

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:

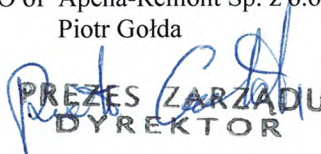
1282/PZ-TSB-COV/2020/NC

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


**PREZES ZARZĄDU
DYREKTOR**

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