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 SUPER All-in-one diapers for adults	extra small (XS), small (S), medium (M), large (L), extra large (XL)	5900516AAVXXXXY6
SENI SUPER PLUS All-in-one diapers for adults	extra small (XS), small (S), medium (M), large (L), extra large (XL), extra extra large (XXL)	5900516AAVXXXXY6
SENI SUPER TRIO All-in-one diapers for adults	small (S), medium (M), large (L), extra large (XL)	5900516AAVXXXXY6
SENI SUPER QUATRO All-in-one diapers for adults	small (S), medium (M), large (L), extra large (XL)	5900516AAVXXXXY6

Risk class and classification rule: I/1

Product application: Products are designed for people with urinary and/ or faecal incontinence.

EMDN code: T04010103

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, 16.07.2024

Jolanta Kruszyńska

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/

Document ID: 735c7bcc-6dbe-401d-8a16-70d7d55fb7f4 (1/2)

Heruntergeladen von Gast (IP 216.73.217.12) am 09.11.2026 um 09:44 Uhr · sana.swiss

SIGNATURES & SEALS

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

Certificate for a document with an Autenti ID: 735c7bcc-6dbe-401d-8a16-70d7d55fb7f4
created at: 2024-07-16 08:37 (GMT+02:00)

The document sent for signature by Toruńskie Zakłady Materiałów Opatrunkowych S.A. anna.sobocinska@tzmo-global.com is secured with an electronic seal, protecting it against any changes.

2024-07-16 08:37 (GMT+02:00)

JOLANTA KRUSZYŃSKA

Qualified electronic signature

Authentication: QSCD

Reason: Document signing

PNOPL-68062405304

IP address: 195.66.68.36

2024-07-16 09:07 (GMT+02:00)

Electronic signatures, the authenticity and integrity of the document after signing have been secured with an electronic seal

2024-07-16 09:07 (GMT+02:00)

This document certifies that electronic signatures have been created.

Each signatory signed the document electronically in accordance with the Autenti Terms and Conditions (available at: https://autenti.com/en/terms) and has declared the correctness and truthfulness of the data provided for identification purposes. Signers have been authenticated in terms of the data contained in the electronic signature.

The service has been provided in accordance with the Regulation (EU) No 910/2014 of the European Parliament and of the Council of 23 July 2014 on electronic identification and trust services for electronic transactions in the internal market and repealing Directive 1999/93/EC.

Heruntergeladen von Gast (IP 216.73.217.12) am 09.11.2026 um 09:44 Uhr · sana.swiss