DECLARATION OF CONFORMITY EC

No. 67/D/EN/3

MANUFACTURER

REH4MAT

PRODUCT

POSTURAL DYNAMIC SUPPORT PRODUCTS FlexPoint

MODEL: FP-01; FP-02; FP-03; FP-04; FP-05; FP-06; FP-07; FP-08; FP-09; FP-10; FP-11; FP-12; FP-13; FP-14; FP-15; FP-16; FP-17; FP-18; FP-19; FP-20; FP-21; FP-22; FP-23; FP-24; FP-25; FP-26; FP-27; FP-28; FP-29; FP-30; FP-31; FP-32; FP-33; FP-34; FP-35; FP-36; FP-37; FP-38; FP-39; FP-40; FP-41; FP-42; FP-43; FP-4; 4FP-45; FP-46; FP-47; FP-48; FP-49; FP-50

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