DECLARATION OF CONFORMITY EC

No. 48/D/EN/3

MANUFACTURER

REH4MAT

PRODUCT

CUSHION

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

QUALITY SYSTEM CERTIFICATION DNV·GL ISO 13485

COMPANY OWNER
Sławomir Wroński

Głogów Małopolski 27.09.2019

APPENDIX NO. 1

To declaration of conformity no. 48/D/EN/3

PRODUCT:
CUSHION

MODELS:
CUSHION KO-PU-B
CUSHION KW-PU-01
CUSHION PP-FF-02
CUSHION PP-FF-03
CUSHION PP-VM-Z
CUSHION PP-VM-B
CUSHION PA-VM-04
CUSHION PA-VM-05
CUSHION PA-VM-06
CUSHION PA-VM-07
CUSHION PA-FF-01
CUSHION PP-FF-01
CUSHION PA-VM-08
CUSHION PA-VM-09
CUSHION PA-VM-10
CUSHION PA-VM-11
CUSHION PA-VM-12
CUSHION PA-VM-13
CUSHION PA-VM-14
CUSHION PA-VM-15
CUSHION PA-VM-01
CUSHION PA-VM-02
CUSHION PA-VM-03

QUALITY SYSTEM CERTIFICATION DNV·GL ISO 13485

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Sławomir Wroński

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