorised representative are governed by Article 12 EU-IVDR.

Art. 45 Person responsible for regulatory compliance

[1] Authorised representatives shall have permanently and continuously at their disposal at least one person who possesses the requisite expertise as regards the requirements for in vitro diagnostic medical devices under this Ordinance and who is responsible for regulatory compliance.

[2] In other respects, Article 42 paragraphs 2–4 shall apply mutatis mutandis.

Section 3 Importers

Art. 46

[1] Importers may only place on the market devices that comply with this Ordinance. Before placing devices on the market, they shall verify that:

a. the device bears the conformity marking;

b. the declaration of conformity has been drawn up;

c. the manufacturer is identified and has designated an authorised representative in accordance with Article 44;

d. the device is labelled in accordance with this Ordinance and accompanied by the instructions for use;

e. the manufacturer has assigned a UDI where applicable.

[2] Importers shall indicate on the device or on its packaging or in a document accompanying the device, their name, place of business and the address where they can be contacted.

[3] Where an importer considers or has reason to believe that a device is not in conformity with the requirements of this Ordinance, it must not place the device on the market until it has been brought into conformity.

[4] The further obligations of importers prior to and after placing a device on the market are governed by Articles 13 and 16 paragraphs 3 and 4 EU-IVDR[47]. In particular, importers must comply with the following obligations:

a. storage, transport and quality management system;

b. cooperation with the manufacturer, authorised representative, designated body and competent authorities;

c. the provision of information to the manufacturer, authorised representative, designated body and competent authorities.

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

Section 4 Distributors

Art. 47

[1] When making a device available on the market, distributors must, in the context of their activities, act with due care in relation to the requirements applicable. Before making a device available on the market, distributors must verify that:

a. the device bears the conformity marking;

b. the declaration of conformity has been drawn up;

c. the device is accompanied by the product information;

d. where devices have been imported, the importer has provided the information required in Article 46 paragraph 2;

e. the manufacturer has assigned a UDI where applicable.

[2] With the exception of paragraph 1 letter d, a sampling method may be used for the purposes of verification.

[3] Where a distributor considers or has reason to believe that a device is not in conformity with the requirements of this Ordinance, it must not make the device available on the market until it has been brought into conformity.

[4] The further obligations of distributors prior to and after making a device available on the market are governed by Articles 14 and 16 paragraphs 3 and 4 EU-IVDR[48]. In particular, distributors must fulfil the following obligations:

a. storage, transport and quality management system;

b. cooperation with the manufacturer, authorised representative, importer and competent authorities;

c. the provision of information to the manufacturer, authorised representative, importer and competent authorities.

Section 5 Registration of Economic Operators

Art. 48

[1] Manufacturers or their authorised representatives and importers must register the information required by Part A, Section 1, of Annex VI to EU-IVDR[49] with Swissmedic within three months of placing a device on the market for the first time.

[2] The economic operator in question must report any changes to the information provided to Swissmedic within one week.

[3] Further obligations and registration modalities are governed by Article 27 paragraph 3 and Article 28 EU-IVDR.

48 See the footnote to Art. 4 para. 1 let. e.
49 See the footnote to Art. 4 para. 1 let. e.

[4] Swissmedic shall verify the information provided by the economic operators and assign them a Swiss single registration number (CHRN).

Chapter 6 Device Surveillance

Section 1 Post-market Surveillance

Art. 49 System

[1] For each device, manufacturers must plan, establish, document, implement, maintain and update a post-market surveillance system in a manner that is proportionate to the risk class and appropriate for the type of device. That system shall be an integral part of the manufacturer's quality management system.

[2] The system must be suited to actively and systematically gathering, recording and analysing relevant data on the quality, performance and safety of a device throughout its entire lifetime, and to drawing the necessary conclusions and to determining, implementing and monitoring any preventive and corrective actions.

[3] The modalities of the system, particularly the resulting actions, updates and amendments to technical documentation, are governed by Article 78 paragraph 3 EU-IVDR[50].

Art. 50 Incidents and actions

[1] Should it become evident in the course of post-market surveillance that preventive and/or corrective actions are necessary, the manufacturer shall implement the appropriate measures and inform the competent authorities and, if applicable, the designated body.

[2] If a manufacturer becomes aware of a serious incident in connection with a device that has been made available on the market, or takes action to prevent or minimise the risk of such an incident for medical or technical reasons (field safety corrective actions), it must report the fact in accordance with Article 59.

Art. 51 Plan

The post-market surveillance plan must satisfy the requirements of Section 1 of Annex III to EU-IVDR[51]. The plan shall be part of the technical documentation referred to in Annex II to EU-IVDR.

Art. 52 Report

[1] Manufacturers of class A and B devices must draw up a post-market surveillance report.

