



www.tzmo-global.com

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 NITRYL

Types/models/versions: powder free; sizes:
XS (code: MA-144-XS00-018),
S (code: MA-144-S000-018),
M (code: MA-144-M000-018),
L (code: MA-144-L000-018),
XL (code: MA-144-XL00-018)

Classification: **class I (according to Medical Device Directive 93/42/EEC),**
category III (according to Regulation (EU) 2016/425 of the European
Parliament and of the Council on personal protective equipment)

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 is in conformity with the provisions of PPE Regulation (EU) 2016/425 and is the subject of EC certificate of conformity No 2777/11464-01/E14-01, issued by: SATRA Technology Europe Limited, Bracetown Business Park, Clonee, D15YN2P, Republic of Ireland (2777).

The above mentioned product conforms to the following harmonised standards:

PN EN 455-1:2004	PN EN 1041+A1:2013	PN EN ISO 10993-1:2010
PN EN 455-2:2015	PN EN ISO 14971:2012	PN EN ISO 10993-5:2009
PN EN 455-3:2015	PN EN 420+A1:2012	
PN EN 455-4:2010	PN EN ISO 374-1:2017	
PN EN ISO 15223-1:2017	PN EN ISO 374-5:2017	

TZMO S.A. is registered to ISO 9001:2015, certificate No PL008673/P and ISO 13485:2016, certificate No 283504-2019-AQ-POL-FINAS.

Toruń, June 8th 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)