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Conditions for delivery and release of surgical face masks

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Different types of face masks can be used as a means of prevention of and protection against the transmission of the SARS-CoV-2 virus: surgical face masks and respiratory protection masks (so-called "dust masks"').

- **surgical or medical masks**: these masks are medical devices and the competent authority is the Federal Agency for Medicines and Health Products (FAMHP).

e.g.  

Surgical masks are designed to protect the patient from contact with infectious agents and particles from the medical staff. But they might also be intended to be worn by patients and other persons to reduce the risk of infections spreading, for example in epidemic or pandemic situations. Surgical face masks are class I medical devices. They need to comply with the requirements of the Royal Decree of 18/03/1999 on medical devices (transposition of the European Directive 93/42/EEC – 'MDD') or with the requirements of the European Regulation 2017/745 on medical devices ('MDR').

The European harmonised standard these masks have to meet, is EN 14683 "Medical face masks – Requirements and test methods".

More information on medical devices can be found on our website.

- **respiratory protection masks (Type FFP2/FFP3 dust masks)**: these products are personal protective equipment (PPE) and the competent authority is the Federal Public Service of Economy, SMEs, Self-employed and Energy. More information on PPE can be found on the website of FPS Economy.

e.g. 

Conditions for delivery of surgical face masks before release is allowed

The compliance of surgical face masks with the essential requirements as described in the legislation, needs to be assessed by the manufacturer. The manufacturer (or his authorised representative) confirms the compliance of the products in a 'declaration of conformity' ('DoC') that should be available to clients. Compliant products that are not placed on the market in sterile conditions shall bear the CE marking as in the figure below. A CE certificate issued by a notified body ('NB') is not necessary for non-sterile surgical face masks.

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Sterile surgical face masks need to bear a CE marking followed by a 4-digit code. See also figure below. These 4 digits identify the notified body that assessed the elements for securing and maintaining the sterile conditions. The notified body issues a CE certificate for this purpose.

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The CE marking needs to be present on the masks themselves or, when this is not possible, on the packaging/labelling of the masks. It should also appear on the sales packaging (e.g. boxes) and in the instructions for use (if present).

Considering the exceptional situation, we allow for deviations from these rules for CE marking and conformity assessment as described in European Recommendation 2020/403 of the European Commission of 13 March 2020 on conformity assessment and market surveillance procedures in the context of the COVID-19 threat.

Surgical face masks **that do not bear the CE marking may be accepted exceptionally and temporarily**, provided that it is **ensured that the products are made available only during the current crisis and do not enter regular distribution channels**.

For the conformity assessment of surgical face masks, the FAMHP will also exceptionally accept test results according to international standards that can be considered equivalent to EN 14683.

These alternatives might be:

- **USA: ASTM F2100**
- **China: YY 0469:2011 and YY/T: 0969-2013**

Conformity can be demonstrated by test reports or by a third party certificate. If sufficiently documented (certificates, test results according to an equivalent standard, accredited laboratory and possibility to link all documents to the batches or goods concerned), this may be accepted as an alternative.

Currently we find that Chinese masks are being tested according to European standards (for example the standards EN 14683, EN 149) by Chinese laboratories/testing bodies. Normally, compliance with European standards can only be confirmed by European testing labs with an accreditation to do so, but if the laboratory or inspection body figures on the following list of bodies that are accredited by

the Chinese Authorities, their certificates will also be accepted (please also see https://www.cnas.org.cn/english/findanaccreditedbody/04/896740.shtml).

CNAS Accredited Laboratories for Testi

Testing reports from laboratories that are **not on this list, will not be accepted**.

Which documents should definitely be present?

- **For non-sterile surgical face masks with CE marking:**
EU declaration of conformity from manufacturer (or authorised representative)

- For sterile surgical face with CE marking:
EU declaration of conformity from manufacturer (or authorised representative)
CE certificate for the sterile aspects, issued by a notified body that is designated for medical devices under Directive 93/42/EC (MDD)or under Regulation 2017/745 (MDR)

- **For surgical face masks without CE-marking:**
Testing reports from accredited lab/certificate from a third party
Identification of the alternative standard that was used

Offers that are not accompanied by the aforementioned documents will NOT BE TREATED.
Deliveries that are not accompanied by these documents will NOT BE RELEASED.

