

DECLARATION OF CONFORMITY EC

No. 47/D/EN/3

MANUFACTURER

REH4MAT

PRODUCT

MATTRESS

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** 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 13485:2016

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 MANUFACTURER

REH4MAT, 36-060 Głogów Małopolski, ul. Piaski 47, Poland



reh:mat **COMPANY OWNER**

Sławomir Wronski

APPENDIX NO. 1

To declaration of conformity no. 47/D/EN/3

PRODUCT:

MATTRESS

MODELS:

MATTRESS NP-FF-01
MATTRESS NP-FF-02
MATTRESS NP-FF-03
MATTRESS NP-VM-B/B
MATTRESS NP-VM-Z/B
MATTRESS NP-VM-Z/Z
MATTRESS MS-OB-B/B
MATTRESS MS-OB-Z/B
MATTRESS MS-OB-Z/Z
MATTRESS MP-PU-D-B/B
MATTRESS MP-PU-D-Z/B
MATTRESS MP-PU-D-Z/Z
MATTRESS MP-VM-D-B/B
MATTRESS MP-VM-D-Z/B
MATTRESS MP-VM-D-Z/Z
MATTRESS MP-VM-Z/Z
MATTRESS MP-VM-B/B
MATTRESS MP-VM-Z/B
MATTRESS MP-MB-Z/Z
MATTRESS MP-MB-B/B
MATTRESS MP-MB-Z/B
MATTRESS MP-MB-N/F
MATTRESS MP-VM-N/F
MATTRESS MP-VM-D-N/F
MATTRESS MP-PU-D-N/F
MATTRESS NP-VM-N/F
MATTRESS MP-MB
MATTRESS MP-VM
MATTRESS MP-VM-D
MATTRESS MP-PU-D
MATTRESS MS-OB
MATTRESS NP-VM



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