



EC DECLARATION OF CONFORMITY

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

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

Product: *MATOSSET INSTRUMENT surgical scissors, sterile*

Types/models/versions: length from 90mm to 300mm,
straight or curved scissors: sharp/sharp, sharp/blunt; blunt/blunt (with blunt tip)

Classification: II a

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).

Notified Body: Conformity assessments have been carried out in accordance with Annex VII and Annex V of Directive 93/42 / EEC. The above mentioned products are covered under the CE Mark certificate No TNP/MDD/0230/4722/2018-001 (Annex V of Directive 93/42/EEC), issued by TUV NORD Polska Sp. z o.o., (2274).

The above mentioned product conforms to the following harmonized standards:

PN EN 556-1:2002	PN EN ISO 14971:2012
PN EN ISO 15223-1:2017	PN EN ISO 11737-1:2018
PN EN 1041+A1:2013	PN EN ISO 13485:2016
PN EN ISO 10993-1:2010	PN EN ISO 11737-2:2010
PN EN ISO 10993-7:2009	PN EN ISO 11607-1:2017
PN EN ISO 11135:2014	PN EN ISO 11607-2:2017

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)