



## 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**

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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