

1 Aim of this information

Swissmedic, the Swiss Agency for Therapeutic Products, is responsible for the market surveillance of medical devices ([Art. 23 and 24 of the Medical Devices Ordinance MedDO, SR 812.213](#)).

Due to the spread of the novel coronavirus (SARS-CoV-2) in Switzerland, economic operators are directing an increasing number of questions to Swissmedic regarding the placing of protective masks, gloves, hand sanitisers and coronavirus tests on the market. The aim of this information sheet is to answer these regulatory questions and clarify Swissmedic's responsibilities.

2 Outline of the recommended action and health measures specified by the FOPH

You can find **information, recommended action and special measures** relating to the spread of the novel coronavirus on the website of the [Federal Office of Public Health \(FOPH\)](#).

The **FOPH recommendations** for the use of protective masks, gloves and disinfectants must be observed!

3 Regulation of medical devices

Medical devices are not subject to authorisation. As a general rule, medical devices placed on the Swiss market must bear the **CE mark**.

As the market surveillance authority, Swissmedic **does not provide any consulting services**, e.g. regarding conformity assessments for medical devices. For this, please contact a private service provider.

More information concerning Swissmedic's tasks, the market access of medical devices and medical devices in general can be found via the following links:

- [Information videos](#)¹
- [Guide to the regulation of medical devices](#)²
- [Placing on the market of important medical devices for combating the COVID-19 pandemic](#)³

4 Personal protective equipment (PPE)

Many of the products used in the COVID-19 pandemic are not medical devices, but personal protective equipment (PPE). PPE falls under the responsibility of SECO and control boards mandated by SECO. A permit is not required for PPE placed on the market on the basis of the Ordinance on the Safety of Personal Protective Equipment (PPE Ordinance, PPEO, SR 930.115). You will find more information on PSA on the [SECO website](#)⁴.

According to Article 24 of the [COVID-19 Ordinance 3](#), by way of derogation from the legal requirements under PPEO, the placing on the market of PPE is permitted during the COVID-19 epidemic subject to certain conditions. An appropriate safety level relative to the applicable legal requirements under PPEO must be guaranteed. Article 24 paragraph 2 COVID-19 Ordinance 3 sets out the exceptions. More information can be found in the [FAQ](#) "Protective masks and other PPE" (not available in English). [\[Link\]](#)

¹ <https://www.swissmedic.ch/swissmedic/en/home/about-us/publications/video.html>

² https://www.swissmedic.ch/swissmedic/en/home/medical-devices/regulation-of-medical-devices/medical-device-regulation_online-guide.html

³ <https://www.swissmedic.ch/swissmedic/de/home/medizinprodukte/marktkontrolle-medinprodukte/mitteilungen-zu-marktkontrollthemen/inverkehrbringung lebenswichtiger beatmungsgeraete.html>

⁴ <https://www.seco.admin.ch/seco/de/home/Arbeit/Arbeitsbedingungen/Produktsicherheit/Personliche-Schutzausrustungen-PSA.html>

5 Medical devices and the novel coronavirus

5.1 Face masks

In general, medical face masks (surgical masks) in accordance with the standard EN 14683 are medical devices and therefore fall under the responsibility of Swissmedic.

Masks in the context of the COVID-19 epidemic

This table provides an overview of the masks that are available on the market in the context of the COVID-19 epidemic.

Mask type	Respirator	Medical face mask/surgical mask	Other masks
Abbreviations/synonyms	Filtering facepiece (FFP), or FFP2/FFP3 mask, respectively	Surgical mask, sanitary mask	Textile mask, Community mask Self-sewn, self-made textile masks, Do-it-yourself (DIY)-mask, universal mask etc.
Intended purpose Protective effect	Personal protection Protects the wearer from solid and liquid particles and aerosols. Wearing these masks is only useful in conjunction with the recommended hygiene and distancing measures.	Protection of others When used correctly, it primarily protects others from infection, rather than the wearers themselves. It also provides wearers with a lesser degree of protection. Wearing these masks is only useful in conjunction with the recommended hygiene and distancing measures.	At best, some protection of others Especially textile masks according to the standard recommended by the Swiss national COVID-19 science task force can protect others from infection, not the wearers themselves. The FOPH does not recommend wearing self-sewn masks. Wearing these masks is only useful in conjunction with the recommended hygiene and distancing measures.
Medical device/personal protective equipment	Yes	Yes	No
Conformity marking	CE with 4-digit identification number from the conformity assessment body	CE (no identification number)	No state-protected conformity marking
Legal requirement	<ul style="list-style-type: none"> - Ordinance on the Safety of Personal Protective Equipment (PPE Ordinance, PPEO, SR 930.115) - EU PPE Regulation Regulation (EU) 2016/425 	<ul style="list-style-type: none"> - Medical Devices Ordinance (MedDO, SR 812.213) - EU Medical Device Directive Directive 93/42/EEC - EU Medical Device Regulation Regulation (EU) 2017/745 	<ul style="list-style-type: none"> - Federal Act on Foodstuffs and Utility Articles (Foodstuffs Act, FoodA, SR 817.0); or - Federal Act on Product Safety (Product Safety Act, ProdSA, SR 930.11)

