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衛生福利部食品藥物管理署　函

機關地址：11561 臺北市南港區昆陽街161-2號
傳　　真：
聯絡人及電話：江宛真02-2787-7514
電子郵件信箱：joannajiang@fda.gov.tw

241
新北市三重區重新路五段609巷6號3樓之3

受文者：台灣醫療暨生技器材工業同業公會

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主旨：檢送瑞士醫療藥品管理局(Swissmedic)就本(110)年9月初舉辦新醫療器材法規線上說明會發布之相關新聞資料1份，請轉知所屬會員知悉，請查照。

說明：

一、依據駐瑞士代表處經濟組110年9月8日臺瑞字第1100000141號函辦理。

二、瑞士醫療藥品管理局於本年9月2日舉辦新醫療器材法規線上說明會，並於9月7日發布相關新聞資料（含新法之常見問答集），前述資料可於該局官網下載，網址：https://www.swissmedic.ch/swissmedic/en/home/news/mitteilungen/rueckblick-mep-infoanlass.html。

正本：台灣醫療暨生技器材工業同業公會
副本：經濟部國際貿易局

署長吳秀梅

swissmedic

Schweizerisches Heilmittelinstitut
Institut suisse des produits thérapeutiques
Istituto svizzero per gli agenti terapeutici
Swiss Agency for Therapeutic Products

More than 1,600 participants at the information event on the new medical devices regulation

Successful Swissmedic online event on 2 September 2021

07.09.2021

Swissmedic organises regular events to give an insight into current issues and challenges from a regulatory perspective. Some 1,600 professionals from Switzerland and abroad took part in the virtual event on the key aspects of the new medical devices regulation on 2 September 2021. The presentations from the information event are available to all interested parties to download in four languages.

Interest in the online event on the new medical devices regulation on 2 September 2021 was considerable, with some 1,600 participants from the fields of medical devices and healthcare attending. The event kicked off with information on the role of Swissmedic, focusing on medical devices and the effects of the lack of update to the MRA. The subsequent presentations covered topics ranging from developments in clinical trials of medical devices to the rights and obligations of economic operators, including registration obligations, requirements for devices on the market and notification and monitoring obligations of all parties involved.

The final two presentations were aimed at hospitals and other healthcare institutions, which must meet significantly higher requirements in terms of ensuring the safety of medical devices and thereby patient safety under the new regulation.

The presentations, which also answer many of the queries sent in advance to Swissmedic, are available to all interested parties:

➔ Presentations from the online event on the new medical devices regulation (/swissmedic/en/home/services/veranstaltungen/info-medizinprodukte-regulierung.html)

As a supplement to the legal framework, Swissmedic publishes regularly updated implementation guides and answers to frequently asked questions:

➔ New medical devices regulation – FAQ (/swissmedic/en/home/medical-devices/neue-eu-verordnungen-mdr-ivdr/faq.html)

See also

26.05.2021

➔ New regulations applicable to medical devices as of 26 May 2021
(/swissmedic/en/home/news/mitteilungen/neue-regulierug-mep-26-05-2021.html)
Modification of the Medical Devices Ordinance (MedDO) in the context of pending agreements between Switzerland and the EU

https://www.swissmedic.ch/content/swissmedic/en/home/news/mitteilungen/rueckblick-mep-infoanlass.html

swissmedic

Schweizerisches Heilmittelinstitut
Institut suisse des produits thérapeutiques
Istituto svizzero per gli agenti terapeutici
Swiss Agency for Therapeutic Products

Frequently Asked Questions on medical devices – FAQ MD

General

Economic stakeholders

Economic stakeholders (MDR: operators) are manufacturers, authorised representatives, importers, distributors and persons referred to in Article 22(1) and 22(3) EU-MDR. (Art. 4 MedDO)

Manufacturer

Any 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. (Art. 4 MedDO)
Obligations: Art. 46 to 50 MedDO

Importer (Switzerland)

