

EC DECLARATION OF CONFORMITY

Manufacturer:

JJW Spółka Jawna J. Karpiński, J. Rudnicki, W. Lewin

Plac Zgody 6

05-520 Konstancin-Jeziorna

declares that the medical device, described as follows:

Prophylactic medical socks

in varieties – commercial names:

DeoMed® COTTON

Medic Deo® COTTON

DeoMed® BAMBOO

Medic Deo® LONG

DeoMed® BAMBOO LONG

SILVER SeaCell®

classified into class I according to the rule 1 of the regulation of the Health Ministry, dated November 5, 2010, on the classification of medical devices (Gazette of the Acts, No 215 of 2010, item. 1416) complies with the essential requirements of the Council Directive 93/42/EEC, implemented to the legal system of Poland by the Act of May 20, 2010 on medical devices (Journal of Laws No. 107 of 2010, item. 679) and harmonized standards:

EN 980:2008

[PN-EN 980:2010] Symbols for use in the marking of medical devices

EN ISO 15223-1:2012

[PN-EN ISO 15223-1:2012] Medical devices - Symbols to be used in the labeling of medical devices, in their marking, and in information provided to them - Part 1: General requirements

EN 1041:2008+A1:2013

[PN-EN 1041+A1:2013-12] Information supplied by the manufacturer of medical devices

EN ISO 14971:2012

[PN-EN ISO 14971:2012] Medical products. Application of risk management to medical devices.

and manufacturer standards:

ZN-JJW-W-001:2011 MEDIC DEO COTTON socks – the manufacturing process

ZN-JJW-W-002:2011 DEOMED COTTON socks - the manufacturing process

ZN-JJW-W-005:2011 DEOMED BAMBOO socks - the manufacturing process

ZN-JJW-W-006:2011 SILVER SEACELL socks - the manufacturing process

ZN-JJW-W-007:2011 MEDIC DEO LONG knee socks - the manufacturing process

ZN-JJW-W-008:2012 DEOMED BAMBOO LONG knee socks - the manufacturing process

Conformity assessment was carried out in accordance with the requirements of the Council Directive 93/42/EEC, Annex VII.

Janusz Karpiński



Jerzy Rudnicki



Włodzimierz Lewin



Konstancin-Jeziorna, March 16, 2015