



## **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 LADY Bladder control pads	SUPER NIGHT	5900516AARXXXXWS

Risk class and 1/1

classification rule:

**Product application:** Products are designed for incontinence protection, dedicated to night time.

**EMDN code:** T04010102

**Applied standards:** PN-EN ISO 13485:2016; PN-EN 62366-1:2015; PN-EN ISO 14971:2020;

PN-EN ISO 15223-1:2022; PN-EN ISO 20417:2021; 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.

Toruń, 27.03.2024

Jolanta Kruszyńska

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

Jolanta Emnysiske

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

/qualified electronic signature/

TZMO-DoC-EN-Seni-I-10.2022 1/1

## **SIGNATURES & SEALS**



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

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