

## EC Declaration of conformity

Manufacturer:	<b>Volz Filters SK s.r.o.</b> Československej armády 10121/3 036 01 Martin SK
Product name:	<b>MEDIsyntex FM II, Medical face mask</b>
Medical device class:	Class I.
Conformity assesment procedure:	Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, annex VII.
Applicable standards:	EN 14683+AC:2019 Medical face masks –Requirements and tests methods
Quality management certificate:	EN ISO 9001:2015 SK14/2218

Herewith we declare that the above mentioned medical device meets the applicable provisions, especially the essential requirements of the Council Directive 93/42 EEC of 14th June, 1993.

The required conformity assessment procedure acc. to Annex VII has been performed and the technical documentation is kept available.

In Martin, the 4.6.2020

  
Michal Byroš, Quality manager

**VOLZ Filters SK s.r.o.**

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