

# DECLARATION OF CONFORMITY



**MANUFACTURER:** Medical Protection Sp. z o.o. Sp. K.  
ul. Biały Kamień 2/U6, 02-593 Warsaw, Poland

**MEDICAL COMPONENT:** Name: Medical Mask SAFE® BFE ≥ 95%  
Type I / ES

**I declare with full responsibility that the above-mentioned medical device:  
has been classified as class I in accordance with Regulation I.**

**And it complies with the requirements of Council Directive 93/42 / EEC of June 14, 1995 on medical devices, as amended by Directive 2007/47 / EC of the European Parliament and of the Council of September 8, 2007, and the standards harmonized with it:**

- PN-EN 14683: 2019 - Surgical masks - Requirements and test methods
- PN-EN ISO 14971: 2020-05 Application of risk management to medical devices
- PN-EN 1041 + A1: 2013-12 Information provided by manufacturers of medical devices
- PN-EN ISO 15223-1: 2017-02 Symbols for use on medical device labels, labeling and information provided with them

Conformity is assessed in particular on the basis of the following provisions:

- Act of May 20, 2010 on medical devices
- Regulation of the Minister of Health of 12 January 2011 on essential requirements and conformity assessment procedures for medical devices

The following documents were also used to assess compliance:

- Test report No. 1084 / PZ-TSB-COV / 2020 / NC from CIOP Department of Chemical, Dust and Biological Hazards Warsaw
- Oeko-Tex Standard 100 certificate - report no. HKLO 064653.1
- GGTC certificate: No. 200056356 OKNF - 5656-04

The manufacturer declares that he has taken all necessary measures to ensure compliance of the marketed products with the technical documentation and the basic requirements for this type of product.

Technical documentation and all laboratory tests are archived at Medical Protection Sp. z o.o. Sp. K.

date of issue: 1.09.2020

Place of issue: Warsaw, Poland

He issued the declaration: Tomasz Nowicki

Signature and company stamp:

**Medical Protection Sp. z o.o. Sp. K.**  
ul. Biały Kamień 2/U6  
02-593, Warszawa  
NIP: 5213897353  
REGON: 38612591700000

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**MANUFACTURER:** Medical Protection Sp. z o.o. Sp. K.  
ul. Biały Kamień 2/U6, 02-593 Warsaw, Poland

**MEDICAL COMPONENT:** Name: Medical Mask SAFE® BFE ≥ 98%  
Type II / ES

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Type IIR / ES

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