Information sheet
Systems and procedure packs

Identification number:	MU600_00_018
Version:	1.0
Valid from:	04.08.2025

List of contents

1 Introduction

This information sheet is intended for assemblers, Swiss authorised representatives and users of systems and procedure packs domiciled in Switzerland, as well as economic operators that place systems and procedure packs on the market, or make them available on the market, in Switzerland.

1.1 Scope

This information sheet describes the obligations for the assembly and labelling of systems and procedure packs, as well as the associated obligations of economic operators in Switzerland. Please refer to other existing information sheets for details of the general obligations of economic operators in connection with individual medical devices.

2 Definitions, abbreviations

2.1 Definitions

Assembler	Natural or legal **person who assembles or sterilises systems or procedure packs**; System and Procedure Pack Producer, **SPPP**.
Authorised representative	If the manufacturer of a device is not domiciled in Switzerland, its devices may only be placed on the market once an **authorised representative** domiciled in Switzerland has been designated. The manufacturer has mandated (in writing) an authorised representative to act on the manufacturer's behalf in relation to specified tasks.
Certificate of conformity	Also known as an “EU certificate” or an “EC certificate”. The certificate of conformity is issued by the designated / notified body which checks the manufacturer’s conformity assessment and confirms its compliance with the legal requirements in this certificate. Whether or not a designated body is involved in the conformity assessment procedure depends on the classification of the device; it is a requirement , for medical devices associated with moderate and high risks. If a check by a designated body is required, the CE mark may only be affixed to a device if a corresponding certificate has been issued by the designated body. This CE mark is then accompanied by the 4-digit identification number of the designated body (CE xxxx). In this information sheet the term EU certificate is used analogously with the certificate of conformity specified in the new legislation (EU MDR, EU IVDR); the term EC certificate is used to refer to a certificate of conformity issued under the old legislation (MDD, AIMDD, IVDD).
Conformity assessment	**Conformity assessment** refers to the procedure used to determine whether the legal requirements of the MedDO / the IvDO (analogous to the EU MDR / EU IVDR) are fulfilled by a device. Depending on the risk class of the medical device, a designated / notified body must be involved in the conformity assessment procedure in order to check compliance with the legal requirements. Once this procedure has been successfully concluded, the CE mark (or an MD mark for the Swiss market only) may be affixed to the device.
Declaration of conformity	Also known as “**DoC**”. This is a declaration issued by the manufacturer in which they confirm that the device complies with the legal requirements. An EU declaration of conformity (which confirms the conformity of the device with EU MDR / EU IVDR or the regulations under the old legislation) is recognised in Switzerland. A declaration of conformity is a legally required evidence of conformity for all medical devices, irrespective of whether or not a designated / notified body was involved in the procedure.
Designated body	**Designated bodies** are organisations designated and monitored by the government. They act on behalf of the manufacturers, supporting and checking their conformity assessments of, for example, various types of medical devices (conformity assessment bodies). They are referred to in the EU MDR / EU IVDR as notified bodies.
Device	The term "device" comprises **medical devices** and associated**accessories**, **products without an intended medical purpose** from the product groups in Annex 1 MedDO, and **in vitro diagnostic medical devices**.
Distributor	A **distributor** is any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a device available on the Swiss market, up until the point of putting into service.

