EC DECLARATION OF CONFORMITY

Manufacturer:

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

Plac Zgody 6

05-520 Konstancin-Jeziorna, Poland

declares that the medical product, described as follows:

Prophylactic medical socks DEOMED WOOL

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 with later changes) and harmonized standards:

EN 980:2008	[PN-EN 980:2010] Symbols for use in the marking of medical products
EN 1041:2008+A1:2013	[PN-EN 1041+A1:2013-12] Information supplied by the manufacturer of medical products
EN ISO 14971:2012	[PN-EN ISO 14971:2012] Medical products. Application of risk management to medical products.
EN ISO 15223-1:2016	[PN-EN ISO 15223-1:2017-02] Medical devices - Symbols to be applied on the labeling of medical devices, their marking and with the information provided with them - Part 1: General requirements

and manufacturer standard

ZN-JJW-W-011:2017 DEOMED WOOL 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, 17.10.2017

Place, date