

## Declaration of Conformity

Manufacturer: ..... Apena-Remont Sp. z o.o.  
43-300 Bielsko-Biała  
Partyzantów 61a

Medical device: ..... **Medical face mask (EN 14683:2019,  
type I, type II)**

The device complies with applicable essential requirements of Council Directive 93/42/EEC.

The device has been classified as Class I medical device, pursuant to Rule 1, in accordance to attachment IX of Council Directive 93/42/EEC.

To prove safety and efficiency of the medical device, the following harmonized standards were applied:

**PN-EN 14683, PN-EN 1041, PN-EN ISO 14971, PN-EN ISO 15223-1**

In order to prove compliance with PN-EN 14683, accredited body Central Institute For Labour Protection – National Research Institute (CIOP BIP) has performed the tests. The results have been confirmed with a test report number:

**1282/PZ-TSB-COV/2020/NC**

Quality Management System ISO 9001:2015

has been approved by: ..... Polish Foreign Trade Chamber Certification  
Sp. z o.o.  
81-322 Gdynia ul. Kołłątaja 1  
No of PCA Accreditation: AC 070 QMS

Bielsko-Biała, 28.09.2020

CEO of Apena-Remont Sp. z o.o.  
Piotr Gołda

*Piotr Gołda*  
**PREZES ZARZĄDU  
DYREKTOR**

**APENA - REMONT  
Sp. z o.o.**  
ul. Partyzantów 61a  
43-300 Bielsko-Biała

NIP: 937-21-76-881

Regon: 072161448

Bank: PEKAO S.A. O/ Bielsko-Biała

Konto: 70 1240 6449 1111 0000 5284 4614

Sąd Rejonowy w Bielsku-Białej VIII Wydział Gospodarczy

Numer KRS: 0000140697

ISO 9001:2015 *Piotr Gołda*



PRZEDSIĘBIORSTWO  
**FAIR PLAY 2019**