

DECLARATION

OF EC CONFORMITY

MANUFACTURER REH4MAT LTD. DECLARE, THAT
PRODUCT: UPPER - EXTREMITY SUPPORT
LIST OF ITEMS IN APPENDIX NO. 1

of intended use: provides stabilization and relief of upper limb. It is used in case of painful syndrome and/or injuries of upper extremity.

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 - UPPER - EXTREMITY SUPPORT
MODELS:

OKG-17	(Basic UDI-DI 59009497OKG-17LZ),	OKG-51	(Basic UDI-DI 59009497OKG-51LZ),
OKG-18	(Basic UDI-DI 59009497OKG-18M3),	OKG-52	(Basic UDI-DI 59009497OKG-52M3),
OKG-19	(Basic UDI-DI 59009497OKG-19M5),	OKG-53	(Basic UDI-DI 59009497OKG-53M5),
OKG-20	(Basic UDI-DI 59009497OKG-20LN),	OKG-54	(Basic UDI-DI 59009497OKG-54M7),
OKG-21	(Basic UDI-DI 59009497OKG-21LQ),	OKG-55	(Basic UDI-DI 59009497OKG-55M9),
OKG-22	(Basic UDI-DI 59009497OKG-22LS),	OKG-56	(Basic UDI-DI 59009497OKG-56MB),
OKG-23	(Basic UDI-DI 59009497OKG-23LU),	OKG-57	(Basic UDI-DI 59009497OKG-57MD),
OKG-24	(Basic UDI-DI 59009497OKG-24LW),	OKG-58	(Basic UDI-DI 59009497OKG-58MF),
OKG-25	(Basic UDI-DI 59009497OKG-25LY),	OKG-59	(Basic UDI-DI 59009497OKG-59MH),
OKG-26	(Basic UDI-DI 59009497OKG-26M2),	OKG-60	(Basic UDI-DI 59009497OKG-60M2),
OKG-27	(Basic UDI-DI 59009497OKG-27M4),	OKG-61	(Basic UDI-DI 59009497OKG-61M4),
OKG-28	(Basic UDI-DI 59009497OKG-28M6),	OKG-62	(Basic UDI-DI 59009497OKG-62M6),
OKG-29	(Basic UDI-DI 59009497OKG-29M8),	OKG-63	(Basic UDI-DI 59009497OKG-63M8),
OKG-30	(Basic UDI-DI 59009497OKG-30LR),	OKG-64	(Basic UDI-DI 59009497OKG-64MA),
OKG-31	(Basic UDI-DI 59009497OKG-31LT),	OKG-65	(Basic UDI-DI 59009497OKG-65MC),
OKG-32	(Basic UDI-DI 59009497OKG-32LV),	OKG-66	(Basic UDI-DI 59009497OKG-66ME),
OKG-33	(Basic UDI-DI 59009497OKG-33LX),	OKG-67	(Basic UDI-DI 59009497OKG-67MG),
OKG-34	(Basic UDI-DI 59009497OKG-34LZ),	OKG-68	(Basic UDI-DI 59009497OKG-68MJ),
OKG-35	(Basic UDI-DI 59009497OKG-35M3),	OKG-69	(Basic UDI-DI 59009497OKG-69ML),
OKG-36	(Basic UDI-DI 59009497OKG-36M5),	OKG-70	(Basic UDI-DI 59009497OKG-70M5),
OKG-37	(Basic UDI-DI 59009497OKG-37M7),	OKG-71	(Basic UDI-DI 59009497OKG-71M7),
OKG-38	(Basic UDI-DI 59009497OKG-38M9),	OKG-72	(Basic UDI-DI 59009497OKG-72M9),
OKG-39	(Basic UDI-DI 59009497OKG-39MB),	OKG-73	(Basic UDI-DI 59009497OKG-73MB),
OKG-40	(Basic UDI-DI 59009497OKG-40LU),	OKG-74	(Basic UDI-DI 59009497OKG-74MD),
OKG-41	(Basic UDI-DI 59009497OKG-41LW),	OKG-75	(Basic UDI-DI 59009497OKG-75MF),
OKG-42	(Basic UDI-DI 59009497OKG-42LY),	OKG-76	(Basic UDI-DI 59009497OKG-76MH),
OKG-43	(Basic UDI-DI 59009497OKG-43M2),	OKG-77	(Basic UDI-DI 59009497OKG-77MK),
OKG-44	(Basic UDI-DI 59009497OKG-44M4),		
OKG-45	(Basic UDI-DI 59009497OKG-45M6),		
OKG-46	(Basic UDI-DI 59009497OKG-46M8),		
OKG-47	(Basic UDI-DI 59009497OKG-47MA),		
OKG-48	(Basic UDI-DI 59009497OKG-48MC),		
OKG-49	(Basic UDI-DI 59009497OKG-49ME),		
OKG-50	(Basic UDI-DI 59009497OKG-50LX),		



President of the board

Sławomir Wroński

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