Economic operator	**Economic operator** refers to a manufacturer, authorised representative, importer, distributor or the person referred to in Article 22 paragraphs 1 and 3 EU MDR.
Healthcare professionnal	Healthcare professions are defined in Art. 2 GesBG.
Importer	An **importer** is any natural or legal person established in Switzerland who places a device from a foreign country on the Swiss market.
Incident	An **incident** refers to any malfunction or deterioration in the characteristics or performance of a device that has already been made available on the market, including use errors due to ergonomic features, as well as any inadequacy in the information supplied by the manufacturer and any undesirable side effect.
Instructions for use	Information provided by the manufacturer to inform the user of a device's intended purpose and proper use and of any precautions to be taken.
Intended purpose	**Intended purpose** refers to the use for which a device is intended according to the data supplied by the manufacturer on the label, in the instructions for use or in promotional or sales materials or information and the information stated in the clinical evaluation.
Labelling	**Labelling** refers to 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.
Layperson	An individual who does not have formal education in a relevant field of healthcare or medical discipline.
Making available	The supply or transfer of a device in return for payment or free of charge. The use of a device by a professional user does not constitute making available on the market.
Manufacturer	A **manufacturer** is 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 own name or trademark.
Placing on the market	**Placing on the market** refers to the first time a device is made available on the Swiss market.
Procedure pack	**Combination of** devices packaged together and placed on the market with the purpose of being used **for a specific medical purpose**.
Product information	Product information comprises the **labelling** and **instructions for use**.
Professional	A person with formal training in the relevant field.
Putting into service	**Putting into service** refers to the stage at which a device is made available to the final user for the first time.
System	**Combination of devices**, either packaged together or not, which are intended to be inter-connected or combined **to achieve a specific medical purpose**.
User	Any healthcare professional, professional or layperson who uses a device.

2.2 Abbreviations

AIMD	Active Implantable Medical Device
AIMDD	Directive 90/385/EEC on active implantable medical devices
oMedDO	Medical Devices Ordinance of 17 October 2001 (SR 812.213)
CH-REP	Swiss authorised representative
DoC	Declaration of Conformity
EU IVDR	Regulation (EU) 2017/746 on in vitro diagnostic medical devices
EU MDR	Regulation (EU) 2017/745 on medical devices
TPA	Therapeutic Products Act (SR 812.21)
IVD	In vitro diagnostic medical device
IVDD	Directive 98/79/EC on in vitro diagnostic medical devices
IvDO	Ordinance on In vitro Diagnostic Medical Devices (SR 812.219) of 4 May 2022
MD	Medical Device
MDD	Directive 93/42/EEC concerning medical devices
MedDO	Medical Devices Ordinance of 1 July 2020 (SR 812.213)
SPP	System and Procedure Pack
SPPP	System and Procedure Pack Producer (assembler)
UDI	Unique Device Identifier

3 Further documents

MU600_00_016	Swissmedic information sheet on the obligations of economic operators
MU600_00_006	Swissmedic information sheet on the procurement of medical devices in healthcare institutions
MDCG 2018-3	Guidance on UDI for systems and procedure packs
MDCG 2018-4	Definitions/descriptions and formats of the UDI core elements for systems or procedure packs
MDCG 2020-16	Guidance on Classification Rules for in vitro Diagnostic Medical Devices under Regulation (EU) 2017/746
MDCG 2021-25	Guidance on Regulation (EU) 2017/745 - application of MDR requirements to 'legacy devices' and to devices placed on the market prior to 26 May 2021 in accordance with Directives 90/385/EEC or 93/42/EEC
MDCG 2021-27	Guidance on Questions and Answers on Articles 13 & 14 of Regulation (EU) 2017/745 and Regulation (EU) 2017/746
MDCG 2023-1	Guidance on the health institution exemption under Article 5(5) of Regulation (EU) 2017/745 and Regulation (EU) 2017/746
MDCG 2024-11	Guidance on qualification of in vitro diagnostic medical devices

4 General

4.1 What are systems and procedure packs

Procedure packs are combinations of devices packaged together and placed on the market with the purpose of being used for a specific medical purpose.[1]
Systems refer to a combination of devices, either packaged together or not, which are intended to be inter-connected or combined to achieve a specific medical purpose.[2]
This can be a combination of a medical device with other medical devices, including in vitro diagnostic medical devices, or other products. The individual products must comply with the applicable regulations and be combined according to their respective intended purpose.[3]
Consequently, systems and procedure packs (SPP) contain at least one medical device.

