DECLARATION OF CONFORMITY EC

No. 81/D/EN/3

MANUFACTURER

REH4MAT

PRODUCT

TORSO SUPPORT

MODEL: OT-11,OT-12, OT-13, OT-14, OT-15, OT-16, OT-17, OT-18, OT-19, OT-20, OT-21, OT-22, OT-23, OT-24, OT-25, OT-26, OT-27, OT-28, OT-29, OT-30, OT-31, OT-32, OT-33, OT-34, OT-35, OT-36, OT-37, OT-38, OT-39, OT-40, OT-41, OT-42, OT-43, OT-44, OT-45, OT-46, OT-47, OT-48, OT-49, OT-50, OT-51, OT-52, OT-53, OT-54, OT-55, OT-56, OT-57, OT-58, OT-59, OT-60, OT-61, OT-62, OT-63, OT-64, OT-65, OT-66, OT-67, OT-68, OT-69, OT-70, OT-71, OT-72, OT-73, OT-74, OT-75, OT-76, OT-77, OT-78, OT-79, OT-80, OT-81, OT-82, OT-83, OT-84, OT-85, OT-86, OT-87, OT-88, OT-89, OT-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