DECLARATION OF CONFORMITY EC

No. 83/D/EN/3

MANUFACTURER

REH4MAT

PRODUCT

UPPER-EXTREMITY SUPPORT

MODEL: OKG-17, OKG-18, OKG-19, OKG-20, OKG-21, OKG-22, OKG-23, OKG-24, OKG-25, OKG-26, OKG-27, OKG-28, OKG-29, OKG-30, OKG-31, OKG-32, OKG-33, OKG-34, OKG-35, OKG-36, OKG-37, OKG-38, OKG-39, OKG-40, OKG-41, OKG-42, OKG-43, OKG-44, OKG-45, OKG-46, OKG-47, OKG-48, OKG-49, OKG-50, OKG-51, OKG-52, OKG-53, OKG-54, OKG-55, OKG-56, OKG-57, OKG-58, OKG-59, OKG-60, OKG-61, OKG-62, OKG-63, OKG-64, OKG-65, OKG-66, OKG-67, OKG-68, OKG-69, OKG-70, OKG-71, OKG-72, OKG-73, OKG-74, OKG-75, OKG-76, OKG-77

marked with the CE sign is Class I medical device, of rule 1, consistent with the requirements of the **Council Directive 93/42/EEC of 14 June 1993 on medical devices** and the **Law of 20 May 2010 on medical devices** as amended. Conformity assessment was carried out on the basis of the **VII Council Directive 93/42/EEC**.

The product meets the requirements of the harmonized standards

PN-EN 1041+A1:2013-12

Information supplied by the manufacturer of medical devices

PN-EN 12182:2012

Assistive products for persons with disability. General requirements and test methods

PN-EN ISO 13485:2016

Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes

PN-EN ISO 14971:2012

Medical devices. Application of risk management to medical device

PN - EN ISO 15223-1:2017-02

Medical devices Symbols to be used with medical device labels, labelling and information to be supplied - Part 1:General requirements

THIS DECLARATION HAS BEEN ISSUED ON THE RESPONSIBILITY OF THE MANUFACTURER

REH4MAT, 36-060 Głogów Małopolski, ul. Piaski 47, Poland

QUALITY SYSTEM CERTIFICATION DNV·GL ISO 13485

COMPANY OWNER

Sławomir Wroński

Głogów Małopolski 27.09.2019