



EC DECLARATION OF CONFORMITY

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

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

Product: *MATODRESS patient gown, surgical shirt, delivery dress; non sterile*

Types/models/versions: surgical shirt - sizes: XS, S, M, L, XL, XXL, XXXL, UNIVERSAL; height: 158-164; 164-170; 170-176; 182-188; 194-200
patient gown – sizes: XS, S, M, L, XL, XXL, XXXL, universal, 54-98, 104-128, 132-146, 150-156, 158-164, 164-170, 170-176, 182-188, 194-200
delivery dress - sizes: XS/S, S/M, L/XL, XXL/XXXL

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 harmonized standards:

PN EN ISO 15223-1:2017

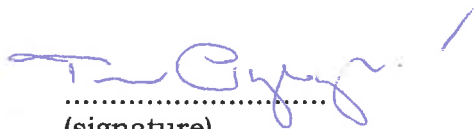
PN EN 1041+A1:2013

PN EN ISO 13485:2016

PN EN ISO 14971:2012

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, January 15th 2020
(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)