



EC DECLARATION OF CONFORMITY

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

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

Product: *SURGIMASK medical face masks type II non sterile*

Classification: I

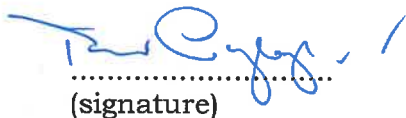
Scope: the above mentioned product conforms to the Essential Requirements of Council Directive 93/42/EEC concerning Medical Devices (date of issue: 14.06.1993 with further amendments).

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 14683+AC:2019
PN EN ISO 14971:2012
PN EN ISO 10993-1:2010
PN EN 62366-1:2015

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, May 28th 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)