

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 18th 2010
(place and date of issue)



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(signature)

Arkadiusz Zawisza
(full name)

Vice General Manager
(position)



.....
(signature)

Sławomir Pełczyński
(full name)

Member of the Management Board
(position)