

DECLARATION OF CONFORMITY

COMPANY REH4MAT DECLARES

that product:

MATTRESS

MODEL: MATTRESS MP-MB-Z/Z; MATTRESS MP-MB-Z/B; MATTRESS MP-MB-B/B; MATTRESS MP-VM-Z/Z; MATTRESS MP-VM-Z/B; MATTRESS MP-VM-B/B; MATTRESS MP-VM-D-Z/Z; MATTRESS MP-VM-D-Z/B; MATTRESS MP-VM-D-B/B; MATTRESS MP-PU-D-Z/Z; MATTRESS MP-PU-D-Z/B; MATTRESS MP-PU-D-B/B; MATTRESS MS-OB-Z/Z; MATTRESS MS-OB-Z/B; MATTRESS MS-OB-B/B; MATTRESS NP-VM-Z/Z; MATTRESS NP-VM-Z/B; MATTRESS NP-VM-B/B; MATTRESS NP-FF-01; MATTRESS NP-FF-02; MATTRESS NP-FF-03

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 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 15223-1:2017-02 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.

Sławomir Wroński

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