

EU DECLARATION OF CONFORMITY

This Declaration of Conformity, issued under the sole responsibility of the manufacturer **Mask Authority Sp. z o.o., Targowa 4, 52-326 Wroclaw, Poland** hereby declaring the following medical disposable mask.

Product description: **VIRSHIELDS VS004**

Type II R Classification: **Class: I, Rule: 1**

is in conformity with the provisions of the following European Regulations and/or Directives:

Medical Devices Directive

and according to Annex IX rules of the Medical Device Directive is classified as a Class I device.

And is in conformity with the provisions of Annex VII and all other applicable provisions of Council Directive 93/42/EEC (Medical Device) including the National Standard transposing the harmonized European Standard
Number:

EN 14683:2019

Medical face masks - Requirements and test methods

EN 1041:2013

Information supplied by the manufacturer of medical devices

ISO 15223-1:2017

Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied

ISO 14971:2012

Medical devices – Application of risk management to medical devices

ISO 62366:2015

Medical devices – Application of usability engineering to medical devices

EN ISO 11737-1:2018

Sterilization of health care products - Microbiological methods - Part 1: Determination of microbial populations on products



Signed by: Robert Zachar CHAIRMAN OF THE BOARD

Date: 07.01.2021

Signature Certificate

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