Any natural or legal person established within Switzerland that places a device from abroad on the Swiss market.
Obligations: art. 53 MedDO

Distributor (Switzerland)

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.
Obligations: art. 54 MedDO

Authorised representative (Switzerland)

Any natural or legal person established within Switzerland who has received and accepted a written mandate from a manufacturer, located outside Switzerland, to act on the manufacturer's behalf in relation to specified tasks with regard to the latter's obligations under the Medical devices ordinance.
Obligations and mandate: art. 51-52 MedDO

If the manufacturer is not established within Switzerland, its devices may only be placed on the market if it has appointed an authorised representative in Switzerland.

If the manufacturer is established in an EU or EEA state or has an authorized representative in an EU or EEA state, the timelines in accordance with Art. 104 MedDO apply.

You can find further information on the Swiss authorised representative (CH-REP) here: Swiss authorised representative (CH-REP).

Registration of economic operators

Economic operators are registered according to Art. 55 of MedDO.

Further information on SRN and CHRN can be found on our website: Unique identification number according to Art. 55 MedDO (CHRN – Swiss Single Registration Number)

The registration responsibilities for manufacturers, authorised representatives and importers according to EU-MDR are detailed in Article 31 EU-MDR.

Implant Card (Guidance document of the MDCG)

For implantable devices, the manufacturer must provide, in addition to the product information stated in Article 16, the information stated in Article 18 paragraph 1 of EU-MDR, including the implant card (Art. 20 MedDO).

Further information is available in the following MDCG guidance documents:

- MDCG 2019-8 Implant Card
- MDCG 2021-11 Implant Card - Device types

Market access

Person responsible for regulatory compliance (PRRC)

The person responsible for regulatory compliance (PRRC) possesses the requisite expertise regarding the requirements for medical devices stated in the MedOD and is responsible for ensuring that manufacturers and authorised representatives comply with the regulations.

Manufacturers: Art. 49 MedDO

Authorised representatives: Art. 52 MedDO

Further information on the PRRC is provided in Art. 15 EU-MDR and in the guidance document MDCG 2019-7.

Medical Devices Nomenclature

02.04.2019. The European Commission, in cooperation with the MDCG (Medical Device Coordination Group), has decided to use the Italian CND nomenclature for the future Eudamed (European database on medical devices), in line with Article 26 of the MDR and Article 23 of the IVDR. Mapping to the GMDN (Global Medical Device Nomenclature) will be made available.
See section on 'European Medical Devices Nomenclature':
Medical Devices – Topics of Interest (europa.eu)

Information on the CND nomenclature can also be found on the website of the Italian authorities:
Ministero della Salute: CND Nomenklatur

Further information is provided in the following MDCG guidance documents as well as in information by the European Commission:

- MDCG 2021-12 FAQ on EMDN
- The EMDN – The nomenclature of use in EUDAMED
- The CND nomenclature – Background and general principles
- EUDAMED Overview (europa.eu)

Unique Device Identifiers (UDI)

Art. 17 the MedDO defines the requirements for Unique Device Identifiers (UDI) and Art. 65 MedDO the recording the UDI.

The timelines for affixing the UDI are listed in Art. 104 MedDO.

Further information can be found on our website: Unique Device Identifier (UDI), in several MDCG guidance documents as well as on the website of the European Commission: Unique Device Identifier (europa.eu).

Access to EUDAMED

Access to EUDAMED

According to the EU Commission publication, Swissmedic will only be able to assign SRNs/register UDIs once the MRA has been updated. You can find information regarding the MRA on the website of the

State Secretariat for Economic Affairs (SECO)

Switzerland is seeking to precisely establish with the EU the conditions that will apply to market access and cooperation in the medical devices field as of 26 May 2021.

For further, specific information, please consult the Actor Module FAQ compiled by EUDAMED – see points 1.2, 1.5, 1.6. – or the

Unique Device Identification (UDI) System - FAQs

As soon as Swissmedic obtains access to EUDAMED, this will be published on our website: Unique identification number according to Art. 55 MedDO (CHRN – Swiss Single Registration Number).

