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1 Aim

This information sheet outlines how Switzerland implements MDCG 2022-18: *Position Paper on the application of Article 97 MDR to legacy devices for which the MDD or AIMDD certificate expires before the issuance of a MDR certificate*.

2 Handling of certification gaps according to MDCG 2022-18

2.1 Introduction

Swissmedic (Switzerland's competent authority for medical devices) implements the medical device legislation (Medical Devices Ordinance; MedDO; SR 812.213) equivalent to the EU in order to ensure an equivalent level of safety.

MDCG 2022-18 aims to achieve a common understanding of and a uniform approach to the application of Article 97 of Regulation (EU) 2017/745 on medical devices (MDR) in situations where a device is not in conformity with the MDR because its certificate issued under the previous legislation (Directives 93/42/EEC; MDD and 90/385/EEC; AIMDD) expires before issuance of the necessary certificate(s) in accordance with the new legislation (**certification gap**).
Where such a device does **not present an unacceptable risk to health and safety**, Article 97 MDR enables competent authorities to require the relevant **manufacturer, or its authorised**

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representative, to **bring the non-compliance to an end within a reasonable and clearly defined period**. This will ensure that the conformity of the devices concerned is established as soon as possible under the conditions set by the competent authority.

The use of Article 97 MDR is meant to be a temporary solution. It will contribute to avoiding disruption of supply of devices needed for health systems and patients.

In particular, the solution described in MDCG 2022-18

- applies to devices that, after the MDR's respective date of application, have fallen within the scope of Article 120(3) MDR and are or were considered to be "**legacy devices**" within the meaning of MDCG 2021-25.
- only applies to devices that are '**in transition**' from the MDD or AIMDD to the MDR or, respectively, for which, despite reasonable efforts undertaken by the manufacturer to obtain certification under the MDR, the relevant conformity assessment procedure involving a notified body has not been concluded in time.
- It does **not** apply to devices for which the certificate issued under the MDD or AIMDD has been suspended or withdrawn by the notified body; in other words, the Directive's certificate must have been valid at the date of its expiry. The evidence for surveillance by the relevant notified body needs to be submitted.
- It does **not** apply either to devices that have undergone a significant change in design or intended purpose within the meaning of Article 120(3) MDR[1] as further explained in MDCG 2020-3.

[1] Corresponding to Art. 101 al. 1 and 2 MedDO

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2.2 Overview: Handling of certification gaps according to MDCG 2022-18 in Switzerland

