

DECLARATION OF CONFORMITY UE



MANUFACTURER: **Leon Kajfasz. Przedsiębiorstwo
Produkcyjno - Handlowo - Usługowe "ADRIANNO - DAMIANII"
Bachowice, ul. Na Wzgórzach 27
34-116 Spytkowice
POLAND**

under the sole responsibility declares that the following medical device described hereafter:

SURGICAL MASK
(EN 14683:2019, type IIR)

(List of available models attached as Annex 1)

Basic UDI-DI: **9036897011MASKACH2RYD**

is in conformity with the Medical Device Regulation (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017.

The device, in accordance with Annex VIII of Regulation 2017/745, has been classified as a class I medical device, according to rule 1.

In order to demonstrate the safety and effectiveness of the medical device, the following European standards were used to assess compliance:

EN 14683:2019+AC:2019

Medical face masks - Requirements and test methods

EN ISO 13485:2016

Medical devices — Quality management systems — Requirements for regulatory

EN 1041:2008

Information supplied by the manufacturer of medical devices

EN ISO 15223-1:2016

Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements

EN ISO 14971:2012

Medical devices. Application of risk management to medical devices

EN ISO 10993-1:2009

Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process

Revision: 2

Valid from: 10.07.2020

Place: Spytkowice, Poland

Approver:

Leon Kajfasz

Stamp & signature:

Przedsiębiorstwo Produkcyjno - Handlowo - Usługowe
"ADRIANNO-DAMIANII"
EXPORT-IMPORT
Leon Kajfasz
Bachowice, ul. Na Wzgórzach 27
34-116 SPYTKOWICE
NIP: 551-100-19-02

List of available models for the product: **SURGICAL MASK**

Product name	Version	Number of pieces in sales packaging	UDI-DI (EAN)
SURGICAL MASK	4-ply polypropylene non-woven mask with earloops, type IIR, blue	50	5 903689 701174
SURGICAL MASK	4-ply polypropylene non-woven mask with straps, type IIR. blue	50	5 903689 701174

Version:3

Creation Date: 10.07.2020

Przedsiębiorstwo Produkcyjno - Handlowo - Usługowe
"ADRIANNO-DAMIANII"
EXPORT-IMPORT
Leon Kajfasz
Bachowice, ul. Na Wzgórzach 27
34-116 SPYTKOWICE
NIP: 551-100-19-02