Further information: Medical Devices – Topics of Interest (europa.eu)

Classification

The Definition of medical devices and accessories is specified in Art. 3 MedDO.

It is the responsibility of the manufacturer to correctly classify his medical devices. Art. 15 MedDO denotes that for classification purposes, Annex VIII of EU-MDR applies.

For information on specific medical devices, e.g. 3D printers or software, please consult our website: Information on specific medical devices.

MDCG classification guidance documents:

- MDCG 2019-11 Qualification and classification of software
- MDCG 2020-16 Classification Rules for in vitro Diagnostic Medical Devices

Medical Device Software

We have compiled an overview regarding regulation, qualification, classification and the relevant regulations for software in our information sheet: Information sheet Medical Device Software

Further information is provided in the following MDCG guidance documents:

- Is your software a Medical Device?
- MDCG 2020-1 Clinical and Performance Evaluation
- MDCG 2019-16 Cybersecurity for medical devices
- MDCG 2019-11 Qualification and classification of software

In vitro diagnostic medical devices

Art. 105 para. 1 MedDO defines that until a corresponding special ordinance is enacted MedDO of October 17th 2001

applies for in vitro diagnostic medical devices.

Further information is provided in the following MDCG guidance documents as well as on the website of the European Commission:

- MDCG 2021-4 Application of transitional provision for certification of class D IVDs
- MDCG 2020-16 Classification rules for IVDs
- Factsheet for manufacturers of in vitro diagnostic medical devices (europa.eu)
- Step-by-step guide for manufacturers of in vitro diagnostic medical devices (europa.eu)

Custom-made devices

"Custom-made device" means any device specifically made in accordance with a written prescription of any person authorised by national law by virtue of that person's professional qualifications which gives, under that person's responsibility, specific design characteristics, and is intended for the sole use of a particular patient exclusively to meet their individual conditions and needs.

However, mass-produced devices which need to be adapted to meet the specific requirements of any professional user and devices which are mass-produced by means of industrial manufacturing processes in accordance with the written prescriptions of any authorised person shall not be considered to be custom-made devices. (Art. 4 para. 2 MedDO; Art. 2 para 3 EU MDR)

According to Art. 10 MedDO, the requirements stated in Annex XIII EU MDR apply. When placed on the market, a custom-made device must be accompanied by the statement specified in Annex XIII section 1 EU-MDR.

In addition Art. 10 MedDO specifies the requirements for custom-made devices pertaining to conformity assessment and documentation.

Art. 19 MedDO defines the corresponding notification obligations.

See also: Notification of medical devices (swissmedic.ch)

The MDCG provides further information in a Questions and Answers document: MDCG 2021-3

Systems and procedure packs

"Procedure pack" means a combination of products packaged together and placed on the market with the purpose of being used for a specific medical purpose. (Art. 4 para. 2 MedDO ; Art. 2 para. 10 EU-MDR)

"System" means a combination of products, either packaged together or not, which are intended to be inter-connected or combined to achieve a specific medical purpose. (Art. 4 para. 2 MedDO; Art. 2 para 11 EU-MDR)

Requirements relating to the placing on the market of systems and procedure packs are defined in Art. 11 of MedDO.

For further requirements, please refer to the following provisions in MedDO:

- Art. 17 MedDO UDI requirements
- Art. 51 para. 5 MedDO Obligations of authorised representatives
- Art. 55 MedDO Registration of economic operators
- Art. 66 MedDO Vigilance reporting obligation
- Art. 104a para. 2 MedDO Timeline for appointing an authorised representative by 31July 2022
- Art. 108 MedDO Reporting obligations

The MDCG also provides information about UDIs for systems and procedure packs:

- MDCG 2018-3 UDI for systems and procedure packs
- MDCG 2018-4 UDI core elements for systems and procedure packs

Delimitation of medical devices

An intended medical purpose as well as claims about medical effects are solely permissible for medicinal products and medical devices.

