

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

Place

02.08.2020

Chisinau (MD)

