

DECLARATION OF CONFORMITY

(ANNEX VII DIRECTIVE 93/42/EEC)



The Manufacturer

DR. FILTREX

FILTRANIUM S.r.l.

Str. Matei Basarab, 1A, Ialoveni, Chisinau - Moldova (MD)

Of the device:

Denomination	SIGLE USE MEDICAL FACE MASK
Device Type	Class I - Non sterile
Brand	FILTRANIUM S.r.l.
Serial	
Model	Dr. Filtrex
Year of production	2020

Declares under his own responsibility that the above mentioned device complies with the provisions of the following directives and subsequent amendments:

93/42/EEC	Medical Device Directive
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Declares that the product complies with the following standards:

EN 14683: 2019	Medical face masks - Requirements and test methods
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This product belongs to class I, for rule 1 of Annex IX of Directive 93/42 / EEC, and meets the essential requirements of Annex I of the same Directive, it is also subject to the procedure provided for in Article 11, point 5 of the Medical Devices Directive 93/42 / EEC.

Date

02.08.2020

Place

Chisinau (MD)

