



## **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 SMART SAN Anatomically shaped pads with a sensor		normal, uni, regular, maxi, plus	5900516AASXXXXX5
Risk class and classification rule:	I/1		
Product application:	Products are design	ed for incontinence protection.	
EMDN code:	T04010102		
Applied standards:		016; PN-EN ISO 15223-1:2022; PN 2021; PN-EN ISO 10993-5:2009; I 021	-

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, 23.05.2024

Jolanta Iningriske

Jolanta Kruszyńska

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

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

/qualified electronic signature/

## **SIGNATURES & SEALS**



## this is legal evidence of all created e-signatures and e-seals

Certificate for a document with an Autenti ID: 6d4ee07e-2f86-46bf-b8ef-75f4db7347d1 created at: 2024-05-23 09:32 (GMT+02:00)

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The service is provided by Autenti, a limited liability company, located in Poznań at ul. Święty Marcin 29/8, registered in the District Court Poznań - Nowe Miasto and Wilda in Poznań, 8th Commercial Division of the National Court Register under the number KRS: 0000436998, Tax Identification Number: PL7831693251, share capital: PLN 6 811 700,00.