- **Examples of systems**
  - Modular components of a knee implant
  - Computed tomography system consisting of a device, monitor and software
  - X-ray system
- **Examples of procedure packs**
  - Combination of surgical instruments for a specific operation
  - First aid kits

4.2 Delimitation from other combinations of products

Depending on the type of combined devices, their intended purposes, aspects of placing on the market and qualification in their own right, it is possible that a combination of devices is not an SPP, but rather a device that is subject to different requirements.
This distinction can only be made on a case-by-case basis, taking all the relevant factors into account. Before a product is placed on the market or put into service, the assembler or manufacturer is basically responsible for clarifying, what product is involved and identifying the associated requirements. A few examples are listed below (list is not exhaustive):

- **IVD kits**

An IVD kit is a set of components that are packaged together and intended to be used to perform a specific in vitro diagnostic examination.[4]

- **Combination products**

Combinations of medicinal products and medical devices that form an inseparable unit are subject to the requirements for medicinal products. Such combination products are human medicinal products comprising a medicinal product and a medical device, in which the medicinal product component has the primary effect and the medical device has a supporting function.[5]

- **Products that are assembled at the request of a professional user or hospital**

[1] Art. 4 para. 2 MedDO in conjunction with Art. 2 no. 10 EU-MDR
[2] Art. 4 para. 2 MedDO in conjunction with Art. 2 no. 11 EU-MDR
[3] Art. 11 para. 1 MedDO in conjunction with Art. 22 para. 1 EU-MDR
[4] Art. 4 para. 2 IvDO in conjunction with Art. 2 para. 11 EU-IVDR, MDCG 2020-16, MDCG 2024-11
[5] Art. 2 para. 1 let. f and g MedDO

Products that are assembled and provided by a natural or legal person in the supply chain at the request of a professional user or hospital, but that are not combined in this overall combination for a specific medical purpose and also not placed on the market.[6]

- **Devices that are manufactured and used within healthcare institutions** [7]

5 Requirements for systems and procedure packs

5.1 Obligations of the assembler to draw up a statement

Any natural or legal person who **combines devices** in order to place them on the market in the form of an SPP must draw up a **statement** declaring that:[8]

a) they verified the mutual compatibility of the devices and, if applicable other products, in accordance with the manufacturers' instructions and have carried out their activities in accordance with those instructions,
b) they packaged the system or procedure pack and supplied relevant information to users incorporating the information to be supplied by the manufacturers of the medical devices, in vitro diagnostic medical devices or other products which have been put together,
c) the activity of combining devices, in vitro diagnostic medical devices and, if applicable, other products as a system or procedure pack was subject to appropriate methods of internal monitoring, verification and validation.

This statement shall be kept at the disposal of the competent authorities after the SPP has been put together for the period that is applicable under Art. 10 para. 8 EU-MDR to the devices that have been combined.[9] Where those periods differ, the longest period shall apply.

The natural or legal **person who sterilises the SPP** for placing on the market shall draw up a **statement** declaring that they have carried out the sterilisation in accordance with the manufacturer's/manufacturers' instructions and have chosen to apply one of the procedures set out in Annex IX or Part A of Annex XI EU-MDR.[10] The successful completion of the conformity assessment procedure for the sterilisation is confirmed with a certificate of conformity issued by a designated / notified body.

A statement according to Art. 22 EU-MDR is not a declaration of conformity for the individual medical devices.

5.2 Obligations as a manufacturer and conformity assessment procedure

Where an SPP incorporates devices

- which do not bear the CE marking, or
- where the combination of devices is not compatible in view of their original intended purpose, or
- where the sterilisation has not been carried out in accordance with the manufacturer's instructions,

[6] MDCG 2018-3

[7] Art. 9 MedDO in conjunction with Art. 5 para. 5 EU MDR, Art. 9 IvDO in conjunction with Art. 5 para. 5 EU IVDR, MDGC 2023-1

[8] Art. 11 para. 1 MedDO in conjunction with Art. 22 para. 1 and 2 EU-MDR

[9] Art. 11 para. 1 MedDO in conjunction with Art. 22 para. 5 EU-MDR and Art. 48 MedDO and Art. 10 para. 8 EU-MDR

[10] Art. 11 para. 2 MedDO in conjunction with Art. 22 para. 3 EU-MDR

the SPP shall be treated as a device **in its own right** and shall be subject to a conformity assessment procedure. In this case, the natural or legal persons who assemble or sterilise such an SPP must fulfil the obligations of a manufacturer.[11] As devices in their own right these are provided with a CE marking.