[2] This report must contain:

50 See the footnote to Art. 4 para. 1 let. e.
51 See the footnote to Art. 4 para. 1 let. e.

a. a summary of the results and conclusions of the analyses of the data gathered as a result of the plan in accordance with Article 51;

b. a description of any preventive and corrective actions taken, including their rationale.

[3] The report is part of the post-market surveillance technical documentation specified in Annex III to EU-IVDR[52].

[4] The manufacturer must update the report when necessary and make it available to the designated body and the competent authority upon request.

Section 2 Safety Report

Art. 53 Obligation

[1] Manufacturers of class C and D devices shall prepare a safety report for each device and, where relevant, for each category or group of devices.

[2] Manufacturers of class C and D devices shall update the safety report when necessary, but at least annually.

Art. 54 Content

[1] The safety report must contain:

a. a summary of the results and conclusions of the analyses of the data gathered as a result of the plan in accordance with Article 51;

b. a description of any preventive and corrective actions taken and their rationale.

[2] Throughout the lifetime of the device concerned, the safety report must set out:

a. the conclusions of the benefit-risk determination;

b. the main findings of the post-market performance follow-up;

c. the total sales volume of the device;

d. an estimate of the size of the population using the device;

e. characteristics of the population in letter d;

f. the frequency of device usage, where practicable.

[3] The safety report forms part of the technical documentation specified in Annexes II and III to EU-IVDR[53].

52 See the footnote to Art. 4 para. 1 let. e.
53 See the footnote to Art. 4 para. 1 let. e.

Art. 55 Review

[1] Manufacturers shall make their safety reports available to the designated body involved in the conformity assessment.

[2] The designated body shall review the safety report for class D devices and record the outcome of its review with details of any action taken.

[3] Manufacturers or their authorised representatives shall, upon request, make the safety report and the outcome of the designated body's review, with details of any action taken, available to the competent authority.

Section 3 Summary of Safety and Performance

Art. 56

[1] For class C and D devices, other than devices for performance studies, the manufacturer must draw up a summary of safety and performance.

[2] This summary shall be written in a way that is clear to the intended user and, if relevant, to the patient.

[3] The minimum content of the summary is governed by Article 29 paragraph 2 EU-IVDR[54].

[4] The draft of the summary, together with the documentation, must be submitted to the designated body involved in the conformity assessment for validation by that body.

[5] The manufacturer shall publish the summary after it has been validated.

[6] The manufacturer must mention on the label or instructions for use where the summary is available.

Section 4 Traceability and Recording of Device Identification

Art. 57 Traceability

[1] Distributors and importers shall co-operate with manufacturers or authorised representatives to achieve an appropriate level of traceability of devices.

[2] The duty of disclosure under Article 47c TPA applies for at least 10 years from the date on which the device was acquired or delivered.

Art. 58 Storage of the UDI

Economic operators and healthcare institutions shall store and keep, preferably by electronic means, the UDI of devices which they have supplied or with which they have been supplied. The list of these devices, device categories or device groups is

54 See the footnote to Art. 4 para. 1 let. e.

specified in implementing acts[55] of the EU Commission in accordance with Article 24 paragraph 11 letter a EU-IVDR[56].

Section 5 Vigilance

Art. 59 Reporting obligation

[1] Manufacturers of devices made available on the market in Switzerland must report to Swissmedic:

a. any serious incidents involving the device in question that have occurred in Switzerland as soon as they become aware of them;

b. any field safety corrective actions undertaken in Switzerland.

[2] Exemptions from this reporting obligation, modalities, periodic summary reports, trend reporting and analyses of serious incidents and field safety corrective actions are governed by Article 24 paragraph 5 and Articles 82–84 EU-IVDR[57].

[3] Where an authorised representative is required pursuant to Article 44, this representative is responsible for the reporting obligation in paragraph 1. Furthermore, the authorised representative shall submit the trend reports pursuant to paragraph 2 on incidents in Switzerland and abroad to Swissmedic without being requested to do so. Final reports prepared in accordance with Article 84 paragraph 5 EU-IVDR should be submitted to Swissmedic. The transfer of these obligations from the manufacturer to the authorised representative must be agreed in writing in the mandate.

[4] Any professional who becomes aware of a serious incident when using devices must report this to the supplier and Swissmedic. The report may be submitted by a professional association. The timelines for doing so are as set out in Article 82 EU-IVDR.

[5] Reports must be submitted to Swissmedic electronically and in machine-readable format. Swissmedic publishes information on electronic submission and the forms to be used with content specifications.

Art. 60 Reporting systems in hospitals

[1] Hospitals must set up an internal reporting system within the framework of an established quality management system for the purpose of reporting under Article 59 paragraph 4.

[2] They must designate a suitable competent person (vigilance contact person) with a medical or technical qualification to assume responsibility for reporting to Swissmedic. They must supply this person's contact details to Swissmedic.

