

DECLARATION OF CONFORMITY EC

No. 48/D/EN/5

THE REH4MAT MANUFACTURER DECLARES THAT

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 Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.

Conformity assessment was carried out in accordance with the requirements of the Regulation (EU) 2017/745 of the European Parliament and of the Council.

In order to demonstrate the safety and effectiveness of the medical device, the following standards were used to assess conformity:

PN-EN 1041+A1:2013-12

Information provided by the producer together with the medical product.

PN-EN 12182:2012

Assistive products for persons with disability - General requirements and research methods.

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.

PN-EN ISO 13485:2016

Medical products - Quality management systems - Requirements for law regulations aims.

PN-EN ISO 14971:2020

Medical devices - Application of risk management to medical devices.

THIS DECLARATION HAS BEEN ISSUED ON THE RESPONSIBILITY
OF THE MANUFACTURER

REH4MAT, 36-060 Głogów Małopolski, ul. Piaski 47, Poland
SINGLE REGISTRATION NUMBER (SRN): PL-MF-000009271


re4mat COMPANY OWNER
Sławomir Wroński

APPENDIX NO. 1

To declaration of conformity no. 48/D/EN/5

PRODUCT: CUSION

MODELS:

CUSHION KO-PU-B (Basic UDI-DI 590128913KO-PU-BF5);
CUSHION KW-PU-01 (Basic UDI-DI 590128913KW-PU-01T5);
CUSHION PP-FF-02 (Basic UDI-DI 590128913PP-FF-02KQ);
CUSHION PP-FF-03 (Basic UDI-DI 59009497PP-FF-03TM);
CUSHION PP-VM-Z (Basic UDI-DI 59009497PP-VM-ZV2);
CUSHION PP-VM-B (Basic UDI-DI 59009497PP-VM-BTJ);
CUSHION PA-VM-04 (Basic UDI-DI 59009497PA-VM-04SR);
CUSHION PA-VM-05 (Basic UDI-DI 59009497PA-VM-05ST);
CUSHION PA-VM-06 (Basic UDI-DI 59009497PA-VM-06SV);
CUSHION PA-VM-07 (Basic UDI-DI 59009497PA-VM-07SX);
CUSHION PA-FF-01 (Basic UDI-DI 59009497PA-FF-01KJ);
CUSHION PP-FF-01 (Basic UDI-DI 59009497PP-FF-01TH);
CUSHION PA-VM-08 (Basic UDI-DI 59009497PA-VM-08SZ);
CUSHION PA-VM-09 (Basic UDI-DI 59009497PA-VM-09T3);
CUSHION PA-VM-10 (Basic UDI-DI 59009497PA-VM-10SL);
CUSHION PA-VM-11 (Basic UDI-DI 59009497PA-VM-11SN);
CUSHION PA-VM-12 (Basic UDI-DI 59009497PA-VM-12SQ);
CUSHION PA-VM-13 (Basic UDI-DI 59009497PA-VM-13SS);
CUSHION PA-VM-14 (Basic UDI-DI 59009497PA-VM-14SU);
CUSHION PA-VM-15 (Basic UDI-DI 59009497PA-VM-15SW);
CUSHION PA-VM-01 (Basic UDI-DI 59009497PA-VM-01SK);
CUSHION PA-VM-02 (Basic UDI-DI 59009497PA-VM-02SM);
CUSHION PA-VM-03 (Basic UDI-DI 59009497PA-VM-03SP).