



EU DECLARATION OF CONFORMITY

Manufacturer

Ligatio P.S.A.

ul. Bonifraterska 17, 00-203 Warsaw, Poland

SRN: PL-MF-000045533

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

Poliwater

Basic UDI-DI: 59074196490PTPWTFREF

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

	SIZE	UDI-DI
Poliwater PRO	5cmx25cm	05907419649811
Poliwater PRO	5cmx35cm	05907419649804
Poliwater PRO	5cmx45cm	05907419649798
Poliwater PRO	5cmx60cm	05907419649781
Poliwater PRO	7,5cmx25cm	05907419649774
Poliwater PRO	7,5cmx35cm	05907419649767
Poliwater PRO	7,5cmx40cm	05907419649750
Poliwater PRO	7,5cmx55cm	05907419649743
Poliwater PRO	7,5cmx70cm	05907419649736
Poliwater PRO	7,5cmx90cm	05907419649729
Poliwater PRO	10cmx35cm	05907419649712
Poliwater PRO	10cmx50cm	05907419649705
Poliwater PRO	10cmx55cm	05907419649699
Poliwater PRO	10cmx60cm	05907419649682
Poliwater PRO	10cmx75cm	05907419649675

Poliwater PRO	10cmx90cm	05907419649668
Poliwater PRO	12,5cmx55cm	05907419649651
Poliwater PRO	12,5cmx65cm	05907419649644
Poliwater PRO	12,5cmx90cm	05907419649637

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.

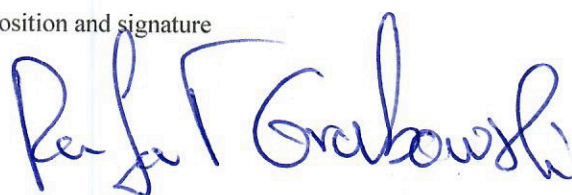
List of standards used during the conformity assessment:

- 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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