



EC DECLARATION OF CONFORMITY

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

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

Product: *BOM*

Gusseted paper – film pouches for sterilization

Flat paper – film pouches for sterilization

Gusseted paper – film reels for sterilization

Flat paper – film reels for sterilization

Paper – film adhesive pouches for sterilization

Types/models/versions: with or without chemical indicators of the sterilization process; in sizes:
reels – width from 50mm to 650 mm and length from 60m to 200m;
pouches – width from 40mm to 600mm and length from 90mm to 1200mm

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 14971:2012

PN EN ISO 11607-1:2017

PN EN ISO 11607-2:2017

PN EN ISO 13485:2016

PN EN ISO 11140-1:2015

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, July 1st 2020
(place and date of issue)

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(signature)

Tomasz Przybylski
(full name)

Proxy TZMO SA
(position)

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(signature)

Agnieszka Górna
(full name)

Member of the Board TZMO SA
(position)