



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
Ambulex P Examination and disposable protective gloves	powder free, sizes: XS (code: MA-144-XS00-006), S (code: MA-144-S000-006), M (code: MA-144-M000-006), L (code: MA-144-L000-006), XL (code: MA-144-XL00-006)	non sterile	5900516AAKXXXXUD

Risk class and classification rule: I/1

Product application : Products reduce the risk of infection during the study and treatment and contact with contaminated medical material.

UMDNS code: 11882

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 455-1:2020
PN-EN 455-2:2015; PN-EN 455-3:2015; PN-EN 455-4:2010; PN-EN ISO 21420:2020
PN-EN ISO 374-1:2017; PN-EN ISO 374-5:2017 PN-EN ISO 10993-1:2010
PN-EN ISO 10993-5:2009 PN-EN ISO 10993-10:2010

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.

The above mentioned product is in conformity with the provisions of PPE Regulation (EU) 2016/425 and is the subject of EC certificate of conformity No VN620 143495, Additum 19, issued by: ÖTI – Institut für Ökologie, Technik und Innovation GmbH, Spengergasse 20, 1050 Vienna, Austria (0534).



This is a category III product (according to Regulation (EU) 2016/425 of the European Parliament and of the Council on personal protective equipment).

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, 20.05.2021

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: ffad374e-26db-4db2-b85d-42d04f7e8f30
created at: 2021-05-21 16:18 (GMT+02:00)

