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SPOTLIGHT

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Changes in medical device legislation – new exemption rules for non-conforming medical devices

The medical device law is currently under revision. Since 1 August 2020, new rules and extended exemptions regarding non-conforming medical devices apply in Switzerland.

Various incidents and scandals involving medical devices have raised doubts in the EU about the system for controlling medical devices. In order to improve the quality and safety of medical devices, the Medical Devices Regulation (MDR) and the In Vitro Diagnostic Medical Device Regulation (IVDR) were enacted in the EU, which tighten the regulations.

In order to create coherence in Switzerland with the developments in the EU (MDR and IVDR), the Medical Devices Ordinance (MedDO), which had been in force since 1 January 2002, needed to be revised. As a result of the postponement of the entry into force of the MDR, the most important provisions and the stricter rules of the revised Medical Devices Ordinance will not enter into force until 26 May 2021 (and not, as originally planned, on 26 May 2020).

As part of the revision, the Government also adapted the exemption rules for non-conforming medical devices. In order to avoid supply bottlenecks and protect public health, the Federal Council decided to enact the new rules for non-conforming medical devices already on 1 August 2020.

Conformity assessment procedure

According to current and future law, proof of conformity must be provided by means of a conformity assessment procedure for all medical devices that are to be placed on the Swiss market. Depending on the classification of the medical device, a declaration of conformity by the manufacturer is sufficient. In the case of medical devices with a higher classification, the involvement of a conformity assessment body is required, which certifies the conformity by means of a certificate. It is a peculiarity of Switzerland that the product information of a medical device must generally be written in three official languages in order for the medical device to be marketed in Switzerland (Art. 7 MedDO).

Exemption rules since 1 August 2020

Since 1 August 2020, Swissmedic may authorise the first placing on the market and the putting into service of a specific medical device on the basis of Art. 9 para. 4 MedDO, provided that the use of this medical device is in the *„interest of public health or patient safety or health, even if: a) the relevant conformity assessment procedure has not been carried out; or b) the language requirements in accordance with Article 7 para. 2 are not fulfilled.“*

Such an exemption may be granted for specific medical device types and may apply to all identical medical devices of that product type. It is also possible to apply for the approval of different medical device types with the same application, for example, if there is a systematic link between these medical device types.

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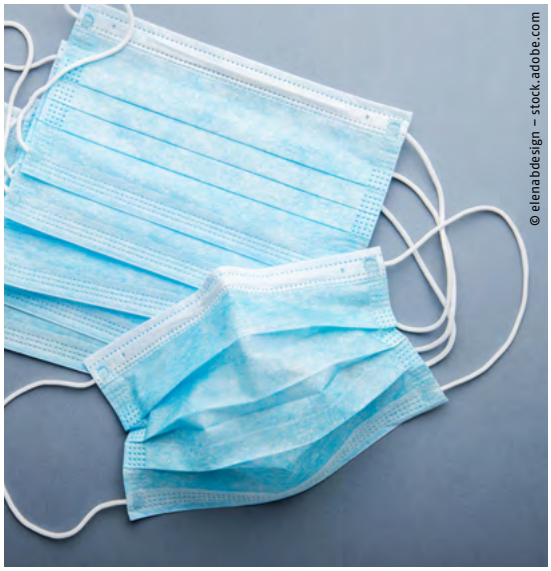
In addition, since 1 August 2020, individual medical devices for which the relevant conformity assessment procedure has not been carried out may even be placed on the market and used without a Swissmedic authorisation based on Art. 9 para. 5 MedDO, if

- they serve to remedy life-threatening conditions or to eliminate permanent impairments of a bodily function;
- no conforming medical device is available for the specific indication;
- they are used exclusively by medical personnel on individuals;
- the medical practitioner has informed the individual concerned of the non-compliance of the medical device and the risks involved; and
- the individual concerned has consented to the use of the medical device.

Changes compared to the previous rules

In contrast to the previous version of Art. 9 para. 4 MedDO, the provision applicable since 1 August 2020 does not contain a definitive list of criteria for the granting of an exemption authorisation by Swissmedic for the placing on the market or putting into service of non-conforming medical devices. Instead, Swissmedic will base the grant of an exceptional authorisation on whether the use of a medical device is *„in the interest of public health or of patient safety or health"*. This open wording gives Swissmedic considerable discretionary powers. If these conditions are met, Swissmedic can now also waive the language requirement of Art. 7 para. 2 MedDO, which was previously only possible under restrictive conditions (Art. 7 para. 3 MedDO). Where the use of a medical device is urgently required, Swissmedic can therefore override the strict language requirements.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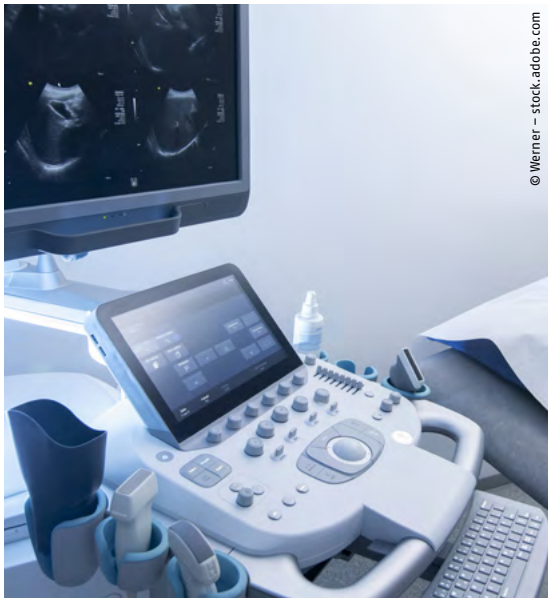
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An absolute novelty is the possibility of placing non-conforming medical devices on the market or using them even without Swissmedic's authorisation, provided that the strict conditions of Art. 9 para. 5 MedDO are met. Until now, an authorisation for exemption had to be applied for from Swissmedic in each case.

Effects of the new provisions

It is to be expected that Swissmedic will increasingly issue exceptional authorisations for medical devices that are non-conforming or do not meet the language requirements based on the new and relatively open wording of Art. 9 para. 4 MedDO, provided that their availability is in the public interest. Possible exceptional authorisations include medical devices used for the treatment of rare diseases which are not available in Europe. Swissmedic can also apply the exemption rules in situations where a conformity assessment procedure cannot be carried out in time due to bottlenecks at notified bodies (conformity assessment bodies) and as a result of the more stringent conditions.

It should be emphasised that Swissmedic can also issue and publish these exemptions as a general ruling, which is likely to increase the effects significantly due to their general validity. Based on the exemption rules, it would be possible, for example, for Swissmedic to issue exceptional authorisations for protective material as a measure in the context of the Covid-19 pandemic after the Federal Council's emergency legal competence has ceased.