



DECLARATION OF COMPLIANCE



Manufacturer:

Name: DISPOTECH SRL
Address: CHIAVENNA (SO)- VIA MARIO DEL GROSSO, 8/12
VAT number: 00672170149
R.E.A.: 47213

DECLARES under its own responsibility that the product: DISPOMASK IIR SURGICAL MASK

satisfies all the essential requirements as recommended in the Directive 93/42/EEC (Medical Devices) and successive modifications (included directive 2007/47/EC).

Classe of Medical Device: I enclosure IX rule 1

In accordance with harmonized standard:

European Directive 93/42/EEC and successive modifications (included European Directive 2007/47/EC)
MEDDEV 2.12-1 rev.8 Guidelines on a medical devices vigilance system
UNI EN ISO 13485:2016 Medical devices -- Quality management systems -- Requirements for regulatory purposes
UNI CEI EN ISO 15223-1:2017 Symbol to be used with medical device labels, labelling and information to be supplied
UNI CEI EN ISO 14971:2012 Application of risk management to medical devices
UNI CEI EN 1041:2013 Information supplied by the manufacturer of medical devices
ISO 10993-1:2018 Biological evaluation of medical devices Evaluation and testing within a risk management process
UNI EN 14683:2019 Medical face masks - Requirements and test methods
MEDDEV 2.7.1 Clinical Evaluation: a guide for manufacturers and notified bodies

Place: Gordona

Date 12/11/2020

Legal Representative
(responsible for the release of the product)



Dispotech srl

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