



EC DECLARATION OF CONFORMITY

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

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

Product: *Examination gloves, non sterile*
AMBULEX VINYL

Types/models/versions: powdered or powder free; sizes: XS, S, M, L, XL

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 later amendments).

The above mentioned product conforms to the following harmonised standards:

PN EN 455-1:2004
PN EN 455-2:2011
PN EN 455-3:2007
PN EN 455-4:2010
PN EN ISO 15223-1:2017
PN EN 1041+A1:2013
PN EN ISO 14971:2012
PN EN ISO 10993-1:2010
PN EN ISO 10993-5:2009

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)