

DECLARATION

OF EC CONFORMITY

MANUFACTURER REH4MAT LTD. DECLARE, THAT
PRODUCT: POSTURAL COMPRESION ORTHOSES
LIST OF ITEMS IN APPENDIX NO. 1

of intended use: provide dynamic compression and muscles control with pediatric neurologic disorders.

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

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

Rzeszów, 27.03.2024 No. 84/D/EN/7 page 1/2

APPENDIX NO. 1

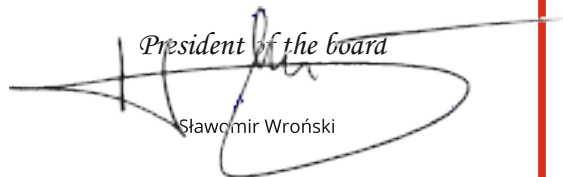
TO DECLARATION OF CONFORMITY

PRODUCT - POSTURAL COMPRESSION ORTHOSES

MODELS:

PCO-T-01	(Basic UDI-DI 59009497PCO-T-01UT),	PCO-L-07	(Basic UDI-DI 59009497PCO-L-07TF),
PCO-T-02	(Basic UDI-DI 59009497PCO-T-02UV),	PCO-L-08	(Basic UDI-DI 59009497PCO-L-08TH),
PCO-T-03	(Basic UDI-DI 59009497PCO-T-03UX),	PCO-L-09	(Basic UDI-DI 59009497PCO-L-09TK),
PCO-T-04	(Basic UDI-DI 59009497PCO-T-04UZ),	PCO-L-10	(Basic UDI-DI 59009497PCO-L-10T4),
PCO-T-05	(Basic UDI-DI 59009497PCO-T-05V3),	PCO-L-11	(Basic UDI-DI 59009497PCO-L-11T6),
PCO-T-06	(Basic UDI-DI 59009497PCO-T-06V5),	PCO-L-12	(Basic UDI-DI 59009497PCO-L-12T8),
PCO-T-07	(Basic UDI-DI 59009497PCO-T-07V7),	PCO-L-13	(Basic UDI-DI 59009497PCO-L-13TA),
PCO-T-08	(Basic UDI-DI 59009497PCO-T-08V9),	PCO-L-14	(Basic UDI-DI 59009497PCO-L-14TC),
PCO-T-09	(Basic UDI-DI 59009497PCO-T-09VB),	PCO-L-15	(Basic UDI-DI 59009497PCO-L-15TE),
PCO-T-10	(Basic UDI-DI 59009497PCO-T-10UU),	PCO-L-16	(Basic UDI-DI 59009497PCO-L-16TG),
PCO-T-11	(Basic UDI-DI 59009497PCO-T-11UW),	PCO-L-17	(Basic UDI-DI 59009497PCO-L-17TJ),
PCO-T-12	(Basic UDI-DI 59009497PCO-T-12UY),	PCO-L-18	(Basic UDI-DI 59009497PCO-L-18TL),
PCO-T-13	(Basic UDI-DI 59009497PCO-T-13V2),	PCO-A-01	(Basic UDI-DI 59009497PCO-A-01QN),
PCO-T-14	(Basic UDI-DI 59009497PCO-T-14V4),	PCO-A-02	(Basic UDI-DI 59009497PCO-A-02QQ),
PCO-T-15	(Basic UDI-DI 59009497PCO-T-15V6),	PCO-A-03	(Basic UDI-DI 59009497PCO-A-03QS),
PCO-T-16	(Basic UDI-DI 59009497PCO-T-16V8),	PCO-A-04	(Basic UDI-DI 59009497PCO-A-04QU),
PCO-T-17	(Basic UDI-DI 59009497PCO-T-17VA),	PCO-A-05	(Basic UDI-DI 59009497PCO-A-05QW),
PCO-T-18	(Basic UDI-DI 59009497PCO-T-18VC),	PCO-A-06	(Basic UDI-DI 59009497PCO-A-06QY),
PCO-T-19	(Basic UDI-DI 59009497PCO-T-19VE),	PCO-A-07	(Basic UDI-DI 59009497PCO-A-07R2),
PCO-T-20	(Basic UDI-DI 59009497PCO-T-20UX),	PCO-A-08	(Basic UDI-DI 59009497PCO-A-08R4),
PCO-T-21	(Basic UDI-DI 59009497PCO-T-21UZ),	PCO-A-09	(Basic UDI-DI 59009497PCO-A-09R6),
PCO-T-22	(Basic UDI-DI 59009497PCO-T-22V3),	PCO-A-10	(Basic UDI-DI 59009497PCO-A-10QP),
PCO-T-23	(Basic UDI-DI 59009497PCO-T-23V5),	PCO-H-01	(Basic UDI-DI 59009497PCO-H-01S7),
PCO-T-24	(Basic UDI-DI 59009497PCO-T-24V7),		
PCO-T-25	(Basic UDI-DI 59009497PCO-T-25V9),		
PCO-T-26	(Basic UDI-DI 59009497PCO-T-26VB),		
PCO-T-27	(Basic UDI-DI 59009497PCO-T-27VD),		
PCO-T-28	(Basic UDI-DI 59009497PCO-T-28VF),		
PCO-T-29	(Basic UDI-DI 59009497PCO-T-29VH),		
PCO-L-01	(Basic UDI-DI 59009497PCO-L-01T3),		
PCO-L-02	(Basic UDI-DI 59009497PCO-L-02T5),		
PCO-L-03	(Basic UDI-DI 59009497PCO-L-03T7),		
PCO-L-04	(Basic UDI-DI 59009497PCO-L-04T9),		
PCO-L-05	(Basic UDI-DI 59009497PCO-L-05TB),		
PCO-L-06	(Basic UDI-DI 59009497PCO-L-06TD),		



President of the board

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