



## DECLARATION OF CONFORMITY

**Supplier:** Toruńskie Zakłady Materiałów Opatrunkowych SA  
**Address:** Toruń, ul. Żółkiewskiego 20/26, POLAND  
**Product:** **ALL-IN-ONE DIAPERS**  
**SENI STANDARD, SENI STANDARD PLUS – extra small, small, medium, large, extra large**

**Classification:** I

**Scope:** the above mentioned product conforms to the Essential Requirements listed in Annex I of Council Directive 93/42/EEC concerning Medical Devices ( date of issue: 14.06.1993).

The above mentioned product conforms to the following harmonised standards:

EN 980:2003  
EN 1041:1998  
EN ISO 14971:2000

The supplier TZMO S.A. is registered to ISO 9001:2008, certificate No PL9000267/D and ISO 13485:2003, certificate No PL9000268.

**Toruń, January 18<sup>th</sup> 2010**  
(place and date of issue)

.....  
(signature)

Arkadiusz Zawisza  
( full name )

Vice General Manager  
(position)

.....  
(signature)

Sławomir Pełczyński  
( full name )

Member of the Management Board  
(position)