

EC DECLARATION OF CONFORMITY

Manufacturer: Toruńskie Zakłady Materiałów Opatrunkowych S.A. (TZMO S.A.)

Address: Toruń, ul. Żółkiewskiego 20/26, POLAND

Product: **SENI LADY**
ANATOMICALLY SHAPED BLADDER CONTROL PADS

Type/model/version: micro, mini, mini plus, normal, extra, extra plus, super, plus

Classification: I

Scope: the above mentioned product conforms to the Essential Requirements of Council Directive 93/42/EEC concerning Medical Devices (date of issue: 14.06.1993 with further amendments).

The above mentioned product conforms to the following harmonised standards:

PN EN ISO 15223-1:2017

PN EN ISO 14971:2012

PN EN 1041+A1:2013

PN EN ISO 13485:2016

TZMO S.A. is registered to ISO 9001:2015, certificate No PL008673/P (issued by Bureau Veritas Polska Sp. z o.o.) and ISO 13485:2016, certificate No 283504-2019-AQ-POL-FINAS (issued by DNV GL Business Assurance Finland Oy Ab).

Toruń, March 15th 2019
(place and date of issue)



(signature)

Tomasz Przybylski
(full name)

Proxy TZMO SA
(position)



(signature)

Agnieszka Górna
(full name)

Member of the Board TZMO SA
(position)