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Information on the Alternative Test Protocol (ATP) for surgical face masks

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The COVID-19 pandemic is hampering the supply of various health care materials, including medical devices such as surgical masks.

The FAMHP inspection services have noted that a large number of the surgical face masks offered do not have the declarations, certificates and test reports necessary to demonstrate unequivocally that they meet the requirements of the applicable European standard (EN 14683:2019 + AC:2019) or one of the international standards which are currently also authorised on an exceptional basis (ASTM F2100, YY 0469:2011 and YY/T 0969-2013)[1].

Under normal circumstances, these masks would not be put into service, as their quality and effectiveness cannot be guaranteed. Due to the high level of demand in this crisis situation, and in order to reduce the significant shortage of masks, these masks can now be subjected to a simplified test protocol which only takes into account the test results of two important parameters: the Alternative Test Protocol (ATP).

Masks with a positive ATP result can be used as surgical face masks.

The standard defining the requirements for surgical masks is EN 14683:2019 + AC:2019. This is met on the basis of four test parameters:

- Bacterial Filtration Efficiency (BFE): this test determines the filtration efficiency for the microorganisms tested. It takes several days because the protocol requires the growth of culture media to quantify the microorganisms.
- Differential pressure (ΔP): this test consists of passing a flow of air at constant speed through the mask while measuring the differential pressure (Pa/cm²). This is how breathing resistance is determined. It is a test that can be done fairly quickly.
- Splash resistance (for type IIR masks): this test determines to what extent the mask can prevent the penetration of external liquids.
- Microbial cleanliness: this test makes it possible to determine the microbial contamination of the mask.

Alternative Test Protocol (ATP)
The ATP only looks at the Bacterial Filtration Efficiency (BFE) and Differential Pressure (ΔP) test results. These are the most important parameters in the current context. Centexbel, the only accredited laboratory in Belgium authorised to carry out tests in accordance with this standard, has studied the correlation between these two parameters in recent weeks. The indications already provided by this study were taken into account during the development of this ATP. All ATP tests are carried out by Centexbel. The tests are carried out as follows:

First, the differential pressure (ΔP) (Pa/cm²) is tested. Depending on the result of this test, subsequent work is carried out as follows:

[1] https://www.afmps.be/sites/default/files/content/info_offres_masques_chirurgicales_2.pdf

- ΔP <25: there is a small chance (<30%) that the BFE test gives a favourable result (BFE ≥ 95%). If the importer/supplier of the masks wishes, the BFE test will still be carried out. If the BFE result is ≥ 95%, the masks can be marketed as surgical masks. If the ABE result is <95%, or if the BFE is not tested, the masks can only be marketed as "comfort masks".

- 25≤ ΔP <35: there is little correlation between ΔP and BFE in this range. In this case, it is highly recommended to also test the BFE. If the BFE result is ≥ 95%, the masks can be marketed as surgical masks. If the BFE test result is less than 95%, or if the importer/supplier does not want to have the BFE tested, the masks can only be marketed as "comfort masks".

- 35 ≤ ΔP ≤ 65: within this range, we can be sufficiently certain that the masks will have a BFE ≥ 95% (and probably ≥ 98%). BFE is no longer tested in this case and the masks can be marketed as surgical masks.

Marketing as a surgical mask based on positive ATP results
Based on the positive results of the ATP, the masks can be marketed as surgical masks. The importer/supplier draws up a declaration in which it confirms that its customers will be informed that:

- the masks do not meet the requirements of European regulations relating to medical devices and have not been fully tested in accordance with the applicable standard EN 14683;
- the masks have been tested in accordance with the Alternative Test Protocol;
- an explication of the ATP can be found on the FAMHP website;
- masks based on this ATP have been deemed suitable for use as surgical masks;
- these masks can only be marketed as surgical masks in the current crisis situation.

Information on the masks released under the ATP will be available on the FAMHP website.

Marketing as a comfort mask based on negative ATP results
If the results of the ATP determine that the masks must only be marketed as comfort masks, the importer/supplier shall draw up a declaration in which it confirms that its customers will be informed that:

- the masks do not meet the requirements of European regulations relating to medical devices and have not been fully tested in accordance with the applicable standard EN 14683;
- the masks have been tested in accordance with the alternative test protocol or the choice has been made not to follow this ATP or not to follow it in its entirety;
- an explication of the ATP can be found on the FAMHP website;
- the masks have proven to be unsuitable for use as a surgical mask or that there is no information on the their effectiveness and they have therefore been downgraded to a comfort mask.

Additionally, a warning is given that these masks cannot be used as surgical masks on the basis of the alternative test protocol, worded as follows:

Ongeschikt als surgisch masker
Enkel te gebruiken als comfortmasker
Dit is geen medisch hulpmiddel!

Not suitable as a surgical mask
To be used only as a comfort mask
This is not a medical device!

Conditions
Masks which only meet the requirements of the ATP do not comply with the European standard for surgical masks and do not meet the requirements of the European regulation on medical devices. They cannot therefore be marketed in the usual way.

The following conditions apply to non-compliant masks authorised for use as surgical masks in accordance with the ATP:

- these masks are only to be used during this crisis period;
- the end user is explicitly informed that the masks have not been fully tested in accordance with standard EN 14683;
- the end user is informed about the ATP and its application;
- in the interests of transparency, information about the masks released under the ATP can be consulted on the FAMHP website.

The following conditions apply to non-compliant masks classified as comfort masks according to the ATP:

- the end user is explicitly informed that the masks have been downgraded to be used as "comfort masks" and that they CANNOT be used as surgical masks;
- a warning to this effect must appear on the packaging.

The ATP is limited to the two main parameters of the EN 14683 standard in the current context of the COVID-19 crisis. The correlation between these two parameters is taken into account on the basis of the results of a limited study carried out during the crisis. The results of any other studies will also be taken into account in order to optimise the protocol, if necessary.

Benefits of the ATP
This protocol makes it possible to determine whether the non-compliant masks, which could not be released under normal circumstances, are of sufficient quality to be used as surgical masks in the current crisis situation.

Thanks to the ATP, considerable time can be saved when testing surgical masks, which translates into an increase in testing capacity at Centexbel.

Centexbel contact details
Face masks are tested at:
Centexbel
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