[3] Records and all documents created under the vigilance quality management system must be retained for at least 15 years.

55 See Annex 3.
56 See the footnote to Art. 4 para. 1 let. e.
57 See the footnote to Art. 4 para. 1 let. e.

Chapter 7 Conduct in relation to Devices

Art. 61 Supply

[1] Devices are supplied in accordance with their intended purpose and the information provided by the manufacturer.

[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[58] on Human Genetic Testing also applies.[59]

[3] Dispensing devices for the diagnosis of human communicable diseases to the general public is prohibited. Swissmedic may approve exceptions in the interests of public health.

Art. 62 Advertising

[1] Claims for devices must only contain statements that correspond to the product information.

[2] Misleading statements, particularly concerning the intended purpose, safety and performance of a device, are prohibited.

[3] Devices intended solely for use by healthcare professionals must not be advertised to the public.

Art. 63 Use

Any professional who uses a device from a foreign country directly without placing it on the market is responsible for the conformity of that device.

Art. 64 Maintenance

[1] Any professional using devices must ensure that the devices are maintained and tested in accordance with the regulations.

[2] Maintenance must be carried out in accordance with the principles of a quality management system, is to be organised appropriately, and must be guided in particular by:

a. the manufacturer's instructions;

b. the particular risk associated with the device and its use.

[3] For devices with a measurement function, test procedures may be required in accordance with the Measuring Instruments Ordinance of 15 February 2006[60].

58 SR **810.12**
59 Amended by Annex No 2 of the O of 29 Sept. 2023, in force since 1 Nov. 2023 (AS **2023** 576).
60 SR **941.210**

[4] Swissmedic may issue and publish requirements for maintenance measures. These requirements shall be deemed to constitute the current scientific and technological standards.

Art. 65 Cyber security

[1] Healthcare institutions must put in place all technical and organisational resources required by the state of the art to ensure that network-compatible devices are protected against electronic attack and unauthorised access.

[2] Hospitals must identify, evaluate and document the measures taken under paragraph 1 in accordance with the principles of a risk management system. This system forms an integral part of the hospitals' quality management system.

Chapter 8 Market Surveillance

Art. 66 Principle

[1] Inspections under the auspices of market surveillance shall cover devices made available on the market, conformity assessment procedures, device surveillance, device handling and economic operators' fulfilment of their obligations. They shall also cover devices made available in contracting states by natural or legal persons domiciled in Switzerland, the conformity assessment procedures and surveillance activities for such devices and the natural or legal persons' fulfilment of their obligations.

[2] The market surveillance activities undertaken by Swissmedic and the Cantons are governed by Article 66 TPA and Articles 88–90, 92 and 93 EU-IVDR[61]. Article 92 paragraph 3 and Article 93 paragraphs 3 and 4 EU-IVDR are excluded.

[3] The Cantons shall draw up annual plans for their market surveillance activities under paragraph 2. They shall provide Swissmedic with an annual summary of the results of their surveillance activities. Swissmedic may determine both the content of the summary and the form in which it is made available.

[4] If necessary for the protection of public health, Swissmedic shall decree its measures under Article 66 TPA in a general ruling.

Art. 67 Common activities and use of information

[1] The market surveillance authorities may reach agreement with organisations that represent the economic operators or users on the implementation of common activities designed to promote conformity and other similar purposes.

[2] They may use all the information obtained in connection with these activities for market surveillance.

61 See the footnote to Art. 4 para. 1 let. e.

Art. 68 Additional measures

In addition to the measures stated in Article 66 paragraph 2, the competent authorities may institute the following measures in particular:

a. They may require economic operators to issue the relevant information required to establish the ownership of websites, if the information concerned is connected with the subject of the investigation.

b. They may request the removal of content from an online interface or the explicit display of a warning for users, provided there is no other option for eliminating a serious risk.

c. If the request stated in letter b is ignored, they may instruct providers of information society services to restrict access to the online interface, for example by asking a third party to implement this measure.

d. To protect public health, they may require a provider of information society services to discontinue its activities in Switzerland.

Art. 69 Responsibilities

[1] Swissmedic is responsible for monitoring:

a. devices and device conformity;

b. vigilance;

c. the maintenance of devices:

1. in hospitals,

2. that are intended for use in hospitals.

[2] Certain aspects of the monitoring activities set out in paragraph 1 remain the responsibility of other federal offices or institutions.

[3] The Cantons are responsible for monitoring:

a. the retail trade and dispensing points;

b. the maintenance of devices by the professionals using them and in healthcare institutions with the exception of hospitals.

Art. 70 Powers

[1] For the purposes of verifying conformity, the authorities responsible for monitoring under Article 69 may, without providing compensation:

a. demand the proof and information required;

b. take samples;

c. have the samples tested or submitted to laboratory examination;

d. enter and inspect, during normal working hours and with advance notice or, if necessary, unannounced, the business premises and facilities of natural or legal persons who have an obligation to provide information;

e. consult documents and demand that they, or additional information, be provided in one of the official languages of Switzerland or in English.

