

# 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:

## **MEDICAL FACE MASK**

(EN 14683:2019, type II)

(List of available models attached as Annex 1)

Basic UDI-DI: **5903689MASKAM26F**

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: 24.04.2020

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: 557-100-19-02

List of available models for the product: **MEDICAL FACE MASK**

Product name	Version	Number of pieces in sales packaging	UDI-DI (EAN)
MEDICAL FACE MASK	3-ply polypropylene non-woven mask with earloops, blue	50	593689701105
MEDICAL FACE MASK	3-ply polypropylene non-woven mask with earloops [B], white	50	593689701129
MEDICAL FACE MASK	3-ply polypropylene non-woven mask with earloops	50	5903689701112
MEDICAL FACE MASK	3-ply polypropylene non-woven mask with straps	50	5 903689 701198

Version:3

Creation Date: 01.07.2020

Przedsiębiorstwo Produkcyjno - Handlowo - Usługowe

**"ADRIANNO-DAMIANII"**

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