

## 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 LADY SLIM Bladder control pads | MICRO, MICRO PLUS, MINI, MINI PLUS, NORMAL, EXTRA | 5900516AARXXXWS   |

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

**Product application:** Products are designed for incontinence protection.

**EMDN code:** T04010102

**Applied standards:** PN-EN ISO 13485:2016; PN-EN ISO 14971:2020; PN-EN ISO 15223-1:2022; PN-EN ISO 20417:2021; PN-EN 62366-1:2015; PN-EN ISO 10993-1:2021; PN-EN ISO 10993-5:2009

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, 12.06.2023



**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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