

## 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 ACTIVE PLUS<br>Elastic disposable underwear | small (S), medium (M), large (L), extra large (XL),<br>extra extra large (XXL) | 5900516AAUXXXXXT  |

**Risk class and classification rule:** I/1

**Product application :** Products are designed for people with moderate and heavy urinary incontinence.

**UMDNS code:** 11239

**Applied standards:** PN-EN ISO 13485:2016; PN-EN ISO 62366-1:2015; PN-EN ISO 14971:2020  
PN-EN ISO 15223-1:2017; PN EN ISO 1041+A1:2013; PN-EN-ISO 10993-1:2010;  
PN-EN 10993-5:2009; 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/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, 17.05.2021

***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/

poświadczenie złożenia podpisów i pieczęci elektronicznych

Certyfikat dla dokumentu o Autenti ID: 3b005ec3-5a1b-484c-846b-a836557f3203  
utworzonego: 2021-05-17 10:04 (GMT+02:00)