

Declaration of Conformity

The declaration of conformity is issued under the sole responsibility of the manufacturer

Manufacturer

Extrapack OOD
1A Kozludzha Str.,
5000 V. Tarnovo
Bulgaria

Product

EP Hygitex Mask IIR



We declare that the product described above, Class I medical device, to which this declaration of conformity refers to, complies with the requirements of the following legislation:

EU regulation 93/42 on medical devices

through the standards specified below:

EN 14683:2019+AC:2019 – Medical face masks – Requirements and test methods

EN ISO 14971:2012 – Medical devices – Application of risk management to medical devices

26 January 2021

V. Tarnovo, Bulgaria



Galina Nikolova, Project manager