[2] If a manufacturer fails to fulfil its obligations under Article 59, Swissmedic may impose appropriate measures to protect health, up to and including prohibiting the making available on the market or the putting into service of the devices in question.

Art. 71 Duty to cooperate and provide information

[1] Economic operators that place a device on the market in Switzerland or in a contracting state, and economic operators, professionals and healthcare institutions that make a device available or put it into service in Switzerland or a contracting state have a duty to cooperate on matters of enforcement. In particular, they must provide, free of charge, all necessary information and all necessary proof and documentation to the enforcement bodies.

[2] The providers of information society services also have a duty to cooperate on matters of enforcement. In particular, they should inform the competent authorities about suspected illegal activities by, or information from, users of their service and, upon request, provide information that enables the users of their service with whom they have concluded agreements about storage to be identified.

Chapter 9 Data Processing

Art. 72 Data processing in general

The provisions of Chapter 10 of MedDO, with the exception of Article 90 MedDO[62], apply mutatis mutandis to data process by Swissmedic and third parties contracted by Swissmedic.

Art. 73 Publication of data

Swissmedic may publish the following in the medical devices information system:

a. device data, as specified in Part B of Annex VI to EU-IVDR[63];

b. information on economic operators and devices, as specified in Part A of Annex VI to EU-IVDR;

c. the general information specified in Article 31 paragraph 7 EU-IVDR governing the assessment, designation and notification of conformity assessment bodies and for the monitoring of designated bodies, and on changes that have a significant impact on such tasks;

d. summaries of the annual report on monitoring and on-site assessment activities drawn up in accordance with Article 40 paragraph 12 EU-IVDR;

e. summaries of safety and performance in accordance with Article 56;

62 SR **812.213**
63 See the footnote to Art. 4 para. 1 let. e.

f. information on certificates issued under Articles 24 and 35–37;

g. field safety notices for users or customers issued in the course of field safety corrective actions in accordance with Article 84 paragraph 8 EU-IVDR;

h. summaries of the reports on Swissmedic's activities in monitoring market surveillance;

i. information on market surveillance measures, particularly recalls, on non-conforming devices and preventive health protection measures.

Chapter 10 Final Provisions
Section 1 Enforcement

Art. 74 Amendment of Annexes

[1] The FDHA may amend Annexes 1, 2 and 4 to this Ordinance in line with international and technical progress.

[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.

Art. 75 Information on directly applicable legal acts of the European Commission

Swissmedic shall provide on its website information on legal acts of the European Commission that, in accordance with this Ordinance, are directly applicable in Switzerland in the version mandatory for the Member States of the EU and as listed in Annex 3.

Art. 76 Harmonisation of enforcement

When implementing this Ordinance, Swissmedic shall respect implementing acts adopted by the European Commission on the basis of EU-IVDR[64].

Art. 77 Cooperation with the European Commission and authorities of the contracting states

[1] Where provided for by international agreements, Swissmedic, the designated bodies, economic operators and the providers of information society services shall cooperate with the European Commission and the authorities of the contracting states.

[2] Swissmedic may appoint experts who are qualified to assess conformity assessment bodies in the field of in vitro diagnostic medical devices.

[3] Swissmedic may appoint experts to participate in expert groups of the European Commission and the authorities of the contracting states.

64 See the footnote to Art. 4 para. 1 let. e.

Art. 78 Collaboration with the customs authorities

[1] The customs authorities provide Swissmedic with information on the import, export and transit of devices.

[2] Swissmedic may mandate the customs authorities to detain devices for further inspection and to obtain samples.

[3] It may provide the customs authorities with information about ongoing or concluded administrative or criminal proceedings and sanctions in connection with market surveillance.

Art. 79 EU reference laboratories in Switzerland

[1] Laboratories that wish to be designated an EU reference laboratory by the European Commission according to Article 100 paragraph 1 EU-IVDR[65] may apply to Swissmedic for this designation.

[2] They must demonstrate to Swissmedic in particular that they:

a. meet the criteria set out in Article 100 paragraph 4 EU-IVDR;

b. have arranged appropriate liability insurance cover; and

c. are able to assume the tasks under Article 100 paragraph 2 EU-IVDR in accordance with the requirements in each case.

[3] If the requirements are met, Swissmedic shall propose to the European Commission that the laboratory be designated an EU reference laboratory.

Section 2
Amendment of other Legislation and Transitional Provisions

Art. 80 Amendment of other legislation

The amendment of other legislation is regulated in Annex 5.

Art. 81[66] Validity of certificates issued under the old legislation

[1] Certificates issued before 25 May 2017 under the old legislation retain their validity until the expiry date stated therein, but no longer than 26 May 2025.