In practice, the distinction between medical devices and the following product groups is particularly important:

- Medicinal products (Human / Veterinary / Complementary and herbal)
- Chemicals Common notification authority for chemicals of the FOEN, FOPH and SECO
- Electrical installations Legal texts
- Food, commodities (e.g. hygiene articles, cosmetics incl. teeth whitening products) FSVO
- Personal protective equipment SECO
- Products that emit non-ionizing radiation and sound NIRSA
- Products that emit ionizing radiation Radiological protection FOPH

Further information on delimitation can be found on our website: Questions on delimitation, as well as in the Information on specific medical devices.

We also recommend you to consult MEDDEV 2.1/3 rev. 3 on Borderline Products. A MDCG Borderline & Classification Guidance is scheduled to be issued by MDCG in 2021.

Placing on the market

Section two of the MedDO defines the requirements for the placing on the market and putting into service of medical devices.

- A device may be placed on the market or put into service only, if it meets the general safety and performance requirements set out in Annex I EU-MDR, taking into account its intended purpose. (Art. 6 MedDO)

We have compiled information about market access for medical devices for you here:

- Market access
- Import, sale and distribution
- Conformity assessment (Art. 21 MedDO)

Products without an intended medical purpose

(Annex 1 MedDO in conjunction with Annex XVI of EU-MDR)

According to Art. 1 para. 1 let. b and para. 2 MedDO products without an intended medical purpose (e.g. coloured contact lenses, IPL devices for hair removal, subdermal fillers for anti-wrinkle injections or liposuction devices) fall within the scope of the MedDO. A list of the currently six product groups without an intended medical purpose can be found in Annex 1 MedDO.

The corresponding common specifications (CS) are being prepared by the European Commission and have not yet been published; Swissmedic is not aware of the final content or the precise publication date of these CS.

Until Swissmedic has designated common specifications according to Art. 8 para. 1 MedDO for products without an intended medical purpose according to Annex 1 MedDO, the hitherto existing law shall continue to apply to these products (Art. 106 MedDO).

Product information

The product information includes the label and instructions for use and is based on Annex I Chapter III of EU-MDR.

It must be drafted in the three official languages. Symbols specified in technical standards can replace verbal statements (Art 16 MedDO).

"Label" means the written, printed or graphic information appearing either on the device itself, or on the packaging of each unit or on the packaging of multiple devices (Art. 4 para. 2 MedDO; Art. 2 point 13 EU-MDR).

Conformity assessment

Arts. 21–29 MedDO outline the principles of **conformity assessment**:

Anyone who places a device on the market or puts a device into service without placing it on the market must, prior to the placing on the market or putting into service, undertake an assessment of the conformity of that device with the general safety and performance requirements.

The **conformity assessment procedure** is based on Articles 52 and 54 of the EU-MDR, and Annexes IX–XI EU-MDR, taking into account the amendments to Article 52 paragraph 4 subparagraph 2 EU-MDR, implemented by the European Commission by means of delegated acts (Art. 23 MedDO).

The use of **designated bodies** and the provisions relating to their **certificates of conformity** can be found in Art. 24 - 28 MedDO. Further information on designated bodies can be found in Chapter 5 of MedDO, and on our website: Designated bodies.

The manufacturer draws up a **declaration of conformity (Art. 29 MedDO)**, if the applicable conformity assessment procedure has demonstrated that the requirements of MedDO are fulfilled and accepts the responsibility for ensuring that the device complies with the requirements of this ordinance and all other legal requirements. The manufacturer shall continuously update this declaration. The declaration of conformity contains the information specified in Annex IV EU-MDR.

