

Personal protective equipment

Overview of the test and certification process



Filtering half mask



Outcome



Certification



Technical file



Validity of certificate



CE-marking on product



Production control (audit)



Note

Trajectory 1 FFP2	Limited test According to RfU 02/075 version 3	Test report Approx. 4 weeks*	Conformity assessment Temporary Module B only for COVID-19 protection	Limited See page 4 of application form	6 months from issue date	Yes Without NB number.	No Instead the product shall be re-examined when the certificate expires.	Getting masks on the market in a fast way - as soon as the test report is complete and the application for temporary approval is submitted to us.
Trajectory 2 FFP1 FFP2 FFP3	Full test According to EN 149	Test report Approx. 4-6 weeks*	EU type examination Module B General purpose FFP2 classification	Full technical file See page 3 of application form More info See annex III of Regulation 2016/425	5 Years Full certification according to EN 149 will be valid for 5 years.	Yes With NB number placed on products.	Yes Module C2 or D. - C2 module with FORCE Certification A/S	May be placed on the market when the type-examination is complete.

Have a test report, but need a certificate?

FORCE Certification A/S can carry out the type approval (issue certification) in accordance with standard e.g. EN 149 and EN 166, if you already have conducted the testing with an EU accredited European laboratory. FORCE Certification A/S is an accredited certification body providing services within certification, verification and inspection of products, systems and personnel. FORCE Certification A/S is appointed as Notified Body (Notified Body no. 0200) for a number of European directives and is a 100% subsidiary of FORCE Technology.

Test of medical face masks according to EN 14683

§5.2.2 Bacterial Filtration Efficiency (BFE)	Lead time 2-3 weeks*
§5.2.3 Breathability	Lead time 2-3 weeks*
§5.2.4 Splash resistance	Lead time 2-3 weeks*
§5.2.5 Microbial Cleanliness (Bioburden)	Lead time 2-3 weeks*
Full EN 14683:2009 Without biocompatibility: For type I and II / For type IIR	Lead time 3-4 weeks*
With biocompatibility: For type I, II and IIR	Lead time 3-4 weeks*

* Subject to alteration at time of order if significant change in order load