[2] Certificates that have been issued since 25 May 2017 under the old legislation, were valid on 26 May 2022 and have not subsequently been revoked shall, following expiry of the period indicated on the certificate, be deemed valid until 31 December 2027.

65 See the footnote to Art. 4 para. 1 let. e.
66 Amended by No I of the O of 20 Nov. 2024 (Amendment to the Transitional Regulations and Provision of Details on the Authorised Representative), in force since 1 Jan. 2025 (AS **2024** 741).

[3] Certificates that have been issued since 25 May 2017 under the old legislation, were valid on 26 May 2022 and expired before 9 July 2024 shall be deemed valid until 31 December 2027 if any of the following conditions is met:

a. Before the certificates expired, the manufacturer and a designated body in accordance with Chapter 4 or a notified body in accordance with EU-IVDR[67] domiciled in an EU or EEA state signed a written agreement in accordance with section 4.3 subparagraph 2 of Annex VII EU-IVDR regarding the conformity assessment of devices with expired certificates or devices intended as their replacements.

b. Swissmedic has granted an exemption from the applicable conformity assessment procedure in accordance with Article 18 paragraph 1 letter a, or a competent authority of an EU or EEA state has granted a derogation from the applicable conformity assessment procedure in accordance with Article 54 paragraph 1 EU-IVDR.

c. Within the context of market surveillance activities as described in Article 66 paragraph 2 of this Ordinance or in Article 92 paragraph 1 EU-IVDR, the competent authority has required the manufacturer to carry out the applicable conformity assessment procedure.

Art. 82 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 specified dates:

a. devices with a certificate valid under Article 81: until 31 December 2027;

b. devices that did not require the involvement of a designated body for the conformity assessment procedure under the old legislation, for which a declaration of conformity was issued before 26 May 2022 and which require the involvement of a designated body for the conformity assessment procedure in accordance with this Ordinance:

1. Class D devices: until 31 December 2027,
2. Class C devices: until 31 December 2028,
3. Class B devices: until 31 December 2029,
4. Class A devices placed on the market in a sterile condition: until 31 December 2029.[68]

[1bis] Devices shall not be placed on the market or brought into service in accordance with paragraph 1 unless the following conditions have been met:

a. The devices still conform with the old legislation.

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

67 See footnote to Art. 4 para. 1 let. e.
68 Amended by No I of the O of 20 Nov. 2024 (Amendment to the Transitional Regulations and Provision of Details on the Authorised Representative), in force since 1 Jan. 2025 (AS **2024** 741).

c. The devices do not pose any unacceptable risks to the health and safety of patients, users or other persons or to any other aspects of public health protection.

d. The manufacturer has established a quality management system in accordance with Article 10 paragraph 8 EU-IVDR[69] by no later than 26 May 2025.

e. The manufacturer or authorised representative has submitted, by the date specified, a formal application in accordance with Annex VII section 4.3 subparagraph 1 EU-IVDR for assessment of the conformity of the following devices or of devices intended to replace the following devices to a designated body in accordance with Chapter 4 or a notified body in accordance with EU-IVDR domiciled in an EU or EEA state:

1. for products specified in paragraph 1 letters a and b number 1: by 26 May 2025;
2. for products specified in paragraph 1 letter b number 2: by 26 May 2026;
3. for products specified in paragraph 1 letter b numbers 3 and 4: by 26 May 2027.

f. The manufacturer and the designated or notified body in accordance with letter e has signed a written agreement in accordance with Annex VII section 4.3 subparagraph 2 EU-IVDR by the specified date:

1. for products specified in paragraph 1 letters a and b number 1: by 26 September 2025;
2. for products specified in paragraph 1 letter b number 2: by 26 September 2026;
3. for products specified in paragraph 1 letter b numbers 3 and 4: by 26 September 2027.[70]

[2] The post-market surveillance of devices specified in paragraph 1, their market surveillance, vigilance, 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 2022 under the old legislation and devices legally placed on the market in accordance with paragraph 1 from 26 May 2022 may continue to be made available on the market or put into service.[71]

[4] …[72]

69 See footnote to Art. 4 para. 1 let. e.
70 Inserted by No I of the O of 20 Nov. 2024 (Amendment to the Transitional Regulations and Provision of Details on the Authorised Representative), in force since 1 Jan. 2025 (AS **2024** 741).
71 Amended by Annex No 2 of the O of 29 Sept. 2023, in force since 1 Nov. 2023 (AS **2023** 576).
72 Repealed by Annex No 2 of the O of 29 Sept. 2023, with effect from 1 Nov. 2023 (AS **2023** 576).

