



## EC DECLARATION OF CONFORMITY

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

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

**Product:** *PLASTOFILM transparent microporous adhesive tape*  
*PLASTOFIX nonwoven adhesive tape*  
*PLASTOPORE hypoallergic nonwoven adhesive tape*  
*PLASTOSILK hypoallergic silk adhesive tape*  
*PLASTOVIS textile adhesive tape*

**Type/model/version:** PLASTOFILM: sizes: length: 5m; 9,14m; width: 1,25cm, 2,5cm and 5cm  
PLASTOFIX: sizes: length 10m; width: 2,5cm, 5cm, 10cm, 15cm, 20cm, 30cm  
PLASTOPORE: sizes: length: 5m; 9,14m; width: 1,25cm, 2,5cm and 5cm  
PLASTOSILK: sizes: length: 5m; 9,14m; width: 1,25cm, 2,5cm and 5cm  
PLASTOVIS: sizes: length: 5m; 9,14m; width: 1,25cm, 2,5cm and 5cm

**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 harmonised standards:

PN EN ISO 15223-1:2017

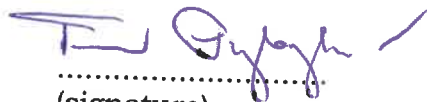
PN EN ISO 13485:2016

PN EN ISO 14971:2012

PN EN 1041+A1:2013

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)