OPHARM®

EC Declaration of Conformity

Nr OP/KN/2020/11-1/EN

Opharm Sp. z o.o.
With main office registered at: Pokrzywnica 62, 99-120 Piątek, Polska, NIP: 5070096769

Declares under sole responsibility as a manufacturer of:

OPHARM Medical Mask type KN95 (Item No K-2)

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

The following (harmonized) norms have been applied:

- EN 14683+AC:2019 - Medical face masks - Requirements and test methods
- ISO 10993-1:2010 - Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
- EN 1041:2008+A1:2013 - 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 - Part 1: General requirements
- EN 11737-1:2018 - Sterilization of health care products — Microbiological methods — Part 1

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

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

CE

Date: 10.11.2020
Location: Pokrzywnica, Polska

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