



EU DECLARATION OF CONFORMITY

Manufacturer

Ligatio Prosta Spółka Akcyjna

ul. Bonifarterska 17, 00-203 Warsaw, Poland

SRN: PL-MF-000045533

We hereby declare in our sole responsibility that the medical device:

Poliwater ORT

intended use: a device used as an orthosis, for stabilizing and immobilizing limbs

Basic UDI-DI: 5907419649PWTRORTGX

available in types and sizes [cm x cm]:

Forearm (XS) 4x20; Forearm (S) 5x25; Forearm (M) 6,5x29; Forearm (L) 7,5x30; Humeral (S) 5x40; Humeral (M) 6,5x50; Humeral (L) 7,5x55; Shin (S) 5,5x30x17*; Shin (M) 7x40x28*; Shin (L) 10x45x30*; Femoral (S) 5,5x45x18*; Femoral (M) 8x70x29*; Femoral (L) 10x90 x32*

* foot size

are in compliance with

REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC, according to Annex VIII, and were classified as class I rule 1.

Device meets the requirements of REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices.

Devices are manufactured in accordance with the requirements of standards for medical devices and relevant legal regulations.

List of standards used during the conformity assessment:

- PN-EN ISO 14971:2020-05 Medical devices — Application of risk management to medical devices,
- EN ISO 20417:2021 Medical devices — Information to be supplied by the manufacturer,
- PN-EN ISO 10993-1:2026-06 Biological evaluation of medical devices – Part 1: Assessment and testing in the risk management process,
- PN-EN ISO 15223-1:2017-02 Medical devices — Symbols to be used with information to be supplied by the manufacturer. Part 1: General requirements.

This declaration of conformity is issued under the sole responsibility of the manufacturer.

Warsaw, date 12.10.2026

Position and signature

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