

DECLARATION OF CONFORMITY

Jakubów, PL 11/01/2021

Version 2/2021

1. The manufacturer: TW Plast Sp. z o.o.
2. Manufacturer address: ul. Mińska 69 | 05-306 Jakubów, Poland
3. Product: Three ply medical masks **PRAESIDIUM**
4. BASIC UDI DI: 3661812ZD
5. Types / models / versions: Type II, non-sterile with elastic ear loop
6. Risk class: 1, Rule 1
7. Intended use: Respiratory tract protection (mouth and nose) against airborne diseases and medical procedures demanding respiratory tract protection
8. Expiry date: 48 months from the date of production



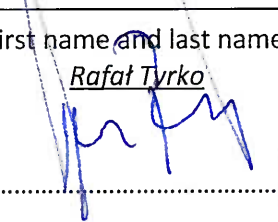
9. Scope of the declaration
The product mentioned in this declaration complies with the essential requirements of Annex 1 to Regulation (EU) 2017/45 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/835/EEC and 93/42/EEC and the essential requirements of the Regulation of the Minister of Health of February 17. 2016 on the essential requirements and conformity assessment procedures of medical devices.
10. Compliance with essential requirements is confirmed by the device manufacturer.
11. The product mentioned in this declaration complies with the following standards:

PN-EN ISO 13485:2016
PN-EN 14683:2019
PN-EN ISO 15223-1:2017
PN-EN 1041:2013
PN-EN ISO 14971:2012
PN-EN ISO 10993-1:2010

TW Plast Sp. z o. o. has a Quality Management System that complies with the requirements of ISO 13485: 2016-4. We hereby declare that the manufactured medical device to which this declaration refers is compliant with the reference documents.

This document is issued under the sole responsibility of the manufacturer.

Place and date of issue:
Jakubów, 2021-11-01

First name and last name:
Rafał Tyrko

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NIP 937-27-22-562 REGON 383776873
KRS 0000792916



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