



EC Declaration of Conformity

No MMWM001/EN

Przedsiębiorstwo Prywatne REZAL

with main office registered at: ul. Łęczycka 11/13, 93-193 Łódź, Polska, NIP: 7270002923

declares under sole responsibility as a manufacturer of product:

Medical Mask

Product comply with essential requirements of Council Directive 93/42/EEC concerning medical device (MDD) and has been classified as a medical device Class I (non sterile), rule 1 according to Annex IX of the MMD.

The following norms have been applied:

- EN 14683:2019 + AC:2019 – Medical Face Masks – Requirements and test methods
- ISO 22609:2004 - Medical Face Masks – The method for Resistance against penetration by synthetic blood
- EN ISO 15223-1:2017 – Medical Device – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements

Medical Face Mask has been classified in accordance with EN 14683:2019 + AC:2019 as a medical mask **Type IIR**.

Manufacturer declares that following the conformity assessment in accordance with 93/42/EEC the Product is entitled to affix a CE marking.

Date: 16/02/2021

Location: Lodz, Poland

PRZEDSIĘBIORSTWO PRYWATNE
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