



DECLARATION

OF EC CONFORMITY

MANUFACTURER REH4MAT LTD. DECLARE, THAT
PRODUCT: CERVICAL COLLAR
LIST OF ITEMS IN APPENDIX NO. 1

of intended use: stabilization and relief of cervical spine.

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.

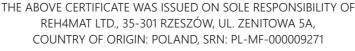
PN-EN ISO 14971:2020-05

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





President of the board
Sławomir Wroński













APPENDIX NO. 1 TO DECLARATION OF CONFORMITY

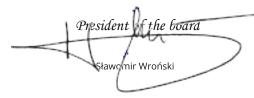
PRODUCT - CERVICAL COLLAR MODELS:

CERVICAL COLLAR AM-KOL-01
CERVICAL COLLAR AM-KOL-02
CERVICAL COLLAR AM-KOL-03
CERVICAL COLLAR AM-KOL-04
CERVICAL COLLAR AM-KOL-05
CERVICAL COLLAR 4ARMY-KOL-01
CERVICAL COLLAR 4ARMY-KOL-02
CERVICAL COLLAR 4ARMY-KOL-03
CERVICAL COLLAR 4ARMY-KOL-04
CERVICAL COLLAR 4ARMY-KOL-04
CERVICAL COLLAR 4ARMY-KOL-05
CERVICAL COLLAR 4ARMY-KOL-05

(Basic UDI-DI 59009497AM-KOL-01ZS), (Basic UDI-DI 59009497AM-KOL-02ZU), (Basic UDI-DI 59009497AM-KOL-03ZW), (Basic UDI-DI 59009497AM-KOL-0423), (Basic UDI-DI 59009497AM-KOL-0525), (Basic UDI-DI 590094974ARMY-KOL-015E), (Basic UDI-DI 590094974ARMY-KOL-035J), (Basic UDI-DI 590094974ARMY-KOL-045L), (Basic UDI-DI 590094974ARMY-KOL-055N), (Basic UDI-DI 590094974ARMY-KOL-055N),









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. 62/D/EN/8 page 2/2

