

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
Risk class and classification rule:	I/1
UMDNS code/EMDN code:	11239/ T04010103
Applied standards:	PN-EN ISO 13485:2016; PN-EN ISO 14971:2020; PN-EN ISO 15223-1:2022; PN-EN ISO 20417:2021; PN-EN 62366-1:2015; PN-EN ISO 10993-1:2021; PN-EN ISO 10993-5:2009

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.

Product name	Types/models	BASIC UDI-DI code	Product application
SENI ACTIVE BASIC Elastic disposable underwear	medium (M), large (L), extra large (XL)	5900516AAUXXXXXT	Products are designed for people with moderate incontinence.
SENI ACTIVE CLASSIC Elastic disposable underwear	small (S), medium (M), large (L), extra large (XL)	5900516AAUXXXXXT	Products are designed for people with moderate and heavy urinary incontinence.
SENI ACTIVE CLASSIC HE Elastic disposable underwear	medium (M), large (L), extra large (XL)	5900516AAUXXXXXT	Products are designed for people with moderate urinary incontinence.
SENI ACTIVE Elastic disposable underwear	small (S), medium (M), large (L), extra large (XL)	5900516AAUXXXXXT	Products are designed for people with moderate and heavy urinary incontinence.
SENI ACTIVE NORMAL Elastic disposable underwear	small (S), medium (M), large (L), extra large (XL)	5900516AAUXXXXXT	Products are designed for people with moderate urinary incontinence.
SENI ACTIVE PLUS Elastic disposable underwear	small (S), medium (M), large (L), extra large (XL), extra extra large (XXL)	5900516AAUXXXXXT	Products are designed for people with heavy urinary incontinence.
SENI ACTIVE SUPER Elastic disposable underwear	small (S), medium (M), large (L), extra large (XL)	5900516AAUXXXXXT	Products are designed for people with moderate and heavy urinary incontinence.
SENI ACTIVE TRIO Elastic disposable underwear	medium (M), large (L), extra large (XL)	5900516AAUXXXXXT	Products are designed for people with heavy incontinence.

Toruń, 13.05.2022




Tomasz Przybylski

Piotr Kowalski

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

Member of the Board TZMO SA
CFO, TZMO SA

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