Art. 83 Requirements for devices manufactured and used in healthcare institutions

The requirements set out in Article 9 for devices manufactured and used in healthcare institutions apply from the following dates:

a. the requirements set out in Article 5 paragraph 5 letters b, c and e-i EU-IVDR[73]: from 26 May 2024;

b.[74] the requirements set out in Article 5 paragraph 5 letter d EU-IVDR: from 31 December 2030.

Art. 84 Exemptions for in vitro diagnostic medical devices

Exemptions issued by Swissmedic under Article 9 paragraph 4 and Article 17 paragraph 3 MedDO[75] in the version dated 1 August 2020[76] shall retain their validity.

Art. 85 Affixing the UDI

The UDI must be affixed in accordance with Article 16 paragraph 2:

a. for class D devices: from 26 May 2023;

b. for class B and C devices: from 26 May 2025;

c. for class A devices: from 26 May 2027;

Art. 86 Designation of an authorised representative

If the manufacturer is domiciled in an EU or EEA state or has designated an authorised representative domiciled in an EU or EEA state, that manufacturer must designate an authorised representative in accordance with Article 44 paragraph 1 for all devices placed on the market as from 26 May 2022 within the following time periods:

a. for class D devices: by 31 December 2022;

b. for class B and C devices: by 31 March 2023;

c. for class A devices: by 31 July 2023.

73 See the footnote to Art. 4 para. 1 let. e

74 Amended by No I of the O of 20 Nov. 2024 (Amendment to the Transitional Regulations and Provision of Details on the Authorised Representative), in force since 1 Jan. 2025 (AS **2024** 741).

75 SR **812.213**

76 AS **2001** 3487; **2020** 2975

Art. 87[77]

Art. 88 Registration of economic operators

Economic operators that have placed devices on the market prior to 26 May 2022 in accordance with Article 22*a* MedDO[78] in the version dated 26 November 2017[79] must register the information required under Article 48 paragraph 1 by 26 November 2022.

Art. 89 Conformity assessment bodies

[1] Conformity assessment body designations issued under Section 4 of MedDO[80] in the version dated 26 November 2017[81] shall become void for in vitro diagnostic medical devices.

[2] A conformity assessment body whose designation has become void in accordance with paragraph 1 and that issued the certificates under the old legislation remains responsible for the appropriate surveillance of all applicable requirements relating to the devices it has certified, unless the manufacturer has agreed with a designated body in accordance with Chapter 4 or a notified body in accordance with EU-IVDR[82] domiciled in an EU or EEA state that this body will carry out the surveillance.[83]

[2bis] The designated body under Article 82 paragraph 1[bis] letter f shall be responsible for surveillance of the devices covered by the written agreement from 26 September 2025 at the latest. If the written agreement covers devices intended to replace other devices for which certificates were issued under the under the old legislation, the surveillance shall be carried out in relation to the devices that are being replaced.[84]

[2ter] The arrangements for the transfer of surveillance from the designated body that issued the certificate to a designated body in accordance with Chapter 4 or a notified body in accordance with EU-IVDR domiciled in an EU or EEA state shall be defined in an agreement between the manufacturer and the body that assumes the task of surveillance, and, if possible, the designated body that issued the certificate. The designated body in accordance with Chapter 4 is not responsible for conformity assessment activities that were carried out by the designated body that issued the certificate.[85]

77 Repealed by No I of the O of 20 Nov. 2024 (Amendment to the Transitional Regulations and Provision of Details on the Authorised Representative), with effect from 1 Jan. 2025 (AS **2024** 741).
78 SR **812.213**
79 AS **2017** 5935
80 SR **812.213**
81 AS **2001** 3487; **2010** 1215; **2015** 999; **2017** 5935
82 See footnote to Art. 4 para. 1 let. e.
83 Amended by No I of the O of 20 Nov. 2024 (Amendment to the Transitional Regulations and Provision of Details on the Authorised Representative), in force since 1 Jan. 2025 (AS **2024** 741).
84 Inserted by No I of the O of 20 Nov. 2024 (Amendment to the Transitional Regulations and Provision of Details on the Authorised Representative), in force since 1 Jan. 2025 (AS **2024** 741).
85 Inserted by No I of the O of 20 Nov. 2024 (Amendment to the Transitional Regulations and Provision of Details on the Authorised Representative), in force since 1 Jan. 2025 (AS **2024** 741).

2quater A conformity assessment body whose designation has become void in accordance with paragraph 1 and which remains responsible for surveillance in accordance with paragraph 2 shall be subject to supervision by Swissmedic.[86]

3 Conformity assessment body designations issued under Section 4*a* of MedDO in the version dated 1 August 2020[87] retain their validity for in vitro diagnostic medical devices.

4 If an application for designation as a conformity assessment body according to Section 4*a* of MedDO in the version dated 26 November 2017[88] was submitted before 26 May 2022, the designation is issued according to the new legislation.

