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Change history

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1 Introduction

This Information Sheet answers frequently asked questions on the issuing of unique identification numbers in accordance with Art. 55 MedDO.

2 Objective

This Information Sheet describes when, how and to whom Swissmedic will issue a unique identification number and answers frequently asked questions associated with unique identification numbers.

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3 Scope

The Information Sheet applies to the issuing of unique identification numbers by Swissmedic in accordance with Art. 55 MEdDO. It is aimed at manufacturers, authorised representatives and importers of medical devices according to Art. 3 MedDO.

4 Terms, definitions, abbreviations

4.1 Terms, definitions

4.1.1 Swiss Single Registration Number

The Swiss Single Registration Number (CHRN) is a unique identification number that Swissmedic assigns to Swiss manufacturers, authorised representatives and importers on a once-only basis.

4.1.2 Manufacturer

Art. 4 para. 1 let. f MedDO defines the term "manufacturer" as "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; (…)".

4.1.3 Authorised representative

Art. 4 para. 1 let. g MedDO defines the term "authorised representative" as "any natural or legal person established within Switzerland who has received and accepted a written mandate from a manufacturer located in another country to act on the manufacturer's behalf in relation to specified tasks with regard to the latter's obligation under this Ordinance".

4.1.4 PRRC - Person responsible for regulatory compliance

The term “Person responsible for regulatory compliance” (PRRC) is defined as follows in Art. 49 paragraphs 1-4 MedDO: “Manufacturers must have available within their organisation at least one person responsible for regulatory compliance who possesses the requisite expertise in the field of medical devices. (…)”.

In Art. 52 paragraphs 1 and 2 MedDO it is likewise stated that: “Authorised representatives must ensure that they have permanently and continuously at their disposal at least one person who possesses the requisite expertise as regards the requirements for medical devices under this Ordinance and who is responsible for regulatory compliance. In other respects, Article 49 paragraphs 2–4 shall apply.”

4.1.5 Importer

Art. 4 para. 1 let. h MedDO defines the term "importer" as "any natural or legal person established within Switzerland that places a device from a foreign country on the Swiss market".

4.1.6 Distributor

Art. 4 para. 1 let. i MedDO defines the term "distributor" as "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".

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4.2 Abbreviations

Abbreviation	Term
FeeO-Swissmedic	Ordinance on the Fees charged by the Swiss Agency for Therapeutic Products, (SR 812.214.5)
IVDR	In Vitro Diagnostic Medical Devices Regulation, (EU) 2017/746
MDR	Medical Devices Regulation, (EU) 2017/745
MedDO	Medical Devices Ordinance (MedDO, SR 812.213)
PRRC	Person Responsible for Regulatory Compliance
CHRN	Swiss Single Registration Number, unique identification number

5 Issue of CHRN

5.1 Who needs a CHRN?

Under Art. 55 para. 1 MedDO, manufacturers, their authorised representatives if applicable and importers are required to submit to Swissmedic the necessary information under Annex VI Part A section 1 EU-MDR within three months of placing a product on the market for the first time. Distributors do not need a CHRN.

Anyone placing systems and treatment units in accordance with Art. 11 MedDO on the market for the first time must register their name and the address at which they can be contacted with Swissmedic within three months of placing the system or treatment unit on the market. If an authorised representative is required in accordance with Article 51 para. 5 MedDO, their name and address must also be registered with Swissmedic.

Economic operators who have already placed devices on the market before 26 May 2021 in accordance with Article 22a of the Medical Devices Ordinance of 17 October 2001 must carry out the registrations in accordance with Article 55 para.1 MedDO and para. 5 MedDO by 26 November 2021.

5.2 What is the CHRN for?

A CHRN makes it possible to unequivocally identify a manufacturer, authorised representative or importer.

5.3 How do I obtain a CHRN?

In accordance with Art. 55 para. 1 MedDO, manufacturers, authorised representatives and importers must register with Swissmedic within three months of placing a product on the market for the first time.

As regards manufacturers, authorised representatives and importers domiciled in Switzerland, under Art. 55 para. 4 MedDO Swissmedic is responsible for reviewing the data and for assigning CHRNs to manufacturers, authorised representatives and importers in Switzerland.

Data are submitted by means of a registration form: Registration application single registration no. in accordance with Art. 55 MedDO.

Once their registered data have been successfully reviewed, economic operators receive a CHRN from Swissmedic.

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5.4 What information does Swissmedic need to approve registrations?

Swissmedic will verify the following information:

1st Commercial Register extract as proof of the company's existence. If no Commercial Register extract exists, other proof of the company's existence

2nd For Swiss-domiciled authorised representatives for Switzerland: existence of a mandate from a manufacturer domiciled outside Switzerland. This information must be provided with the Mandate registration form.

5.5 How are changes to data reported?

Under Art. 55, para. 2 MedDO, the economic operator in question is responsible for reporting changes in data to Swissmedic within a period of one week. Changes should be registered using a registration form. Change of registration message in accordance with Art. 55 MedDO.

5.6 What fees will be charged for assigning CHRN?

Fees for validating CHRN and the documents required as evidence will be billed on the basis of the work involved in accordance with Art. 4 FeeO-Swissmedic. According to Art. 4 para. 2 FeeO-Swissmedic, the rate for work charged on an hourly basis is CHF 200 per hour.

5.6.1 Invalid / missing documents

If documents are missing from an application or if submitted documents are invalid, Swissmedic will notify the company. If Swissmedic has not received a reply or the requested documents after 30 days, it will not process the application. The costs will be billed on the basis of the work involved.

5.6.2 Withdrawal by the applicant

If a company withdraws its application, a fee based on the work involved will be charged.

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