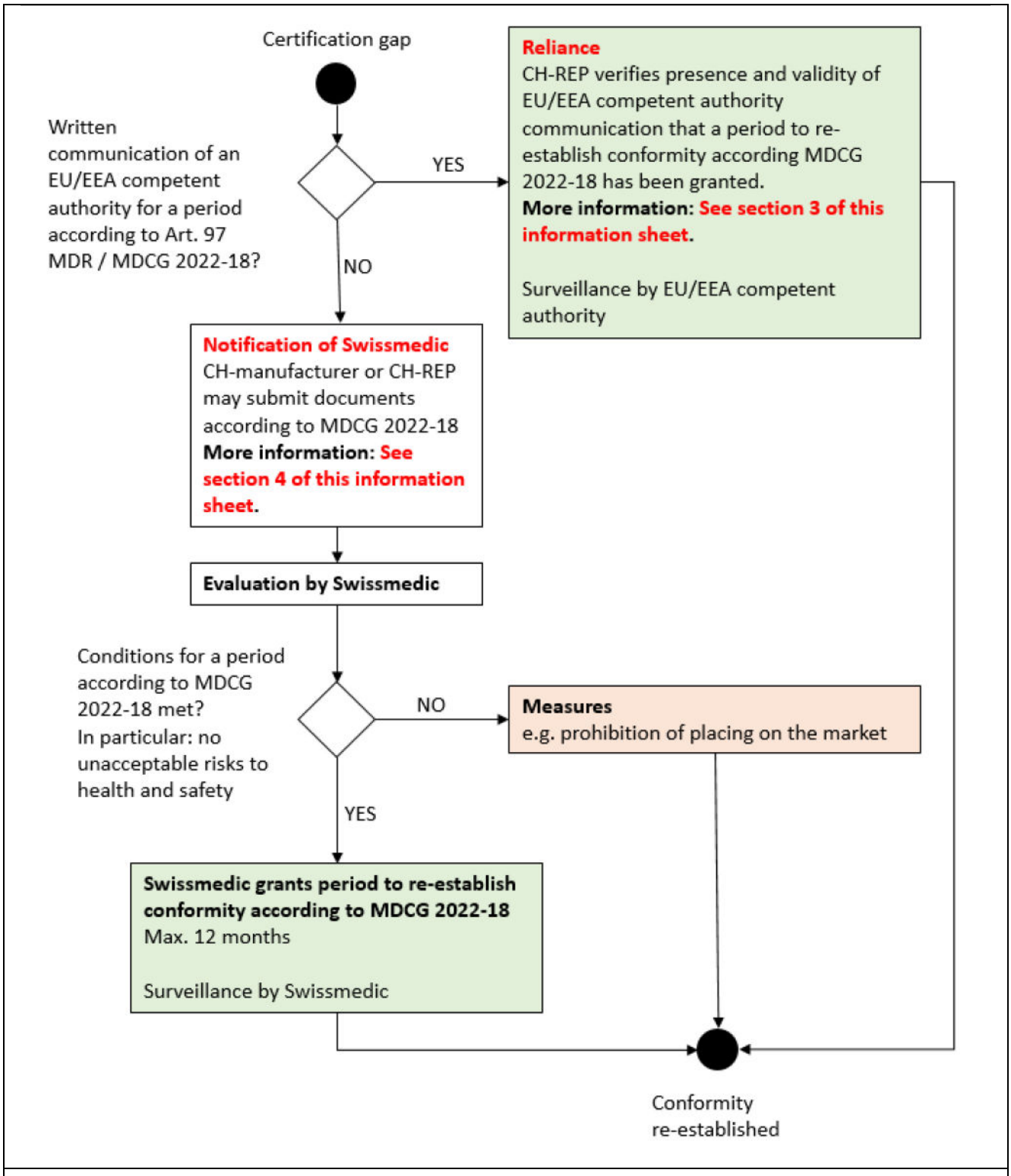

Fig. 1: Flow-chart of the implementation of MDCG 2022-18 in Switzerland.

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3 Reliance on MDCG 2022-18 confirmations of EU/EEA member states

EU/EEA competent authorities, after having performed the evaluation according to MDCG 2022-18, should issue a written communication to the manufacturer, or its authorised representative, requiring the manufacturer to bring the device(s) concerned into compliance within the defined period of time. This will have the effect that the device can be placed and made available on the EU/EEA market, provided that the conditions imposed by the issuing competent authority are met. This communication could be used by the manufacturer or other economic operators as evidence that they place and make available on the EU market a non-compliant device for which a period according to MDCG 2022-18 has been granted.

In order to avoid disruption of supply with medical devices, **the written communications issued by EU/EEA competent authorities are generally accepted in Switzerland as evidence that an evaluation according to MDCG 2022-18 has been conducted and that a period to re-establish conformity has been granted (reliance)**. A notification of Swissmedic or a duplication of this evaluation by Swissmedic is not necessary.

Swiss authorized representatives (CH-REPs) are responsible for formal and safety-related aspects of placing a device on the market (Art. 51 para. 2 MedDO). The duties and obligations of CH-REPs remain in force. The CH-REPs verification and record keeping obligations in relation to the conformity assessment procedures shall be interpreted as shown in Table 1.

Table 1: Verification and record keeping by CH-REPs

Art. 51 para. 3 MedDO Art. 11 para. 3 MDR	Valid conformity assessment certificate	Period according to MDCG 2022-18
Let. a	verify […] that an appropriate conformity assessment procedure has been carried out	Verify that a communication according to MDCG 2022-18 by an EU/EEA competent authority has been issued
Let. b	keep available […] if applicable, a copy of the relevant certificate	Keep available a copy of the relevant communication

4 Market Surveillance procedures according to MDCG 2022-18 in Switzerland

4.1 Procedure

The market surveillance activities undertaken by Swissmedic are governed by Art. 97 para. 1 and 2 MDR (Art. 75 para. 2 MedDO). Notifications according to MDCG 2022-18 concerning a certification gap will be handled by Swissmedic within the framework of medical device market surveillance.

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In cases where no written confirmation by an EU/EEA authority is available, **Swiss manufacturers** and **CH-REP**s of foreign manufacturers may notify a certification gap to Swissmedic. Please refer to section 4.2 for details.

If the conditions according to MDCG 2022-18 are fulfilled, Swissmedic will accept a period (usually 12 months from the expiry of the MDD / AIMDD-certificates) to bring the non-compliance to an end and will issue a written communication.

If the conditions set out in MDCG 2022-18 are **not** fulfilled, Swissmedic may order other, more severe measures suitable to end the non-conforming situation. In particular, in case of unacceptable risks to health and safety, Swissmedic will prohibit the placing on the market of the device and, if necessary, order a recall.

In any case, Swissmedic will charge the fees incurred in the administrative procedure to the Swiss manufacturer or the CH-REP who notified the certification gap. The amount depends on the time spent on the procedure. The hourly rate is CHF 200.- (Art. 61 para. 1 of the Therapeutic Products Act; TPA; SR 812.21; Art. 1, Art. 3 para. 1 and Art. 4 para. 2 of the Ordinance of the Swiss Agency for Therapeutic Products on its feeds; GebV-Swissmedic; SR 812.214.5).

