

EC DECLARATION OF CONFORMITY

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

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

Product: **SUPER SENI, SUPER SENI PLUS, SUPER SENI TRIO, SUPER SENI QUATRO**
ALL-INE-ONE DIAPERS

Type/model/version: SUPER SENI, SUPER SENI PLUS: extra small (XS), small (S), medium (M), large (L), extra large (XL), extra extra large (XXL).
SUPER SENI TRIO, SUPER SENI QUATRO: extra small (XS), small (S), medium (M), large (L), extra large (XL).

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

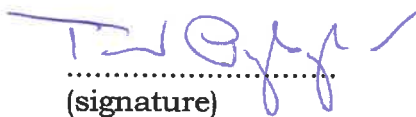
PN EN 1041+A1:2013

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, February 21st 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)