Information sheet
Face masks for public purposes

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1 Purpose of this information sheet

As part of the control measures to combat the coronavirus (SARS-CoV-2), the wearing of face masks in various public areas (e.g. public transport) has either been recommended or made compulsory. This information sheet is designed to help the public identify the appropriate face masks for this purpose.

2 Overview of mask types

Various types of masks are available in the current pandemic situation. For an overview, please see the information sheet "Medical devices in the context of the COVID-19 epidemic".
The following statements apply only to face masks for medical purposes.

3 Face masks for medical purposes

Medical face masks (also known as hygiene masks, surgical masks or OP masks) are classified as medical devices. They were originally manufactured in order to reduce the risk of direct transmission of infectious pathogens (e.g. viruses) between professionals and patients in e.g. doctors' practices or hospitals. However, these masks can also be used by the public in pandemic situations.

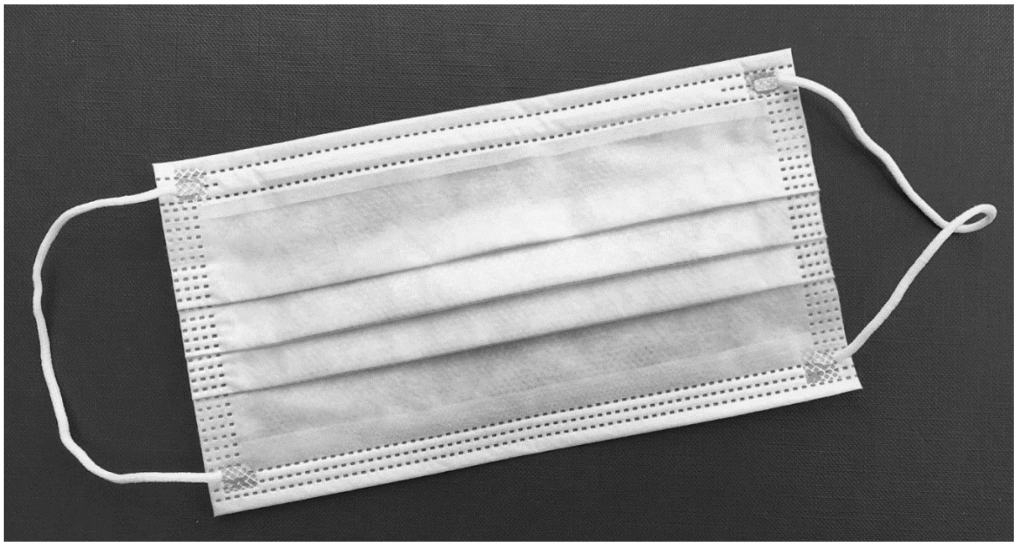
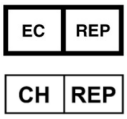


Fig. 1 Example of a medical face mask

4 Identifying features of medical face masks

As a general rule, non-sterile **medical face masks** for single use (Fig.1) in Switzerland may be placed on the market only if they have successfully completed a conformity assessment process and consequently bear a valid **CE mark**.

Such medical face marks are identified on the packaging and any instructions for use as follows:

CE	Conformity symbol (**CE mark**) without an identification number[1].
Standard **EN 14683**[2]	Reference to the **standard**[3] and indication of the **mask type**: Type II, type II or type IIR. NOTE: Healthcare professionals must wear types II and IIR, certainly not type I. Type I can be worn by patients and, in the context of a pandemic, by the public.
Official languages	The information on the packaging and the text of any package leaflet must be written at least in **German**, **French** and **Italian**[4].
Manufacturer's details 	Clear details about the **manufacturer**, including address.
Authorised representative 	If the manufacturer is based outside Europe[5], the name and address of the authorised representative in Switzerland (CH-REP) and/or Europe (EC-REP) must be stated in addition to the manufacturer. If the manufacturer is based in Europe, an authorised representative does not need to be stated[6].

5 Non-conforming medical face masks for general use by the public

Medical face masks that do not satisfy all of the requirements stated in point 4 may, by way of an exemption[7], be issued to the public in order to curb the spread of the coronavirus (SARS-CoV-2). These masks may not be used in medical practices or hospitals, but only in everyday situations, such as rail travel, shopping, etc. Therefore, the packaging and any instructions for use must include the following statement[8]:

Packaging and **package leaflet**	A statement ruling out medical use, e.g. "**for non-medical purposes**".

6 Procedure for defective masks

If the medical face masks on the Swiss market show signs of damage or quality defects (e.g. holes, tears, moisture, unusual smell or mould), please contact the seller.

In addition, Swissmedic (medical.devices@swissmedic.ch[9]) may also be informed directly. To this end, please provide us with the following information and photos:

- Nature of the defects
- Batch (lot or lot number) and details identifying the mask

[1] Art. 13 para. 1 MedDO (Medical Devices Ordinance; SR. 812.213).
[2] Designated standard EN 14683:2019 according to Art. 6 MedDO.
[3] The standard specifies the performance requirements (e.g. filtration efficiency) and test procedures for the respective mask types.
[4] Art. 16 para. 2 MedDO
[5] Europe: Switzerland, contracting states of the European Union, Norway, Iceland, Liechtenstein.
[6] Note: As of 31.07.2022 the designation of a swiss authorized representative (CH-REP) is mandatory for all manufacturers with registered offices outside Switzerland and Liechtenstein (art. 104a MedDO)
[7] Art. 23 para. 4 of the Covid-19 Ordinance 3 (SR 818.101.24).
[8] Art. 23 para. 3 and 4 of the Covid-19 Ordinance 3
[9] https://www.swissmedic.ch/swissmedic/en/home/medical-devices/market-surveillance-of-medical-devices/suspicion-reports.html

- Sales location and name and address of the seller/distributor
- Packaging and any package leaflet for the defective masks concerned:
  - Name and type of the mask
  - Name and address of the manufacturer and/or authorised representative

7 Useful links

You can obtain further information on the following subjects via the following links:

1st **Medical devices –** Video: What is a medical device?[10]

2nd Information, behavioural recommendations and measures connected with the **spread of the coronavirus –** Federal Office of Public Health (FOPH)

3rd **Face masks** as part of personal protective equipment (**PPE**) – State Secretariat for Economic Affairs (SECO)

[10] https://www.swissmedic.ch/swissmedic/en/home/about-us/publications/video/mep-video.html

Change history

Version	Change	sig
2.1	Regular revision, minor content adjustments, updating of links	kom
2.0	Information concerning the CH-REP	kom
1.0	First version: Doc newly created; old doc ID: MU500_00_015e_MB	kom