# EU Certificate

**Quality Management System**
**REGULATION (EU) 2017/745 on Medical Devices**
**Annex IX Chapter I, Section 2 and 3 and Chapter III**

| | |
|---|---|
| Registration No.: | HZ 2631342-1 |
| Manufacturer: | MARGOMED Spółka Akcyjna<br>ul. Erazma Plewińskiego 16<br>20-270 Lublin<br>Poland |
| EUDAMED Single Registration No.: | PL-MF-000009261 |
| Products: | Products of class I, sterile:<br>A02010203 – INFUSION AND IRRIGATION SYRINGES, CATHETER CONE, SINGLE-USE<br>The scope of certification is limited to the aspects relating to establishing, securing and maintaining sterile conditions.<br><br>Products of class I, with measuring function:<br>A02010203 – INFUSION AND IRRIGATION SYRINGES, CATHETER CONE, SINGLE-USE<br>V0380 – DEVICES WITH MEASURING FUNCTIONS - ACCESSORIES<br>The scope of certification is limited to the aspects relating to the conformity of the devices with the metrological requirements. |

Udostępniono firmie KD Consulting Sp. z o.o.

The Notified Body hereby declares that the requirements of Annex IX, Chapter I, Section 2 and 3 of the REGULATION (EU) 2017/745 have been met for the listed products. The above named manufacturer has established and applies a quality management system, which is subject to periodic surveillance, defined by Annex IX, Chapter I, Section 3 of the aforementioned regulation. The requirements of Annex IX, Chapter III are fulfilled.
If class III devices or class IIb implantable devices referred to in the second subparagraph of Article 52(4) are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 4.9 is required before placing them on the market.

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|---|---|
| Report No.: | 84979717-60 |
| Effective date: | 2025-04-25 |
| Expiry date: | 2030-04-24 |
| Issue date: | 2025-04-25 |

Małgorzata Błaźniak
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

This certificate can be validated on https://www.certipedia.com

TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/745 concerning medical devices with the identification number 0197.

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Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-091

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Products of class IIa:

A03040199 – INFUSION KITS (WITH OR W/O PUMP), SINGLE-USE - OTHER

A03020199 – EXTENSIONS - OTHER

A020199 – SYRINGES, SINGLE-USE - OTHER

Z121799 – BLOOD TRANSFUSION INSTRUMENTS – OTHER

Authorized representative(s): Not applicable

Udostępniono firmie KD Medical Polska Sp. z o.o.

| Certificate history | | |
|---|---|---|
| Revision: | Description: | Issue date: |
| 0 | Initial certification | 2025-04-25 |

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