



## 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 21<sup>st</sup> 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)