EC DECLARATION OF CONFORMITY

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

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

Product: ***MATOSET INSTRUMENT anatomical forceps, sterile***

Types/models/versions: length from 80mm to 500mm

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)

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(signature)

Tomasz Przybylski
(full name)

Proxy TZMO SA
(position)

.....
(signature)

Agnieszka Górna
(full name)

Member of the Board TZMO SA
(position)