The administrative procedures are conducted in writing. Swissmedic does not offer consulting services or pre-submission teleconferences.

4.2 Notification to Swissmedic

Swiss manufacturers and **CH-REP**s of foreign manufacturers can notify a certification gap to Swissmedic. The following documents need to be supplied to Swissmedic via E-Mail (medial.devices@swissmedic.ch):

1. **Details of the Swiss manufacturer or CH-REP** notifying the certification gap to Swissmedic: CHRN, name of company, address, PRRC, contact person
2. **List of devices** affected by the certification gap. For **each** device, the following must be included:
    a. Article number
    b. Device Name
    c. Risk class according to MDD (I[2], IIa, IIb, III); AIMDD
    d. Reference to corresponding MDD/AIMDD-certificate(s)
    e. Reference to corresponding Declaration of conformity
3. The **documents according to the Annex of MDCG 2022-18**. Note that the following confirmations need to be **specific for Swissmedic**:
    a. Commitment by the **notified body to inform Swissmedic** about major safety-related shortcomings identified during the conformity assessment
    b. Commitment by the **manufacturer to inform Swissmedic** about any delays

[2] A period according MDCG 2022-18 can only be granted for class I devices that required a conformity assessment procedure involving a notified body that issued a certificate, i.e. class I devices that are provided sterile or that have a measuring function.

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4. **Disclosure** on notifications according to MDCG 2022-18 that have been **submitted to EU/EEA competent authorities** by the manufacturer or its EC-REP.
5. **Disclosure** of any **measures according to Art. 94-97 MDR** of EU/EEA competent authorities that have been communicated to the manufacturer, **including refusal** of periods according to MDCG 2022-18 (include communication of the competent authority).

5 Surveillance and measures by Swiss market surveillance authorities

Swissmedic is the competent authority responsible for the market surveillance of medical devices in Switzerland. Application of Article 97 MDR does not prevent Swissmedic or other Swiss authorities entrusted with enforcement to take measures for the Swiss market, in particular to prohibit placing on the market and ordering recalls of devices that present an unacceptable risk to health and safety.

6 Free sales certificates

Certificates of free sale (FSC) may be issued in accordance with Swiss provisions during a period according to MDCG 2022-18. The relevant written communications by EU/EEA competent authorities or Swissmedic need to be supplied together with the (expired) certificate(s).

7 Frequently asked questions

1. **A derogation according to Art. 22 para 1 MedDO or Art. 59 MDR has been issued for some (or all) of the devices affected by the certification gap. How should I proceed?**
   Include the information on the granted derogation in the product list (section 4.2, point 2) and supply the relevant competent authorities' decisions. Swissmedic will take the derogation into consideration when determining the measures.

2. **MDCG 2022-18 states: "*The use of Article 97 MDR in those situations is meant to be a temporary solution.*" What does this mean?**
   The European Union is evaluating an extension of transitional periods set forth in the MDR. MDCG 2022-18 is considered to be a temporary measure to bridge the time until such an extension is implemented in the European legislation.

3. **Are MDCG 2022-18 periods granted by Swissmedic recognized by EU/EFTA member states?**
   It is always in the competence of the national competent authority whether to accept MDCG 2022-18 periods granted by other competent authorities.

4. **Does an economic operator (manufacturer, CH-REP, importer, distributor) need to notify Swissmedic if they place devices / make devices available on the Swiss market during the period according to MDCG 2022-18 granted by an EU/EEA competent authority?**
   No. Please refer to section 3, reliance solution.

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5. As an importer, how can I verify whether a period according to MDCG 2022-18 has been granted?

The verification duties of the importer are laid down in Art. 53 MedDO.
The CH-REP needs to verify that an appropriate conformity assessment procedure has been carried out. Hence, the importer needs to address questions concerning periods according to MDCG 2022-18 with the CH-REP. Note that the importer must be able to prove that a conformity assessment has been carried out and that the device is conforming (Art. 21 para. 2 MedDO). Therefore, in the case where devices are placed on the market under a period according to MDCG 2022-18, the importer needs to be able to prove that such a period was granted by Swissmedic or a EU/EEA competent authority.

6. As a Swiss manufacturer, we have received a period according to MDCG 2022-18 by an EU/EEA competent authority through our European authorized representative (EC-REP) to bring the device(s) into compliance. How do we need to communicate with Swissmedic and is a second notification for Switzerland necessary?

No. As part of the reliance solution, periods to bring a device into compliance granted by an EU/EEA competent authority according to MDCG 2022-18 are accepted also for Swiss manufacturers received through their respective EC-REP. There is no obligation to notify Swissmedic.

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