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/

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