Exemption authorisations

Medical devices placed on the market in Switzerland must satisfy the requirements of the Medical Devices Ordinance (MedDO):

Information on exemption authorisations for non-conforming medical devices according to Art. 22 MedDO can be found on our website: Exemptions for non-conforming medical devices

Notification obligations for medical devices

Swissmedic has compiled the following websites regarding the notification of medical devices:

- Notification of medical devices
- Notification of IVD medical devices
- Notification of devitalised human tissue

Transitional provisions and timelines

Transitional provisions and timelines

Transitional provisions and timelines are defined in Article 120 of EU MDR, and in Chapter 11 section 2 of MedDO:

- Validity of **certificates issued under the old law** up to, at the latest, 26 May 2022 or 26 May 2024 (Art. 100 MedDO).
- Conditions for placing on the market **devices under the old law** (Art. 101 MedDO).
- Devices with devitalised tissues or cells of human origin (Art. 103 MedDO)
  See also: Notification of devitalised human tissue
- Affixing the **UDI** (Art. 104 MedDO)
  See also: Unique Device Identifier (UDI)
- Designating an **authorised representative** according to Art. 51 MedDO (Art. 104a MedDO)
  See also: Swiss authorised representative (CH-REP)
- **Registrations by economic operators** (Art. 104b MedDO)
  See also: Unique identification number according to Art. 55 MedDO (CHRN – Swiss Single Registration Number)

- In *vitro* diagnostic medical devices (Art. 105 MedDO)
  Conformity assessment bodies for IVDs (Art. 107 para. 4 MedDO)
- Products without an intended medical purpose (Art. 106 MedDO)
  See also: FAQ article on products without an intended medical purpose above
- Notification of devices, systems and procedure packs (Art. 108 MedDO)
  See also: Notification of medical devices
- **Conformity assessment bodies** (Art. 107 MedDO)
- The articles on **product registration** will enter into force at a later date (Art. 110 MepV)

In 2018 (before the date of application of MDR was postponed), the CAMD published a list of FAQs on the transitional provisions in the MDR and IVDR:

- CAMD FAQ– MDR Transitional provisions
- CAMD FAQ – IVDR Transitional provisions

Further information on the application of the EU MDR transitional provisions can be found in the following MDCG guidance documents as well as in the documents provided by the European Commission:

- MDCG 2019-10 Application of transitional provisions concerning validity of certificates
- MDCG 2019-15 Market access for manufacturers of class I medical devices
- MDCG 2020-2 Application of transitional provisions for class I medical devices
- MDCG 2021-1 Practices and alternative technical solutions until EUDAMED is fully functional
- MDCG 2021-4 Application of transitional provision for certification of class D IVDs
- MDR Transition timelines (europa.eu)
- Factsheet for manufacturers of medical devices (europa.eu)
- Step-by-step guide for medical device manufacturers (europa.eu)
- Factsheet for Class I - Medical Devices (europa.eu)
- IVDR Transition timelines (europa.eu)
- Factsheet for manufacturers of in vitro diagnostic medical devices (europa.eu)
- Step-by-step guide for manufacturers of in vitro diagnostic medical devices (europa.eu)
- Factsheet for authorised representatives/importers/distributors (europa.eu)

MRA Switzerland – EU

Export of medical devices to the EU

For regulatory questions arising from EU-MDR, please contact the corresponding EU or EEA member state or corresponding EU panels.

The European Union (EU) has linked the necessary update of the medical devices section of the Mutual Recognition Agreement (MRA) to the conclusion of the Institutional Agreement (InstA).

Since the InstA negotiations have been broken off, the EU now treats Switzerland as a third country where medical devices are concerned.

The EU has published a notice to stakeholders on the status of the EU-Switzerland MRA and the associated consequences: Mutual Recognition Agreement for Medical Devices (europe.eu).

With immediate effect, therefore, Swiss companies must expect to face more demanding requirements when seeking to export medical devices to the EU, e.g. the requirement to appoint an authorised representative and – depending on the risk class of the device – to present a certificate issued by one of the notified bodies featured in the NANDO list.

