

Declaration of Conformity

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

Nazwa wyrobu: **Surgical face mask (EN 14683:2019,
type II, type IIR)**

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, independent laboratory INTERTEK PORTUGAL UNIPESOAAL, LDA. has performed the tests. The results have been confirmed with a test report number:

PRTT00077892

Quality Management System ISO 9001:2015

Has been approved by: Polish Trade Chamber Certification Sp. z o.o.
81-322 Gdynia ul. Kołłątaja 1
Nr akredytacji PCA: AC 070 QMS

Bielsko-Biała 28.09.2020

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

Piotr Gołda

**PREZES ZARZĄDU
DYREKTOR**

Piotr Gołda
mgr inż. Piotr Gołda

APENA - REMONT
Sp. z o.o.
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Konto: 70 1240 6449 1111 0000 5284 4614

Sąd Rejonowy w Bielsku-Białej VIII Wydział Gospodarczy

Numer KRS: 0000140697

ISO 9001: 2015



PRZEDSIĘBIORSTWO
FAIR PLAY 2019