All documents should be linkable to the products in an unambiguous way. Pictures of the product, its packaging and labelling can be added as support in the offer.

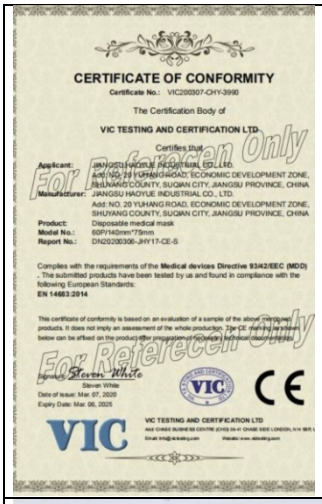
Conditions for delivery of respiratory protection masks (FFP2/FFP3) release is allowed

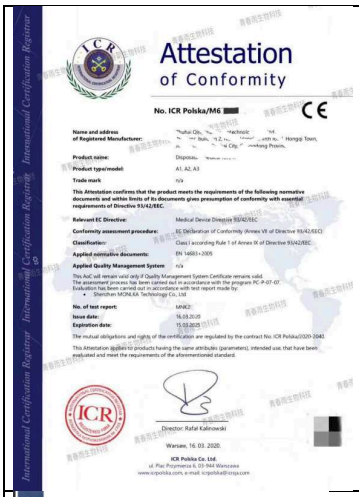
For these masks, all conditions can be found on the website of the FPS Economy using the following link.

ATTENTION: falsified certificates

We bring to your attention that falsified and irrelevant certificates are circulating for surgical face masks and FFP masks, pretending to prove their conformity to European rules.

Below, some examples are presented that were recently seen by the Belgian Authorities. More information and more examples can also be found on the website of the European Safety Federation.

	Falsified certificate – exists for EN 14683 and EN 149. These certificates are often issued very recently.
	Falsified certificate. ISET is a notified body for Personal Protective Equipment (PPE), not for medical devices. Several falsified certificates were seen, mostly for Chinese companies. This type of falsified certificate also exists for medical devices (ex. surgical masks) and falsified testing reports of this kind have also been seen. Falsifications are published by ISET itself on their website as well.

	ICR is not a notified body for medical devices. This kind of attestations is of no value.
	ICR is not a notified body for Personal Protective Equipment (PPE). The certificate is issued on a 'voluntary basis' and is based on testing results of a non-accredited lab. The certificate does not confirm any conformity to EU requirements. ICR also confirms this on its website. The certificate is of no value.
 	Conformity certificates /CE certificates cannot be issued by Chinese testing laboratories, only by European notified bodies. These certificates have no value.
 	ECM is a notified body for medical devices, not for Personal Protective Equipment (PPE). This document only states that the manufacturer has drawn up technical documentation, nothing else. This kind of certificate is not accepted for Personal Protective Equipment (PPE) and has little of no value for medical devices; it does not prove any conformity. The validity of these certificates can be checked on the website of ECM. The same website page also shows a list of fake and falsified ECM certificates.

	ECM is a notified body for medical devices, not for Personal Protective Equipment (PPE). This organisation has no authority to issue these kind of certificates for PPE. They have no legal value. This example is a fake certificate that is also included in the list published by ECM itself.
	Certificate of 'BSI TEST LIMITED' voor respiratory masks. BSI TEST LIMITED was founded on March 19th 2020 and this kind of fake certificates can be purchased on its website.
	This certificate of conformity is issued by a Hong Kong testing lab that is not entitled to issue CE conformity certificates.
	This certificate has been issued by a body that is not notified for medical devices or personal protective equipment under EU legislation. It only states that certain documents have been checked. It is not accepted.