The registration obligations for manufacturers, authorised representatives and importers can be found in Article 31 EU-MDR. Regarding the conditions for exporting MDD products of Swiss manufacturers to the EU area "under the old legislation", a common solution is still being sought between Switzerland and the EU; until such a solution is in place, the same EU requirements also apply for products under the old law.

Specific questions on MRA

Any specific questions on the MRA (extension of the existing agreement, updating in line with the MDR, etc.) should be addressed to SECO.

MRA Switzerland - EU
(www.seco.admin.ch)

International agreements

International agreements

Any questions about international (mutual recognition) agreements in the area of medical devices should be directed to SECO [MRA Switzerland - EU (admin.ch)].

Other information sources

Revision of medical devices legislation
(Federal Office of Public Health FOPH)

New Medical Devices Ordinance (MedDO) in force since 26 May 2021
(/swissmedic/en/home/medical-devices/neue-eu-verordnungen-mdr-ivdr.html)

Regulation (EU) 2017/745 in force since 26 May 2021
EU MDR

Directive 98/79/EC on in vitro diagnostic medical devices
(europa.eu)

Information on specific medical devices (/swissmedic/en/home/medical-devices/overview-medical-devices/information-on-specific-medical-devices.html)

Questions frequently asked by patients about medical devices
(/swissmedic/en/home/medical-devices/regulation-of-medical-devices/questions-frequently-asked-by-patients.html)

Getting ready for the new regulation
(europa.eu)

MRA Switzerland - EU
(www.seco.admin.ch)

Further information can also be found at:

Swiss Medtech

(MDCG) guidance documents:

Guidance | Public Health
(europa.eu)

https://www.swissmedic.ch/content/swissmedic/en/home/medical-devices/neue-eu-verordnungen-mdr-ivdr/faq.html

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Istituto svizzero per gli agenti terapeutici
Swiss Agency for Therapeutic Products

New regulations applicable to medical devices as of 26 May 2021

Modification of the Medical Devices Ordinance (MedDO) in the context of pending agreements between Switzerland and the EU

26.05.2021

On 19 May 2021, the Federal Council approved supplementary provisions to the implementing regulations on medical devices. These enter into force on 26 May 2021, at the same time as the completely revised Medical Devices Ordinance (MedDO) and a new Ordinance on Clinical Trials with Medical Devices (CTO-MedD). In the context of aligning Swiss medical devices legislation to the new EU Medical Device Regulations MDR and IVDR, the MRA (Mutual Recognition Agreement) also needs to be updated so that barrier-free market access and joint surveillance can be ensured. However, the EU Commission is making the updating of the MRA subject to progress being made with the Institutional Agreement and is only prepared to negotiate on transitional provisions for medical devices covered by the old legislation.

Since 2001, Switzerland has regulated medical devices in the same way as the EU and has been integrated in the European market surveillance system and European internal market for medical devices via the MRA. To improve the quality and safety of medical devices – and hence also to increase patient safety – the EU has tightened the requirements for medical devices across Europe. Switzerland, too, has completely revised its medical devices legislation so that it closely approximates to the new EU provisions.

Owing to the COVID-19 pandemic, the EU postponed the full implementation of the European Medical Device Regulation (MDR) by a year, to 26 May 2021. Switzerland has adapted its legal framework for medical devices in order to retain the existing equivalence between Swiss and EU medical device legislation. The legal provisions for in vitro diagnostic medical devices, for which the EU has also approved stricter regulation by way of the IVDR (In Vitro Diagnostic Medical Device Regulation), are still being adapted.

In parallel, the Switzerland-EU agreement on the mutual recognition of certificates of conformity (Mutual Recognition Agreement, MRA) also needs to be updated. It has not yet been possible to complete the updating of this agreement because it has been linked by the EU to progress made with the Institutional Agreement (InstA).

The supplementary provisions on the completely revised MedDO that were approved by the Federal Council on 19 May 2021 are designed to offset the negative consequences of the absence of the MRA update and ensure that the Swiss population is sufficiently supplied with safe medical devices.

