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

Basic UDI-DI: 5907419649OPTPWTREF

intended use: synthetic immobilizing dressing, available for lower and upper limbs for children and adults

	Size	UDI-DI Number
PRO - upper limb	5 cm x 25 cm	05908102362307
PRO - upper limb	5 cm x 35 cm	05908102362314
PRO - upper limb	5 cm x 45 cm	05908102362321
PRO - upper limb	5 cm x 60 cm	05908102362338
PRO - upper limb	7.5 cm x 25 cm	05908102362505
PRO - upper limb	7.5 cm x 35 cm	05908102362482
PRO - upper limb	7.5 cm x 40 cm	05908102362352
PRO - upper limb	7.5 cm x 70 cm	05908102362376
PRO - upper limb	10 cm x 35 cm	05908102362499
PRO - lower limb	5 cm x 45 cm	05908102362345
PRO - lower limb	7.5 cm x 55 cm	05908102362369
PRO - lower limb	7.5 cm x 90 cm	05908102362512
PRO - lower limb	10 cm x 50 cm	05908102362529
PRO - lower limb	10 cm x 55 cm	05908102362383
PRO - lower limb	10 cm x 60 cm	05908102362536
PRO - lower limb	10 cm x 75 cm	05908102362543
PRO - lower limb	10 cm x 90 cm	05908102362550
PRO - lower limb	12.5 cm x 55 cm	05908102362673
PRO - lower limb	12.5 cm x 65 cm	05908102362680
PRO - lower limb	12.5 cm x 90 cm	05908102362697

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.

Rafał Grabowski

Warsaw, date 15.11.2026

Rafał Grabowski, President

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

Ligatio Prosta Spółka Akcyjna
ul. Bonifarterska 17, 00-203 Warszawa
NIP: 1133139720
biuro@ligatio.group
+48 570 772 885