

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 CONTROL Bladder control pads	mini, normal, extra, super, plus, plus extra	5900516AARXXXWS

Risk class and classification rule: I/1

Product application: Products are designed for people with incontinence problem.

UMDNS code/ EMDN code: 16498/ 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, 24.08.2022



Tomasz Przybylski

Proxy TZMO SA
Deputy Director for Production and Innovation, TZMO SA

/qualified electronic signature/



Piotr Kowalski

Member of the Board TZMO SA
CFO, TZMO SA

/qualified electronic signature/

this is legal evidence of all created e-signatures and e-seals

Certificate for a document with an Autenti ID: 5ce203f5-9a41-4353-acdd-9c687188c2dd
created at: 2022-08-24 13:33 (GMT+02:00)