Amendment to the MedDO – transitional provisions

The lack of an updated MRA affects the mutual market access to – and trading of – medical devices, coordinated market surveillance activities and the sharing of information between authorities or the mutual recognition of certificates of conformity.

The market surveillance of medical devices in Europe is based on the extensive sharing of information within the European network of regulatory authorities. Without an updated MRA, Swissmedic will continue to be denied official access to the central European database for medical devices (EUDAMED 3), which has been available since 1 December 2020. Swissmedic is excluded from the working groups on the joint surveillance of new medical devices and does not have access to implementation-related data.

By 26 May 2021, the Federal Council approved an amendment to the MedDO on 19 May 2021 that supplements the revised medical devices legislation. This amendment defines various measures and transitional periods designed to ensure that Switzerland continues to be supplied with safe medical devices and to offset the negative effects on market surveillance.

For example, the provisions allow unilateral market access to medical devices certified in the EU according to the new Regulation and thereby alleviate supply problems in Switzerland. Supplementary requirements such as the registration of economic operators with Swissmedic, the continuous reporting of serious incidents to Swissmedic and the establishment of an authorised representative for manufacturers outside Switzerland are intended to enable Swissmedic to maintain its surveillance system despite its exclusion from the EU authorities' monitoring network.

In the absence of an updated MRA, Swiss manufacturers are already required to appoint an authorised representative in the EU for their products as of 26 May 2021. To avoid jeopardising a sufficient supply of medical devices to Switzerland, the Federal Council has set lengthy **transitional periods** of over one year in most cases.

The transitional provisions also affect registration and reporting obligations in particular: owing to the lack of access to EUDAMED3, economic operators (manufacturers, importers and authorised representatives) must register with Swissmedic and obtain a unique identification number ("Swiss Single Registration Number" CHRN). Swissmedic is already able to issue CHRNs as of 26 May 2021.

➔ Unique identification no. in accordance with Art. 55 MedDO (CHRN – Swiss Single Registration Number) (/swissmedic/en/home/medical-devices/market-access/registriernummer-chrn.html)

Registration of medical devices on the Swiss market at a later date is also planned.

In the absence of access to EUDAMED3, serious incidents and safety reports will still need to be reported to Swissmedic.

➔ Reporting incidents & FSCAs (vigilance) (/swissmedic/en/home/medical-devices/reporting-incidents---fscas.html)

The period between the approval of the amendment to the MedDO (Federal Council decision) and the entry into force of the ordinances is very short. Wherever possible, Swissmedic has revised processes and documents in advance and is making these available from 26 May 2021.

As of 26 May 2021, the existing MedDO is being terminated and the documents relating to the old law are being replaced by new versions on the Swissmedic website. Changes and newly available documents will be communicated continuously. In view of the large number of documents and the short preparation time between the approval and entry into force (one week), delays may occur in individual cases, particularly for the various language versions (not all specification documents will be available in all languages at the same time).

Implementation of the new Swiss medical devices legislation

As part of the alignment of Swiss medical devices legislation to the new EU MDR, Swissmedic has already implemented the following changes:

As of 1 May 2021, applications for clinical trials of medical devices are already being processed according to the new law.

Clinical trials of medical devices (/swissmedic/en/home/medical-devices/klinische-versuche.html)

As of 26 May 2021, export certificates (FSC) for medical devices are issued only according to the new law, and export certificates (FSC) according to the old law are no longer possible.

Issue of export certificates (Free Sales Certificates) for medical devices
(/swissmedic/en/home/medical-devices/md-export-certificates-fsc/exportzertifikate_fsc.html)

See also

Federal Council seeks to guarantee the supply of safe medical devices
(www.admin.ch)

Responsibility for the revision of Swiss medical devices law lies with the FOPH: Revision of medical devices law

Revision of medical devices legislation
(www.bag.admin.ch)

The State Secretariat for Economic Affairs, SECO, is responsible for the MRA negotiations and export-related issues:

MRA Switzerland - EU
(www.seco.admin.ch)