CE EU DECLARATION OF CONFORMITY

Manufacturer

Ligatio Prosta Spółka Akcyjna

ul. Bonifraterska 17, 00-203 Warsaw, Poland

SRN: PL-MF-000045533

We hereby declare under 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]:

	UDI-DI Number
Forearm XS (4 cm x 20 cm)	05908102362390
Forearm S (5 cm x 25 cm)	05908102362222
Forearm M (6.5 cm x 29 cm)	05908102362666
Forearm L (7.5 cm x 30 cm)	05908102362246
Arm S (5 cm x 40 cm)	05908102362208
Arm M (6.5 cm x 50 cm)	05908102362192
Arm L (7.5 cm x 55 cm)	05908102362215
Shin S (5.5 cm x 30 cm x 17 cm*)	05908102362253
Shin M (7 cm x 40 cm x 28 cm*)	05908102362277
Shin L (10 cm x 45 cm x 30 cm*)	05908102362284
Thigh S (5.5 cm x 18 cm* x 45 cm)	05908102362710
Thigh M (8 cm x 29 cm* x 70 cm)	05908102362628
Thigh L (10 cm x 32 cm* x 90 cm)	05908102362635

* foot size

according to Annex VIII of 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, was classified as class I under rule 1.

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

The device is 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,
- PN-EN ISO 20417:2026-10 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 15223-1:2022-01 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 15.11.2026

Rafał Grabowski, President

Full name, position, signature, and stamp of the manufacturer

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