5.3 Obligations to designate a Swiss authorised representative

Individual medical devices that are part of an SPP are placed on the market in Switzerland. All the individual medical devices included in an SPP must fulfil all legal requirements in Switzerland. Among other things, a CH-REP must be mandated for every *individual* medical device from a foreign manufacturer included in an SPP.[12]
If the SPP is assembled or sterilised by a person outside Switzerland, a CH-REP must also be mandated for the SPP.[13] Swissmedic would point out that this requirement applies specifically to Switzerland. This is one of the measures designed to mitigate the negative effects of the absence of a current agreement on the mutual recognition of conformity assessments (Mutual Recognition Agreement, MRA) for medical devices between Switzerland and the European Union (EU), particularly the inability of the Swiss authorities to access the central European Database on Medical Devices (Eudamed 3), and the lack of cooperation in market monitoring.[14]
This CH-REP is responsible for the formal and safety-related aspects of placing the SPP on the market.
However, the responsibility for the *individual* medical devices within the SPP continues to rest with the CH-REP for the individual medical devices.[15]

5.4 Obligations on labelling and the enclosure of product information

SPPs that are not devices in their own right do not themselves bear an additional CE marking, but they do bear the names, registered trade names or registered trade marks of the persons who assemble and sterilise the SPP, as well as the address at which those persons can be contacted.[16]
SPPs from foreign assemblers that are placed on the market in Switzerland must include in their labelling the details of the CH-REP for the SPP (section 5.3).[17] For SPPs produced by foreign assemblers under the old legislation, the details of the CH-REP for the SPP must be provided on the label or in the instructions for use.[18]

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[11] Art. 11 para. 3 MedDO
[12] Art. 51 para. 1 MedDO, MDCG 2021-27
[13] Art. 51 para. 5 MedDO
[14] See also the Explanatory report on the revision of the MedDO, issued by the Federal Office of Public Health, FOPH, in May 2021.
[15] According to Art. 51 para. 1 and 3 MedDO in conjunction with Art. 11 para. 1 EU-MDR, an individual device may only be placed on the market if the manufacturer designates a single authorised representative. As a result, it is not possible for different authorised representatives, e.g. one for the assembler and one for the manufacturer, to be responsible for an individual device at the same time. However, the manufacturers of the individual devices and the assemblers may designate a single authorised representative.
[16] Art. 11 para. 1 MedDO in conjunction with Art. 22 para. 5 EU-MDR
[17] Art. 16 MedDO in conjunction with Ann. I Chap. III point 23.2 let. d EU-MDR, Art. 104a MedDO and Art. 104a^{bis} MedDO
[18] Art. 7 para. 1 let. a and b oMedDO in conjunction with Ann. I point 13.3 MDD

The information (label and instructions for use) specified in Annex I Chap. III para. 23 EU-MDR are enclosed with the SPP.[19]
The labelling includes (not exhaustive) the following information:

a. Name or trade name of the device
b. All the details strictly necessary for a user to identify the device, the contents of the packaging and, where it is not obvious for the user, the intended purpose of the device
c. Name, registered trade name or registered trade mark and address of the manufacturer
d. Name of the authorised representative and address of its registered place of business if the manufacturer has its registered place of business outside Switzerland
g. The lot number or the serial number of the device
i. Indication of the time limit for using the device safely
k. An indication of any special storage and/or handling condition that applies
n. An indication as to whether the device is intended for single use
q. An indication that the device is a medical device.

