

DECLARATION OF CONFORMITY

No. 45/D/EN/1

COMPANY
REH4MAT
DECLARES

that product:

WRIST ORTHOSIS

LIST OF ITEMS IN APPENDIX NO.1

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 May 2010 on medical devices (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	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 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, POLAND

Country of origin: **POLAND**

Company owner



Sławomir Wroński

APPENDIX NO. 1

TO DECLARATION OF CONFORMITY NO. 45/D/EN/1

PRODUCT:

WRIST ORTHOSIS

MODEL:

WRIST ORTHOSIS AM-DON-01
WRIST ORTHOSIS AS-N-02
WRIST ORTHOSIS AM-OSN-U-03
WRIST ORTHOSIS AM-OSN-U-04
WRIST ORTHOSIS AM-OSN-U-05
WRIST ORTHOSIS AM-SN-LM
WRIST ORTHOSIS AM-OSN-L-03
WRIST ORTHOSIS AM-OSN-L-04
WRIST ORTHOSIS AM-SN-02
WRIST ORTHOSIS AS-NX-01
WRIST ORTHOSIS AS-NX-02
WRIST ORTHOSIS MS-N-01
WRIST ORTHOSIS MS-N-02
EB-N
EB-N-01
EB-N-02
U-SN
AM-OSN-U-01
AM-OSN-U-02
AM-OSN-L-01
AM-OSN-L-02
AM-SDP-K-01
AM-SDP-K-02
AM-SN-01
AS-N
AS-N-01
WRIST ORTHOSIS AM-OSN-U-06
WRIST ORTHOSIS AM-OSN-U-07
WRIST ORTHOSIS AM-OSN-U-08
WRIST ORTHOSIS AM-OSN-U-09
WRIST ORTHOSIS AM-OSN-U-10
WRIST ORTHOSIS AM-OSN-U-11
WRIST ORTHOSIS AM-OSN-U-12
WRIST ORTHOSIS AM-OSN-U-13
WRIST ORTHOSIS AM-OSN-U-14
WRIST ORTHOSIS AM-OSN-U-15
WRIST ORTHOSIS AM-OSN-L-05
WRIST ORTHOSIS AM-OSN-L-06
WRIST ORTHOSIS AM-OSN-L-07
WRIST ORTHOSIS AM-OSN-L-08
WRIST ORTHOSIS AM-OSN-L-09
WRIST ORTHOSIS AM-OSN-L-10

Company owner


Sławomir Wroński