1 Aim of this information

Swissmedic, the Swiss Agency for Therapeutic Products, is responsible for the market surveillance of medical devices (Art. 75 and 76 of the Medical Devices Ordinance MedDO, SR 812.213 and art. 66 and 69 of the Ordinance on In Vitro Diagnostic Medical DevicesIvDO, SR812.219).
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, gowns, hand sanitisers, infrared thermometers 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 advisory services**, e.g. regarding conformity assessments for medical devices. For this, please contact a private service provider.

More information on Swissmedic's responsibilities, market access for medical devices, medical devices in general and exemptions under Art. 23 of COVID-19 Ordinance 3 (SR 818.101.24) can be found using the links below:

- Information videos[1]
- Frequently asked questions[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 PPE on the SECO website[4].
In accordance with Art. 23b of COVID-19 Ordinance 3, PPE can be placed on the market for the duration of the COVID-19 pandemic subject to certain conditions and in divergence from the legal requirements under PPEO. An appropriate safety level relative to the applicable legal requirements under PPEO must be guaranteed. Art. 23b para. 2 COVID-19 Ordinance 3 sets out the exceptions.

[1] https://www.swissmedic.ch/swissmedic/en/home/about-us/publications/video.html
[2] Frequently Asked Questions (swissmedic.ch)
[3] https://www.swissmedic.ch/swissmedic/en/home/medical-devices/market-surveillance-of-medical-devices/announcements-on-market-control-issues/inverkehrbringung_lebenswichtiger_beatmungsgeraete.html
[4] https://www.seco.admin.ch/seco/de/home/Arbeit/Arbeitsbedingungen/Produktsicherheit/Persoenliche-Schutzausruestungen-PSA.html

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5 Medical devices and the novel coronavirus

5.1 Face masks

Medical face masks (protective masks) that comply with EN 14683 are classified as medical devices and therefore fall under Swissmedic's responsibility.

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/protective mask	Other masks
Synonyms/abbreviations	Filtering facepiece (FFP) i.e. FFP2/FFP3 mask	Surgical mask, sanitary mask	Textile mask, community mask Self-sewn, self-made textile masks, do-it-yourself (DIY) masks, universal masks, etc.
Protective effect/intended purpose	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 In particular, textile masks according to the standard recommended by the Swiss National COVID-19 Science Task Force can protect others from infection, but 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 of the conformity assessment body	CE (no identification number)	No state-protected conformity marking

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Mask type	Respirator	Medical face mask/protective mask	Other masks
Legal requirement	- Ordinance on the Safety of Personal Protective Equipment (PPE Ordinance, PPEO, SR 930.115) - EU PPE Regulation Regulation (EU) 2016/425	- Medical Devices Ordinance (MedDO, SR 812.213) - EU Medical Device Directive Directive 93/42/EEC - EU Medical Device Regulation Regulation (EU) 2017/745	- 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	EN 149 (Respiratory protective devices – Filtering half masks to protect against particles – Requirements, testing, marking) Classification into FFP-2 or FFP-3 according to this standard: - FFP-3 has a higher bacterial filtration efficiency than FFP-2	EN 14683 (Medical face masks – Requirements and test methods) Classification into Type I, Type II or Type IIR according to this standard: - Type II has a higher bacterial filtration efficiency than Type I; - Type IIR offers the wearer additional splash resistance to bodily fluids (e.g. blood)	Technical standards for determining the flammability of textiles (Ordinance on Articles intended for Human Contact, SR 817.023.41).
Supporting documents	Manufacturer's Declaration of Conformity to Regulation (EU) 2016/425 or Directive 89/686/EEC.	Manufacturer's Declaration of Conformity to Directive 93/42/EEC or Regulation (EU) 2017/745.	---
Other standards and classifications	---	---	- Recommendation of the Swiss National COVID-19 Science Task Force for community masks - SNV – New Swiss rules on community masks (not available in English)

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Note on non-conforming face masks/protective 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 **without prior approval by Swissmedic** if they are intended for non-medical use (Art. 23 para. 4 COVID-19 Ordinance 3).

The conditions to be satisfied are:

1st Placing on the market solely for non-medical use by the general public (e.g. on trains, when shopping or at the hairdresser's)
2nd Face masks must be specifically labelled as **not for 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 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. These must therefore fulfil the relevant requirements on medical devices and bear the CE mark, in accordance with Directive 93/42/EEC and Regulation (EU) 2017/745.
Disposable gloves not intended for medical use (e.g. for household use) are not considered as 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 (FOPH) responsible for the authorisation of biocidal products. More information is available on the relevant website.

5.5 Infrared thermometers

Infrared (IR) thermometers that are specifically intended by their manufacturer for medical use (e.g. measuring temperature to determine a pathological condition) are regarded as active medical devices. They must fulfil the relevant requirements for medical devices and bear the CE mark followed by the four-digit identification number of the conformity assessment body that assessed them, in accordance with Directive 93/42/EEC and Regulation (EU) 2017/745.

5.6 COVID-19 tests

Tests for diagnosing coronavirus (SARS-CoV-2) infection by means of human samples (e.g. nasal swabs, saliva or blood) are medical devices for in-vitro diagnostics (abbreviated to IVD). To be placed on the market, tests must fulfil the relevant requirements for medical devices and bear the CE mark in accordance with Directive 98/79/EC and Regulation (EU) 2017/746[5].

In Switzerland, it is generally forbidden to dispense IVDs for detecting communicable human diseases to the public (Art. 61 para. 3 IvDO).
However, it is permitted to dispense and use **SARS-CoV-2 rapid tests for lay use** provided these SARS-CoV-2 self-tests have been declared by their manufacturer as intended for lay use and are certified to this effect (CE followed by the four-digit identification number of the notified body, i.e. CE

[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 Medical Devices Ordinance of of 17 October 2001.

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xxxx)[6]. The FOPH publishes on its website a list of the SARS-CoV-2 self-tests that are permitted under the COVID-19 Ordinance 3[7].

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 technology 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 Microbiological laboratories. Immunological analysis by means of rapid testing[8] may also be performed in doctors' practices, pharmacies and hospitals, as well as in test centres operated by the Canton or on the Canton's behalf. Further information is available here.

Change history

Version	Valid and binding as of	Description, comments (by author)	Author's initials
3.0	26.05.2022	Insertion of references to the IvDO	kom
2.0	30.08.2021	Modification of the COVID-19 Ordinnance 3 of 25 august 2021	kom
1.0	12.08.2021	First version: Doc newly created; old doc ID: MU500_00_014e_MB	kom

[6] Art 24, para. 4 bis COVID-19 Ordinance 3, Exception: Transitional provision for the dispensing by pharmacies of tests with a Swissmedic exemption; see Art. 28b Covid-19 Ordinance 3.
[7] https://www.bag.admin.ch/bag/fr/home/krankheiten/ausbrueche-epidemien-pandemien/aktuelle-ausbrueche-epidemien/novel-cov/information-fuer-die-aerzteschaft/covid-testung.html
[8] Art. 24 and 24a COVID-19 Ordinance 3

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