DECLARATION OF CONFORMITY EC

No. 82/D/EN/3

MANUFACTURER

REH4MAT

PRODUCT

LOWER-EXTREMITY SUPPORT

MODEL: OKD-31, OKD-32, OKD-33, OKD-34, OKD-35, OKD-36, OKD-37, OKD-38, OKD-39, OKD-40, OKD-41, OKD-42, OKD-43, OKD-44, OKD-45, OKD-46, OKD-47, OKD-48, OKD-49, OKD-50, OKD-51, OKD-52, OKD-53, OKD-54, OKD-55, OKD-56, OKD-57, OKD-58, OKD-59, OKD-60, OKD-61, OKD-62, OKD-63, OKD-64, OKD-65, OKD-66, OKD-67, OKD-68, OKD-69, OKD-70, OKD-71, OKD-72, OKD-73, OKD-74, OKD-75, OKD-76, OKD-77, OKD-78, OKD-79, OKD-80, OKD-81, OKD-82, OKD-83, OKD-84, OKD-85, OKD-86, OKD-87, OKD-88, OKD-89, OKD-90

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