DECLARATION OF CONFORMITY

No. 20200725/1
According to Directive 93/42/EEC

Manufacturer:	ROYAX, s.r.o.
Address:	Obchodni 107, Cestlice, 251 01, Czech Republic
Name of Device:	**Face Mask - Type IIR**
Device Types` Codes:	**R-DP-FM-02**
Class of Device: Class I	According to Rule 1 of the Part III (Classification) namely non-invasive device of Annex IX of the EU Community Council Directive 93/42 EEC.

ROYAX, s.r.o. hereby declares that the above specified medical device has been determined as a Class I device according to the requirements of Annex IX of the European Community Council Directive 93/42/EEC.
ROYAX, s.r.o. further declares that the product complies with the relevant provisions of Directive 93/42/EEC concerning medical devices and in particular the conformity of the product with the Essential Requirements in Annex I of the Directive.
The product has been designed, developed, manufactured and tested in accordance with all applicable standards and by using a quality management system according to DIN EN ISO 13485:2016 for medical devices.

These products have met the requirements of the medical device for placing CE marking and ISO 13485:2016 for medical devices.

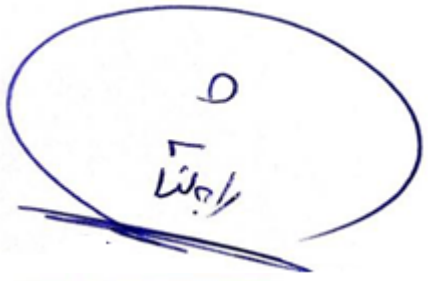
Standards Applied:

ISO 13485:2016 Quality management system for medical device
EN 14683:2019 Medical face masks - Requirements and test methods
EN 1041:2008+A1 2013 information supplied by manufacturer
EN ISO 15223:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied
EN 14971:2019 Medical devices - Application of risk management to medical devices

Prague
ROYAX s.r.o.

Name: Rambod Afrashteh
Position :CEO
SIGNATURE:

Revised date:25/07/2020/Rev:0



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