

DECLARATION OF CONFORMITY EC

No. 67/D/EN/5

THE REH4MAT MANUFACTURER DECLARES THAT

PRODUCT: POSTURAL DYNAMIC SUPPORT PRODUCTS FlexPoint

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


COMPANY OWNER
Sławomir Wroński

APPENDIX NO. 1

To declaration of conformity no. 67/D/EN/5

PRODUCT: POSTURAL DYNAMIC SUPPORT PRODUCTS FlexPoint

MODELS:

FP-01 (Basic UDI-DI 59009497FP-01HY);	FP-33 (Basic UDI-DI 59009497FP-33JD);
FP-02 (Basic UDI-DI 59009497FP-02J2);	FP-34 (Basic UDI-DI 59009497FP-34JF);
FP-03 (Basic UDI-DI 59009497FP-03J4);	FP-35 (Basic UDI-DI 59009497FP-35JH);
FP-04 (Basic UDI-DI 59009497FP-04J6);	FP-36 (Basic UDI-DI 59009497FP-36JK);
FP-05 (Basic UDI-DI 59009497FP-05J8);	FP-37 (Basic UDI-DI 59009497FP-37JM);
FP-06 (Basic UDI-DI 59009497FP-06JA);	FP-38 (Basic UDI-DI 59009497FP-38JP);
FP-07 (Basic UDI-DI 59009497FP-07JC);	FP-39 (Basic UDI-DI 59009497FP-39JR);
FP-08 (Basic UDI-DI 59009497FP-08JE);	FP-40 (Basic UDI-DI 59009497FP-40JA);
FP-09 (Basic UDI-DI 59009497FP-09JG);	FP-41 (Basic UDI-DI 59009497FP-41JC);
FP-10 (Basic UDI-DI 59009497FP-10HZ);	FP-42 (Basic UDI-DI 59009497FP-42JE);
FP-11 (Basic UDI-DI 59009497FP-11J3);	FP-43 (Basic UDI-DI 59009497FP-43JG);
FP-12 (Basic UDI-DI 59009497FP-12J5);	FP-44 (Basic UDI-DI 59009497FP-44JJ);
FP-13 (Basic UDI-DI 59009497FP-13J7);	FP-45 (Basic UDI-DI 59009497FP-45JL);
FP-14 (Basic UDI-DI 59009497FP-14J9);	FP-46 (Basic UDI-DI 59009497FP-46JN);
FP-15 (Basic UDI-DI 59009497FP-15JB);	FP-47 (Basic UDI-DI 59009497FP-47JQ);
FP-16 (Basic UDI-DI 59009497FP-16JD);	FP-48 (Basic UDI-DI 59009497FP-48JS);
FP-17 (Basic UDI-DI 59009497FP-17JF);	
FP-18 (Basic UDI-DI 59009497FP-18JH);	
FP-19 (Basic UDI-DI 59009497FP-19JK);	
FP-20 (Basic UDI-DI 59009497FP-20J4);	
FP-21 (Basic UDI-DI 59009497FP-21J6);	
FP-22 (Basic UDI-DI 59009497FP-22J8);	
FP-23 (Basic UDI-DI 59009497FP-23JA);	
FP-24 (Basic UDI-DI 59009497FP-24JC);	
FP-25 (Basic UDI-DI 59009497FP-25JE);	
FP-26 (Basic UDI-DI 59009497FP-26JG);	
FP-27 (Basic UDI-DI 59009497FP-27JJ);	
FP-28 (Basic UDI-DI 59009497FP-28JL);	
FP-29 (Basic UDI-DI 59009497FP-29JN);	
FP-30 (Basic UDI-DI 59009497FP-30J7);	
FP-31 (Basic UDI-DI 59009497FP-31J9);	
FP-32 (Basic UDI-DI 59009497FP-32JB);	


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