Technical requirements	<p>EN 149 (Respiratory protective devices – Filtering half masks to protect against particles – Requirements, testing, marking)</p> <p>Classification into FFP-2 or FFP-3 according to this standard:</p> <ul style="list-style-type: none"> - FFP-3 has a higher filtration efficiency than FFP-2 	<p>EN 14683 (Medical face masks – Requirements and test methods)</p> <p>Classification into Type I, Type II or Type IIR according to this standard:</p> <ul style="list-style-type: none"> - Type II has a higher filtration efficiency than Type I; - Type IIR offers the wearer additional splash resistance to bodily fluids (e.g. blood) 	<p>Technical standards for determining the flammability of textiles (Ordinance on Articles intended for Human Contact, SR 817.023.41).</p>
Supporting documents	<p>Manufacturer's Declaration of Conformity to Regulation (EU) 2016/425 or Directive 89/686/EEC.</p>	<p>Manufacturer's Declaration of Conformity to Directive 93/42/EEC or Regulation (EU) 2017/745.</p>	---
Other standards and classifications	<ul style="list-style-type: none"> - KN95 (Chinese standard GB2626-20 06, similar to FFP2) - N95 (US standard NIOSH-42C FR84, similar to FFP2) 	---	<ul style="list-style-type: none"> - Recommendation of the “Swiss National COVID-19 Science Task Force” for community masks - AFNOR Spec S76-001 Masques barrières (French standard), etc.

Note on non-conforming face masks / surgical masks for general use by the public

Sections 3 and 4 describe the rules applicable to medical devices in general, a note about personal protective equipment and special permits for the coronavirus pandemic.

An exemption has been issued for medical face masks (also known as surgical or sanitary masks). These may be placed on the market for non-medical use **without prior approval by Swissmedic** ([Art. 23 para. 3 and 4 COVID-19 Ordinance 3](#)).

The conditions to be satisfied are:

- 1) Placing on the market solely for non-medical use by the general public (e.g. on trains, when shopping or at the hairdresser's)
- 2) The face masks are expressly marked as for **non-medical use**.

N.B.: Face masks placed on the market under this special rule do not fully comply with Swiss medical devices requirements. It should not be assumed that these masks comply with the relevant standard EN 14683. Such masks must therefore never be used for direct patient contact in hospitals or doctors' surgeries.

5.2 Disposable gloves

Disposable gloves intended for medical use, such as surgical gloves and examination gloves, are generally considered as medical devices (Art. 1 para. 1 let. c section 1 MedDO). These must therefore fulfil the relevant requirements on medical devices and bear the CE mark, in accordance with Directive 93/42/EEC or Regulation (EU) 2017/745 (Art. 8 para. 1, Art. 10 para. 1 and Art. 22a MedDO). Disposable gloves not intended for medical use (e.g. for household use) are not considered to be medical devices.

5.3 Protective suits, protective goggles and other items of protective equipment

Protective items such as suits, goggles, visors etc. are personal protective equipment (PPE). See section 4 for information on PPE.

5.4 Hand sanitisers

Hand sanitisers are generally not medical devices but rather biocidal products.

The Federal Office of Public Health is responsible for the authorisation of biocidal products. More information is available on the relevant [website](#).

5.5 COVID-19 tests

Tests for the new SARS-CoV-2 coronavirus or coronavirus antibodies in human samples (e.g. saliva, blood) are in vitro diagnostic medical devices (Art. 1 para. 1 let. c section 1 and para. 3 let. a MedDO). In order for tests to be placed on the market, they must fulfil the relevant requirements on medical devices and bear the CE mark, in accordance with Directive 98/79/EC or Regulation (EU) 2017/746⁵ (Art. 8 para. 1, Art. 10 para. 1 and Art. 22a MedDO).

Dispensing **coronavirus tests to the general public** (i.e. to laypeople) is **prohibited** (Art. 17 para. 3 MedDO). In Switzerland, facilities that carry out SARS-CoV-2 testing (e.g. laboratories or hospitals) are subject to the Epidemics Act (EpidA; SR 18.101) and have to have an appropriate establishment licence from Swissmedic. This licensing requirement applies regardless of the method or technique used. Further information on the background, the legal requirements and the laboratories that currently hold a licence can be found on the Swissmedic website at www.swissmedic.ch/microbiolabs.

⁵ With regard to medical devices for in-vitro diagnostics manufactured in house, see Art. 3 para. 1b and b^{bis}, Art. 8 para. 3 and Art. 17 para. 4 MedDO.

Change history

Version	Valid and binding as of	Description, comments (by author)	Author's initials
1.0	16.03.2020	First version	kom
2.0	07.05.2020	Update	kom
3.0	19.05.2020	Update: Information on community masks	kom
4.0	29.05.2020	Update: : Information on community masks	kom
5.0	24.06.2020	Update: COVID-19 Ordinance 3	cif
6.0	02.09.2020	Update: correction of other masks – Table in chapter 5.1	cif