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 SAN CLASSIC Anatomically shaped pads	normal, uni, maxi, plus	5900516AASXXXXX5

Risk class and classification rule: I/1

Product application : Products are designed for incontinence protection.

UMDNS code: 11239

Applied standards: PN-EN ISO 13485:2016; PN-EN 62366-1:2015; PN-EN ISO 14971:2020
PN-EN ISO 15223-1:2017; PN-EN ISO 20417:2021; 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, 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, 07.12.2021

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/

Document ID: 67d2db17-fd17-409f-bcbe-30413bdf0ce0 (1/2)

SIGNATURES & SEALS

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

Certificate for a document with an Autenti ID: 67d2db17-fd17-409f-bcbe-30413bdf0ce0
created at: 2021-12-07 13:28 (GMT+01:00)

The document sent for signature by Toruńskie Zakłady Materiałów Opatrunkowych S.A. anna.sobocinska@tzmo-global.com is secured with an electronic seal, protecting it against any changes.

2021-12-07 13:28 (GMT+01:00)

Tomasz Przybylski

Qualified electronic signature

Authentication: QSCD
Reason: Document signing
PNOPL-75121413839

IP address: 195.66.68.246

2021-12-08 08:11 (GMT+01:00)

Piotr Kowalski

Qualified electronic signature

Authentication: QSCD
Reason: Document signing
PNOPL-71031609850

IP address: 195.66.68.36

2021-12-08 12:40 (GMT+01:00)

Electronic signatures, the authenticity and integrity of the document after signing have been secured with an electronic seal

2021-12-08 12:40 (GMT+01:00)

This document certifies that electronic signatures have been created.

Each signatory signed the document electronically in accordance with the Autenti Terms and Conditions (available at: https://autenti.com/en/terms) and has declared the correctness and truthfulness of the data provided for identification purposes. Signers have been authenticated in terms of the data contained in the electronic signature.

The service has been provided in accordance with the Regulation (EU) No 910/2014 of the European Parliament and of the Council of 23 July 2014 on electronic identification and trust services for electronic transactions in the internal market and repealing Directive 1999/93/EC.