The instructions for use include (not exhaustive) the following information:

a) The name and trade name of the device,
Storage and handling conditions
b) The device's intended purpose with a clear specification of indications, contraindications, patient target group(s) and intended user
e) The performance characteristics of the device
g) Any residual risks, contraindications and any undesirable side-effects, including information to be conveyed to the patient in this regard
j) Any requirements for special facilities, or special training, or particular qualifications of the device user and/or other persons
l) If the device is supplied sterile, instructions in the event of the sterile packaging being damaged or unintentionally opened before use
y) Date of issue of the instructions for use or, if they have been revised, date of issue and identifier of the latest revision of the instructions for use
z) A notice to the user and/or patient that any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established

The product information must be produced in all three official languages of Switzerland. In justified cases, this may be provided in fewer than the three official languages of Switzerland or in English.[20]

5.5 Registration obligations

Anyone who places SPPs on the market under Art. 11 MedDO must, within three months after placing the SPP on the market, register their name and address at which they can be contacted with Swissmedic.[21]

[19] Art. 11 para. 1 MedDO in conjunction with Art. 22 para. 5 EU-MDR with the equivalent terms stated in Annex 2 MedDO
[20] Art. 16 para. 2 and 3 MedDO
[21] Art. 55 para. 5 MedDO

5.6 Notification obligations

According to Art. 108 MedDO, the notification obligations set out in Art. 6 para. 1 and 4 oMedDO continue to apply, until Art. 17 para. 5 MedDO enters into force, to persons who assemble SPPs according to Art. 22 para. 1 and 3 EU-MDR.
Anyone who places SPPs on the market in Switzerland or in a contracting state and who is domiciled in Switzerland must inform the Agency of their name and address, as well as a description of the devices concerned, at the latest by the date when the devices are placed on the market.[22]

5.7 Vigilance

Assemblers of SPPs made available in Switzerland must report serious incidents as well as any field safety corrective actions undertaken in Switzerland to Swissmedic. If an authorised representative is required, the representative shall be responsible for these reports.[23]
Professionals who use SPPs have a legal obligation to report **serious incidents** to Swissmedic (materiovigilance).[24]
Further information on reporting serious incidents can be found on the Swissmedic website at Reporting incidents & FSCA (vigilance) (swissmedic.ch).[25]

6 Frequently Asked Questions (FAQ)

Can systems and procedure packs issued under the old law, and the devices incorporated in them, continue to be placed on the market after the new legal provisions apply?

SPPs issued under both the old and new legislation may continue to be placed on the market provided all the devices that comply with the old legislation fulfil all legal requirements.[26]
Consequently, SPPs that only incorporate devices under the old law can continue to be placed on the market with a valid declaration in accordance with Art. 12 MDD, provided that the devices also comply with the existing legislation and transitional provisions.

Do SPPs under the old law according to Art. 12 MDD need to be newly notified to Swissmedic?
SPPs under the old law according to Art. 12 MDD can no longer be notified to Swissmedic. As of 26 May 2021, such SPPs can only be placed on the market for the first time, and thus notified, with a statement according to Art. 22 MDR.
If a statement according to Art. 22 EU-MDR is issued for the first time for an SPP (formerly issued under the old law), a new notification should be submitted, not a notification of variation.

[22] Art. 108 para. 1 let. a MedDO
[23] Art. 66 para. 1 MedDO
[24] Art. 66 para. 4 MedDO
[25] https://www.swissmedic.ch/swissmedic/en/home/medizinprodukte/vorkommnisse---fsca-melden--materiovigilance-.html
[26] Art. 100 and 101 MedDO; Art. 81 and 82 IvDO, MDCG 2021-25

Systems do not need to be packaged or placed on the market together. How can the legally required information be checked appropriately?
For individual medical devices, the relevant manufacturer or Swiss authorised representative can be contacted, for example, in order to obtain the required information and certificates of conformity.

How can the procedure packs incorporating devices that are packaged together be tested non-destructively?
For SPPs whose devices are packaged together, the relevant assembler or Swiss authorised representative can be contacted, for example, in order to obtain the required information and certificates of conformity.

How can Swiss authorised representatives, healthcare institutions and users identify conforming SPPs?
Procedure packs themselves do not have a CE mark or declaration of conformity. The labelling must include details of the assembler, the sterilisation service provider (if the pack is sterile), the UDI and a lot or serial number. See section 5.4 for more information.

How can importers and distributors identify conforming medical devices incorporated in SPPs?
See Annex 1 of the information sheet on the procurement of medical devices in healthcare institutions for more information.

Change history

Version	Change	sig
1.0	First version	fro, zys