

## 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 |
|---------------------------------------|---|-------------------|
| SUPER SENI PLUS<br>All-in-one diapers | extra small (XS), small (S), medium (M), large (L), extra large (XL), extra extra large (XXL) | 5900516AAVXXXXY6  |

**Risk class and classification rule:** I/1  
**Product application :** Products are for people with urinary and /or faecal incontinence.  
**UMDNS code:** 11239  
**Applied standards:** PN-EN ISO 13485:2016; PN-EN ISO 62366-1:2015; PN-EN ISO 14971:2020  
ISO 15223-1:2021; PN EN ISO 1041+A1:2013; PN-EN-ISO 10993-1:2010;  
PN-EN 10993-5:20009; PN-EN 10993-10:2015

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, certificate number PL008673/1/P (issued by Bureau Veritas Polska Sp. z o.o.) and ISO 13485:2016, certificate number 283504-2019-AQ-POL-FINAS (issued by DNV GL Business Assurance Finland Oy Ab).

Toruń, 16.07.2021



**Tomasz Przybylski**

Deputy Director for Production and Innovation,  
TZMO SA

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

/qualified electronic signature/



**Rafał Budzyński**

Plenipotentiary of the President of the Management Board for  
Production and Innovation, TZMO SA

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

/qualified electronic signature/

This is a legal evidence of all created e-signatures and e-seals

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