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/T04010102
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 SAN Anatomically shaped pads	prima, normal, uni, regular, maxi, plus, regular extra, plus extra	5900516AASXXXXX5	Products are designed for incontinence protection.
SENI SAN for MEN Anatomically shaped pads for men	-	5900516AASXXXXX5	Products are designed for men with heavy incontinence.
SENI SAN ALVI Anatomically shaped pads for faecal incontinence	-	5900516AASXXXXX5	Products are designed for faecal incontinence and for catheterised people.

Toruń, 07.12.2022

Jolanta Kruszyńska

Plenipotentiary to Chairman of the Board for Quality Management, TZMO SA

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

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JOLANTA KRUSZYŃSKA

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