REH4MAT
MANUFACTURER OF MODERN ORTHOPAEDIC BRACES

DECLARATION OF CONFORMITY

COMPANY
REH4MAT

DECLARES

that product:

LOWER-EXTREMITY SUPPORT

MODEL: EB-SK/A; AM-OSK-Z/S-A; AM-OSK-ZJ/3; EB-SK/1R; EB-SKL/3; AM-OSK-OL/3; EB-SKL/2RA; EB-SKL/2RA-ACL; AM-KD-AM/1RE; AM-KD-AM/1RE-03; AM-KD-AM/2RA-03; AM-KDS-AM/1RE; AS-SK/A; EB-SK/2; EB-SK/2RA; AM-OSK-Z/2RA-OR; AM-OSK-ZL/3; AM-KD-AM/3-03; EB-SKL/1R; AM-OSK-ZL/2RA-ACL; AM-KD-AM/1RE-ACL; AM-KDS-AM/1RE-02; AM-KD-AM/2R-03

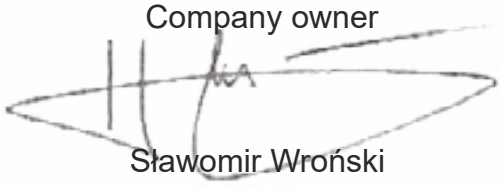
is in conformity with Council Directive 93/42 / EEC of 14 June 1993 concerning medical devices and harmonized with its standards:

PN-EN 1041+A1:2013-12	Information supplied by the manufacturer of medical devices
PN-EN 12182:2012	Assistive products for persons with disability. General requirements and test methods
PN-EN ISO 13485:2012	Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes
PN-EN ISO 14971:2012	Medical devices. Application of risk management to medical devices
PN-EN ISO 15223-1:2012	Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. General requirements

and with the Act of Law of 20 May 2010 on Medical Devices
(Dz. U. 2010 nr 107 poz 679)

THIS DECLARATION HAS BEEN ISSUED ON THE RESPONSIBILITY
OF THE COMPANY REH4MAT, 36-060 Głogów Małopolski, ul. Piaski 47.

Company owner



Sławomir Wroński

Głogów Małopolski., 12.10.2016