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	Product application
SENI MAN Incontinence pads for men	Light Level 1, Normal Level 2	5900516AARXXXXWS	Products are designed for people with very light, light and moderate incontinence.
SENI MAN Incontinence pads for men	Extra Level 3, Extra Plus Level 4, Super Level 5	5900516AASXXXXX5	Products are designed for people with light and moderate incontinence.

Risk class and classification rule: I/1

EMDN code: T04010102

Applied standards: PN-EN ISO 13485:2016, PN-EN ISO 15223-1:2022, PN-EN 62366-1:2015, PN-EN ISO 10993-1:2021, PN-EN ISO 10993-5:2009, PN-EN ISO 14971:2020, PN-EN ISO 20417:2021

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 and ISO 13485:2016.

Toruń, 24.08.2022

Tomasz Przybylski

Proxy TZMO SA
Deputy Director for Production and Innovation, TZMO SA

/qualified electronic signature/

Piotr Kowalski

Member of the Board TZMO SA
CFO, TZMO SA

/qualified electronic signature/

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Tomasz Przybylski

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