DECLARATION OF CONFORMITY

FOR PRODUCTS MANUFACTURED

FROM JANUARY 2024.

DECLARATION

OF EC CONFORMITY

MANUFACTURER REH4MAT LTD. DECLARE, THAT
PRODUCT: UPPER - EXTREMITY SUPPORT
MODELS: AM-AO-KG-02 CLEVER 2 ROTATOR (Basic UDI-DI 59009497AM-AO-KG-01C2RM4),
AM-AO-KG-02 CLEVER 2 ABDUCTOR (Basic UDI-DI 59009497AM-AO-KG-01C2AL2),
AM-OSN-U-01/CCA (Basic UDI-DI 59009497AM-OSN-U-01/CCAF6),
AM-SOB-03/AIR (Basic UDI-DI 59009497AM-SOB-03/AIR8D),

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.

REH4MAT
MANUFACTURER OF MODERN ORTHOPAEDIC BRACES

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

Rzeszów, 08.01.2024 No. 95/D/EN/5

DECLARATION OF CONFORMITY

FOR PRODUCTS MANUFACTURED
BY THE END OF DECEMBER 2023.

DECLARATION

OF EC CONFORMITY

MANUFACTURER REH4MAT SŁAWOMIR WROŃSKI DECLARE, THAT
PRODUCT: UPPER - EXTREMITY SUPPORT
MODELS: AM-AO-KG-02 CLEVER 2 ROTATOR (Basic UDI-DI 59009497AM-AO-KG-01C2RM4),
AM-AO-KG-02 CLEVER 2 ABDUCTOR (Basic UDI-DI 59009497AM-AO-KG-01C2AL2),
AM-OSN-U-01/CCA (Basic UDI-DI 59009497AM-OSN-U-01/CCAF6),
AM-SOB-03/AIR (Basic UDI-DI 59009497AM-SOB-03/AIR8D),

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.

REH4MAT
MANUFACTURER OF MODERN ORTHOPAEDIC BRACES

rehmat
COMPANY OWNER
Sławomir Wroński

THE ABOVE CERTIFICATE WAS ISSUED ON SOLE RESPONSIBILITY OF
REH4MAT SŁAWOMIR WROŃSKI, 36-060 GŁOGÓW MAŁOPOLSKI, UL. PIASKI 47,
COUNTRY OF ORIGIN: POLAND, (SRN): PL-MF-000009271

Głogów Małopolski, 19.07.2023r. No. 95/D/EN/4