

DECLARATION OF CONFORMITY

COMPANY REH4MAT

DECLARES

that product:

LOWER BACK BRACE

MODEL: AM-SO-01; AM-SO-02; AM-SO-03; AM-SO-04; AM-SO-05 AM-SO-06

marked with the CE sign is Class I medical device, of rule 1, consistent with the requirements of the Council Directive 93/42 / EEC of 14 June 1993 on medical devices and the Law of 20 MayN2010 on medical devises (Journal of Laws of 2015, No. 876, as amended). Conformity assessment was carried out on the basis of the VII Council Directive 93/42 /EEC.

The product meets the requirements of the harmonized standards:

PN-EN 1041+A1:2013-12 PN-EN 12182:2012	Information supplied by the manufacturer of medical devices 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 device
PN-EN ISO 15223-1:2017-02	Medical devices Symbols to be used with medical device labels,labelling and information to be supplied - Part 1:General requirements
THIS DECLARATION HAS BEEN ISSUED ON THE RESPONSIBILITY OF THE COMPANY REH4MAT, 36-060 Głogów Małopolski, ul. Piaski 47.	
	Company owner
	- the

17/D/EN/1

Sławomir Wroński