



## EU DECLARATION OF CONFORMITY

**Manufacturer:** Toruńskie Zakłady Materiałów Opatrunkowych S.A. (TZMO SA)  
**Manufacturer address:** ul. Żółkiewskiego 20/26, Toruń, 87-100, Poland  
**SRN number:** PL-MF-000002200

Product name	Types/models	Version	BASIC UDI-DI code
Surgimask Medical face masks type II	with ties, with elastic strips; sizes: Medium, Large	non sterile	5900516AACXXXXRM

**Risk class and classification rule:** I/1

**Product application :** Products are intended to block the transmission of particles emitted outside, contamination with exfoliated epidermis and hair. They are used to limit the transmission of infectious agents from healthcare professionals, using the masks, to patients during surgical procedures in operating and outpatient rooms, and as protection against splashes.

**UMDNS code:** 12458

**Applied standards:** PN-EN ISO 13485:2016; PN-EN ISO 62366-1:2015; PN-EN ISO 14971:2020  
PN-EN ISO 15223-1:2017; PN EN ISO 1041+A1:2013; PN-EN 14683+AC:2019  
PN-EN ISO 10993-1:2010

We declare, under our sole responsibility, that the medical devices described in the declaration bearing the CE marking comply with the requirements of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices (MDR) as amended. The declaration has been drawn up on the basis of the requirements in Annex IV of this Regulation.

TZMO SA has a certified quality management system, in accordance with the requirements of the standards: ISO 9001:2015, certificate number PL008673/P (issued by Bureau Veritas Polska Sp. z o.o.) and ISO 13485:2016, certificate number 283504-2019-AQ-POL-FINAS (issued by DNV GL Business Assurance Finland Oy Ab).

Toruń, 24.05.2021

***Tomasz Przybylski***

Deputy Director for Production and Innovation,  
TZMO SA

acting as representative of Toruńskie Zakłady  
Materiałów Opatrunkowych S.A.

/qualified electronic signature/

***Rafał Budzyński***

Plenipotentiary of the President of the Management Board for  
Production and Innovation, TZMO SA

acting as representative of Toruńskie Zakłady Materiałów  
Opatrunkowych S.A.

/qualified electronic signature/

This is a legal evidence of all created e-signatures and e-seals

Document ID: ba8378ac-2712-4b03-87d9-3620ff746c54  
created at: 2021-05-26 06:15 (GMT+02:00)