Art. 90 Notification of devices

1 Until Article 16 paragraph 5 enters into force, the notification obligation for manufacturers domiciled in Switzerland according to Article 6 paragraphs 2 and 4 MedDO[89] in the version dated 26 November 2017[90] continue to apply.

2 ...[91]

3 The notification obligation according to Article 10 for devices manufactured and used in healthcare institutions applies from the following dates:

a. for class D devices: from 1 July 2024;

b. for class B and C devices: from 1 January 2025;

c. for class A devices: from 1 July 2025.

Art. 91 Entry into force

1 Subject to the exceptions in paragraph 2, this Ordinance enters into force on 26 May 2022.

2 Article 16 paragraph 5 and Article 90 paragraph 2 enters into force at a later date.

86 Inserted by No I of the O of 20 Nov. 2024 (Amendment to the Transitional Regulations and Provision of Details on the Authorised Representative), in force since 1 Jan. 2025 (AS **2024** 741).
87 AS **2017** 5935
88 AS **2017** 5935
89 SR **812.213**
90 AS **2001** 3487; **2017** 5935
91 Enters into force at a later date (see Art. 91 para. 2).

Annex 1
(Art. 5 para. 1)

Equivalent terms

The terms listed below and used in EU-IVDR[92] and this Ordinance are equivalent as follows:

EU	Switzerland
a. English terms	
Union	Switzerland
Member State	Switzerland
Third country	Other state
Union market	Swiss market
Union legislation / Union harmonisation legislation	Legislation
Harmonised standard	Designated standard
State of the art	Scientific and technological standards
EU declaration of conformity	Declaration of conformity
Official Journal of the European Union	Federal Gazette (Bundesblatt)
Established outside / within the Union	Domiciled in / outside Switzerland
Authority	Competent authority under Swiss law
a. Deutsche Ausdrücke	
Union	Schweiz
Mitgliedstaat	Schweiz
Drittstaat / Drittland	anderer Staat
Unionsmarkt	Schweizer Markt
Rechtsvorschriften der Union / Harmonisierungsrechtsvorschriften der Union	Rechtsvorschriften
Harmonisierte Norm	Bezeichnete Norm
Stand der Technik	Stand von Wissenschaft und Technik
EU-Konformitätserklärung	Konformitätserklärung
Amtsblatt der Europäischen Union	Bundesblatt

92 See the footnote to Art. 4 para. 1 let. e.

EU	Switzerland
Ausserhalb / In der Union ansässig	Sitz ausserhalb / in der Schweiz
Behörde	Nach schweizerischem Recht zuständige Behörde
Angehörige der Gesundheitsberufe	Gesundheitsfachpersonen
Aussetzung	Suspendierung
b. French terms	
Union	Suisse
État membre	Suisse
État tiers / pays tiers	autre État
marché de l'Union	marché suisse
législation (actes législatifs) de l'Union / législation d'harmonisation de l'Union	législations
norme harmonisée	norme désignée
état de l'art	état de la science et de la technique
déclaration de conformité UE	déclaration de conformité
Journal officiel de l'Union européenne	Feuille fédérale
situé hors de l'Union / établi dans l'Union	sis à l'étranger / en Suisse
notice d'utilisation	mode d'emploi
conditionnement	emballage
notification des incidents graves	déclaration des incidents graves
autorités	autorités compétentes en vertu du droit suisse
retrait des certificats	révocation des certificats
retrait de la désignation	révocation de la désignation
c. Italian terms	
Unione	Svizzera
Stato Membro	Svizzera
paese terzo	altro Stato
mercato dell'Unione	mercato svizzero
legislativo dell'Unione / normativa di armonizzazione dell'Unione	legislazioni
norma armonizzata	norma designata

EU	Switzerland
stato dell'arte	stato della scienza e della tecnica
dichiarazione di conformità UE	dichiarazione di conformità
marcatura CE di conformità	marchio di conformità
Gazzetta ufficiale dell'Unione europea	Foglio federale
avente sede fuori dall'Unione,/ stabilito nell'Unione	avente sede all'estero/ in Svizzera
autorità	autorità competente secondo il diritto svizzero
operatori sanitari	professionisti della salute
controllata	società controllata
ritiro dei certificati	revoca dei certificati
ritiro della designazione	revoca della designazione
immissione sul mercato	immissione in commercio
segnalazione di incidenti gravi	notifica di incidenti gravi
confezionamento	imballaggio

Annex 2[93]
(Art. 5 para. 2)

Applicable law

1 EU law

Where this Ordinance makes reference to provisions of EU-IVDR[94] that in turn make reference to EU law, the versions below remain applicable:

1. 1 Regulation (EC) 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006, OJ L 353 of 31.12.2008, p. 1; last amended by Delegated Regulation (EU) 2021/1962, OJ L 400 of 12.11.2021, p. 16.

