Federal Public Service Economy, SMEs, Self-employed and Energy

Conditions that deliveries of FFP2 and FFP3 face masks must fulfill in order to be released

Version 20200326

Face masks for protection against the coronavirus

There are different types of face masks: the surgical and respiratory protection masks, so-called “dust masks”.

If they are surgical or medical masks (see example below), you will find additional information at the FAMHP (www.fagg.be).

If they are respiratory protection masks, so-called “dust masks”, these are personal protective equipment (PPE).

A personal protective equipment is designed and manufactured to be worn or held by one person to protect against one or more risks to that person's health or safety.
A PPE face mask protects the user against pathogens that can be spread through the air. Standard EN 149: 2001 + A1: 2009 “Respiratory protective devices - Filtering half masks to protect against particles - Requirements, tests, marking” (types FFP1, FFP2 and FFP3).

The applicable regulation for placing PPEs on the market is European Regulation 2016/425.

You can find more information about this regulation on our website:
https://economie.fgov.be/fr/themes/qualite-securite/securite-des-produits-et/reglementations-specifiques/equipements-de-protection/securite-des-equipements-de

For PPE masks, documents such as the EU declaration of conformity and the EU-type examination certificate issued by a notified body must be present in order to demonstrate the conformity of the products.

In view of the exceptional situation, we take into account 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

We can exceptionally accept masks that do not bear the CE marking, provided it is ensured that such products are made available **only during the current crisis** and **do not enter regular distribution channels**.

For the evaluation of the conformity assessment certification of mouth masks, we also exceptionally take into account certification or test reports according to equivalent international standards.

These alternative standards can be:

- **European Union: EN 149+A1:2009 → FFP2 en FFP3**
- **Australia: AS/NZS 1716:2012 → P3, P2**
- **Brazil: ABNT/NBR 13698:2011 → PFF3, PFF2**
- **China: GB 2626-2006 → KN100, KP100, KN95, KP95**
- **Japan: JMHLW Notification 214, 2018 → DS/DL3, DS/DL2**
- **Korea: KMOEL-2017-64 → Special, 1st Class**
- **Mexico: NOM-116-2009 → N100, P100, R100, N99, P99, R99, N95, P95, R95**
- **USA: 42 CFR 84 → N100, P100, R100, N99, P99, R99, N95, P95, R95**

This list can also be found on: *https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirators-strategy/crisis-alternate-strategies.html*

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

We are aware that Chinese face masks are currently being tested by Chinese inspection bodies / laboratories according to European Standard EN 149. Normally, this can only be done by European notified bodies, but if the inspection body figures on the following list from the Chinese authorities, we will accept these certificates:

https://www.cnas.org.cn/english/findanaccreditedbody/04/896740.shtml

Certificates from laboratories that are NOT on the list will NOT be accepted.

Which documents should definitely be present ?

For face masks with CE marking:

EU declaration of conformity

EU type examination certificate, issued by a notified body competent for PPE-masks

For mouth masks without CE marking

Certificate from a third party body. (certificates, test reports according to a standard, accredited laboratory,...)

Mention of the alternative standard used

Deliveries not provided with these documents will NOT BE RELEASED

It must be possible to link all the documents to the products in an unambiguous way