

DECLARATION

OF EC CONFORMITY

MANUFACTURER REH4MAT LTD. DECLARE, THAT
PRODUCT: POSTURAL DYNAMIC SUPPORT PRODUCTS FlexPoint
LIST OF ITEMS IN APPENDIX NO. 1

of intended use: stabilization of upper the upper body, pelvis, upper and lower limbs while sitting.

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.

The above product to which this declaration applies complies with Regulation (EU) 2017/745 of the European Parliament and of the Council.

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 ISO 20417:2021-10

Medical devices -- Information to be supplied by the manufacturer.

PN-EN ISO 21856:2023-01

Assistive products -- General requirements and test methods.

PN-EN ISO 15223-1:2022-01

Medical devices -- Symbols to be used with information to be supplied by the manufacturer
-- Part 1: General requirements.

PN-EN ISO 13485:2016-04

Medical devices -- Quality management systems -- Requirements for regulatory purposes.

PN-EN ISO 14971:2020-05

Medical devices -- Application of risk management to medical devices.



President of the board
A handwritten signature in black ink, appearing to read 'Sławomir Wroński'.
Sławomir Wroński

THE ABOVE CERTIFICATE WAS ISSUED ON SOLE RESPONSIBILITY OF
REH4MAT LTD., 35-301 RZESZÓW, UL. ZENITOWA 5A,
COUNTRY OF ORIGIN: POLAND, SRN: PL-MF-000009271

APPENDIX NO. 1

TO DECLARATION OF CONFORMITY

PRODUCT - POSTURAL DYNAMIC SUPPORT PRODUCTS FlexPoint

MODELS:

FP-01	(Basic UDI-DI 59009497FP-01HY),	FP-36	(Basic UDI-DI 59009497FP-36JK),
FP-02	(Basic UDI-DI 59009497FP-02J2),	FP-37	(Basic UDI-DI 59009497FP-37JM),
FP-03	(Basic UDI-DI 59009497FP-03J4),	FP-38	(Basic UDI-DI 59009497FP-38JP),
FP-04	(Basic UDI-DI 59009497FP-04J6),	FP-39	(Basic UDI-DI 59009497FP-39JR),
FP-05	(Basic UDI-DI 59009497FP-05J8),	FP-40	(Basic UDI-DI 59009497FP-40JA),
FP-06	(Basic UDI-DI 59009497FP-06JA),	FP-41	(Basic UDI-DI 59009497FP-41JC),
FP-07	(Basic UDI-DI 59009497FP-07JC),	FP-42	(Basic UDI-DI 59009497FP-42JE),
FP-08	(Basic UDI-DI 59009497FP-08JE),	FP-43	(Basic UDI-DI 59009497FP-43JG),
FP-09	(Basic UDI-DI 59009497FP-09JG),	FP-44	(Basic UDI-DI 59009497FP-44JJ),
FP-10	(Basic UDI-DI 59009497FP-10HZ),	FP-45	(Basic UDI-DI 59009497FP-45JL),
FP-11	(Basic UDI-DI 59009497FP-11J3),	FP-46	(Basic UDI-DI 59009497FP-46JN),
FP-12	(Basic UDI-DI 59009497FP-12J5),	FP-47	(Basic UDI-DI 59009497FP-47JQ),
FP-13	(Basic UDI-DI 59009497FP-13J7),	FP-48	(Basic UDI-DI 59009497FP-48JS),
FP-14	(Basic UDI-DI 59009497FP-14J9),	FP-49	(Basic UDI-DI 59009497FP-49JU),
FP-15	(Basic UDI-DI 59009497FP-15JB),	FP-50	(Basic UDI-DI 59009497FP-50JD),
FP-16	(Basic UDI-DI 59009497FP-16JD),		
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),		
FP-33	(Basic UDI-DI 59009497FP-33JD),		
FP-34	(Basic UDI-DI 59009497FP-34JF),		
FP-35	(Basic UDI-DI 59009497FP-35JH),		



President of the board

Sławomir Wroński

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