1. 2 Commission Regulation (EU) No 722/2012 of 8 August 2012 concerning particular requirements as regards the requirements laid down in Council Directives 90/385/EEC and 93/42/EEC with respect to active implantable medical devices and medical devices manufactured utilising tissues of animal origin, OJ L 212 of 9.8.2012, p. 3.

2 Swiss law

Where this Ordinance makes reference to provisions of EU-IVDR that in turn make reference to EU law, the Swiss law below is applicable in place of the EU law:

EU law	Swiss legislation
1. Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, OJ L 311 of 28.11.2001, p. 67	Therapeutic Products Act of 15 December 2000

93 Revised by Annex 2 No II 103 of the Data Protection Ordinance of 31 Aug. 2022, in force since 1 Sept. 2023 (AS **2022** 568).
94 See the footnote to Art. 4 para. 1 let. e.

EU law	Swiss legislation
2. Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, OJ L 136 of 30.4.2004, p. 1	Therapeutic Products Act of 15 December 2000
3. Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products, OJ L 210 of 7.8.1985, p. 29	Product Liability Act of 18 June 1993[95]
4. Directive 2014/30/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to electromagnetic compatibility, OJ L 96 of 29.3.2001, p. 79	Ordinance of 25 November 2015[96] on Electromagnetic Compatibility
5. Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC, OJ L 157 of 09.06.2006, p. 24	Machine Ordinance of 2 April 2008[97]

95 SR **221,112,944**
96 SR **734.5**
97 SR **819.14**

EU law	Swiss legislation
6. Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council, OJ L 316 of 14.11.2021, p. 12	Therapeutic Products Act of 15 December 2000 and Federal Act of 6 October 1995[98] on Technical Barriers to Trade
7. Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data, OJ L 8 of 12.1.2001, p. 1	Data Protection Act of 25 September 2023[99]
8. Regulation (EC) No. 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93, OJ L 218 of 13.8.2008, p. 30	Federal Act of 6 October 1995 on Technical Barriers to Trade and Product Safety Act of 12 June 2009[100]

98 SR **946.51**
99 SR **235.1**
100 SR **930.11**

EU law	Swiss legislation
9. Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, OJ L 396, 30.12.2006, p. 1	Chemicals Act of 15 December 2000[101]
10. Council Directive 80/181/EEC of 20 December 1979 on the approximation of the laws of the Member States relating to units of measurement and on the repeal of Directive 71/354/EEC, OJ L 39 of 15.2.1980, p. 40	Metrology Act of 17 June 2011[102]
11. Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom, OJ L 13 of 17.1.2014, p. 1	Radiological Protection Act of 22 March 1991[103]
12. Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices, OJ L 189 of 20.7.1990, p. 17	Medical Devices Ordinance of 17 October 2001[104]

101 SR **813.1**
102 SR **941.20**
103 SR **814.50**
104 AS **2001** 3487; **2004** 4037; **2008** 4377; **2010** 1215, 2749; **2015** 999; **2017** 5935; **2019** 999, **2020** 2975

EU law	Swiss legislation
13. Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, OJ L 169 of 12.7.1993, p. 1	Medical Devices Ordinance of 17 October 2001
14. Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices, OJ L 331 of 7.12.1998, p. 1.	Medical Devices Ordinance of 17 October 2001
15. 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.	Medical Devices Ordinance of 1 July 2020[105]

105 SR **812.213**

Annex 3
(Art. 16 para. 4, 21 para. 3, 25 para. 2, 38 para. 2, 40 para. 1 and 58)

Delegated acts of the European Commission based on the EU-IVDR

For the purposes of implementing this Ordinance, the legal acts adopted on the basis of the provisions of EU-IVDR[106] set out below apply in Switzerland in the binding version applicable to the EU Member States:

Subject matter	Passed by the European Commission based on the EU-IVDR
Art. 16 para. 4 IvDO	Delegated acts in accordance with Art. 24 para. 10 EU-IVDR
Art. 21 para. 3 IvDO	Delegated acts in accordance with Art. 51 para. 6 EU-IVDR
Art. 25 para. 2 IvDO	Delegated acts in accordance with Art. 17 para. 4 EU-IVDR
Art. 38 para. 2 IvDO	Delegated acts in accordance with Art. 40 para. 11 EU-IVDR
Art. 40 para. 1 IvDO	Delegated acts in accordance with Art. 10 para. 4 EU-IVDR
Art. 58 IvDO	Implementing act in accordance with Art. 24 para. 11 let. a EU-IVDR

106 See the footnote to Art. 4 para. 1 let. e.

Annex 4
(Art. 12 para. 1)

The conformity marking is as follows:

Where a designated body has to be involved, its identification number is to be placed beside its conformity marking:

Annex 5
(Art. 80)

Amendment of other legislation

The legislation below is amended as follows:
…[107]

[107] The amendments may be consulted under AS **2022** 291.