

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	BASIC UDI-DI code
SENI FIX SOFT Elastic supporting briefs	medium (M), large (L), x-large (XL) 2x-large (2XL)	5900516AATXXXXXG

Risk class and classification rule: I/1

Product application : Products are designed for fixing anatomically shaped pads and insert by people with urine and/ or faecal incontinence.

UMDNS code: 12111

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-ISO 10993-1:2010;
PN-EN 10993-5:2009; PN-EN 10993-10:2015

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, 11.06.2021

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: 45796abc-1e24-4c8b-8f29-8dc01267024a
created at: 2021-06-11 13:08 (GMT+02:00)