

DEKLARACJA ZGODNOŚCI UE



Manufacturer : **Mask Authority Sp. z o.o.**
ul. Targowa 4,
52-326 Wrocław

Name of product::

VIRSHIELDS VS002,

Type/ version: Typ II, S20M9S5
Classification: I, reguła: 1,
Basic UDI – DI: 5904067544VS0025D

Application:

The Virshields VS002 medical (surgical) mask is a disposable, non-sterile medical device intended for use in the medical field. It reduces the risk of drip transmission when examining personnel with a patient with the same level of filtration (BFE) of $\geq 98\%$. This article is breathable to breathe in addition to the medical equipment and patient before carrying the wearable. (e.g. body and airborne transmission, infectious agents).

Mask Authority Sp. z o.o. declares that the above-mentioned product meets the requirements of Annex I to the REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL (EU) 2017/745 of April 5, 2017 on general safety and performance requirements that implement the provisions of the Regulation into Polish and EU law.

Mask Authority Sp. z o.o. declares that the above-mentioned product complies with the REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL (EU) 2017/745 of 5 April 2017

Virshields VS002 **version** S20M9S5 applicable harmonized standards have been used to demonstrate safety and efficacy of the medical device.
The following standards were applied:

EN ISO 13485:2016

Medical devices – Quality management systems – Requirements for regulatory purposes

EN 1041:2013

Information supplied by the manufacturer of medical devices

EN ISO 15223-1:2017

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

EN ISO 14971:2012

Medical devices – Application of risk management to medical devices

EN ISO 62366:2015

Medical devices – Application of usability engineering to medical devices

EN ISO 14683:2019

Medical face masks - Requirements and test methods

PN EN ISO 11737-1:2018

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

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

Revision: 1

Approved by:

Robert Zachar CHAIRMAN OF THE BOARD

Effective from: Wrocław 14.06.2021

Prezes Zarządu
Mask Authority Sp. z o.o.

Robert Zachar