

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 product, described as follows:

Prophylactic medical socks

Varieties:

MedicDeo® COTTON

MedicDeo® LONG

DeoMed® COTTON

DeoMed® BAMBOO LONG

DeoMed® BAMBOO

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 products (Gazette of the Acts, No 215 of 2010, item. 1416) complies with the essential requirements of the Council Directive 93/42/EEC, amended by the Directive 2007/47/EC of the Council and the Parliament, implemented to the legal system of Poland by the Act of May 20, 2010 on medical products (Journal of Laws No. 107 of 2010, item. 679) and harmonized standards:

PN-EN 980:2010

Symbols for use in the marking of medical products

PN-EN 1041:2010

Information supplied by the manufacturer of medical products

PN-EN ISO 14971:2012

Medical products. Application of risk management to medical products.

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 Council Directive 93/42/EEC amended by Parliament and Council Directive 2007/47/EC, Annex VII.

Janusz Karpiński

Jerzy Rudnicki

Włodzimierz Lewin

Konstancin-Jeziorna, September 25, 2013

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Place and date

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Name, position and signature