

# DECLARATION OF CONFORMITY

**TW**plast

Piaseczno, PL 30.04.2020

- |                                      |   |
|--------------------------------------|---|
| <b>1. The manufacturer:</b>          | TW Plast Sp. z o.o.   |
| <b>2. Manufacturer's address:</b>    | ul. Puławska 38, 05-500 Piaseczno, Polska   |
| <b>3. Product:</b>                   | Medical masks   |
| <b>4. Types / models / versions:</b> | TYPE II Unsterile with an elastic band  |
| <b>5. Product class:</b>             | I, Rule 1   |
| <b>6. Intended use:</b>              | Respiratory protection (mouth, nose) against drip-borne infections and during medical procedures for respiratory protection |
| <b>7. Shelf life:</b>                | 6 months from the date of production  |



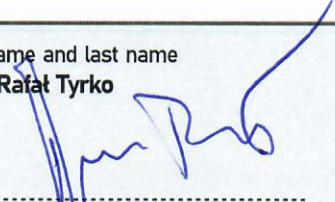
- 8. Scope of the declaration:** The product mentioned in this declaration complies with the essential requirements of Annex I to Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amendment of Directive 2001/83 / EC No. 1223/2009 and repealing Council Directives 90/385 / 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 products

- 9. Compliance with the requirements has been confirmed by the product manufacturer.**  
**10. 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. We declare that the manufactured product to which this declaration relates is consistent with the reference documents.

Place and date of issue:  
Piaseczno, 30.04.2020

First name and last name  
**Rafał Tyrko**  
  
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CEO  
(signature)



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