

DECLARATION OF CONFORMITY

Jakubów, PL 2021-09-20

Version 1/2021

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| 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 JUNIOR |
| 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) 2017/745 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 compliant with the requirements of the PN-EN ISO 13485:2016-4 standard, confirmed by the certificate of the Polish Center for Testing and Certification No. M-85/1/2020. We declare that the manufactured product, to which this declaration refers, complies with the reference documents.

Place and date of issue:
Jakubów, 2021-09-20

First name and last name: <u>Rafał Tyrko</u> Prezes Zarządu Rafał Tyrko.....	TW PLAST Spółka z ograniczoną odpowiedzialnością ul. Mińska 69, 05-306 Jakubów NIP 937-27-22-562 REGON 383776873 KRS 0000792916
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