

## 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 SOFT SUPER DRY<br>Hygienic underpads | 90x60 cm     | 5900516AAXXXXXYU  |

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

**Product application :** Products are used as additional protection for people with incontinence problems and during care treatment

**UMDNS code:** 12110

**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, 05.05.2021

***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: 9574c617-3008-4a6c-9abf-c6fb0201051c  
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