

# EC-Certificate of Conformity

## The Notified Body

**MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH**  
**Pilatuspool 2 – 20355 Hamburg – Germany**

herewith confirms that the company

**RoweMed AG - Medical 4 Life**  
**Juri-Gagarin-Ring 4**  
**19370 Parchim**  
**Germany**

has introduced, applies and maintains a Quality Assurance System  
for the products / product categories:

**See Attachment 1**

The compliance of the Quality Assurance System with the below mentioned  
requirements of the **Council Directive 93/42/EEC** was verified by an audit:

**Annex II** excluding section 4

The license of certification is subject to surveillance by MEDCERT.

**This certificate is valid until: 20 August 2023**

Report No.: 2026FS20F  
Process No.: QS – 2026  
Certificate No.: 2026GB410181130

Hamburg, 30 November 2018

  
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MEDCERT Certification Body  
(Lorenz Runge)

MEDCERT Identification No.: 0482



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
www.zlg.de  
ZLG-BS-237.10.15

## Attachment 1 Certificate QS – 2026

This attachment is valid only in connection with certificate No.: 2026GB410181130

### Products:

- **Infusion Filters / Injection Filters**
- **Infusions Systems**
- **Injection Systems**
- **Transfusion Systems**
- **Tubing Systems for Infusion, Injection, Nutrition and Transfusion**
- **Tubing Systems for Angiography, Cardiology and Radiology**
- **Laserablation Sets**
- **Autologous Retransfusion Sets**
- **Tubing Sets / Dental Irrigation Tubings**
- **Irrigation and Suction Sets for Orthopaedics**
- **Urinary Bladder Puncture Set**

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**MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH**  
**Pilatuspool 2 – 20355 Hamburg – Germany**

herewith confirms that the company

**RoweMed AG - Medical 4 Life**  
**Juri-Gagarin-Ring 4**  
**19370 Parchim**  
**Germany**

has introduced, applies and maintains a Quality Assurance System for the aspects of manufacture **concerned with securing and maintaining sterile conditions** for the products / product categories:

- **Spikes**
- **Cover Foil**
- **Catheter Valves**
- **Hydrophobic Filters**
- **Transfer Systems**

The compliance of the Quality Assurance System with the below mentioned requirements of the **Council Directive 93/42/EEC** was verified by an audit:

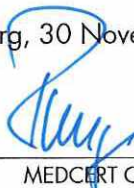
## Annex V

The license of certification is subject to surveillance by MEDCERT.

**This certificate is valid until: 20 August 2023**

Report No.: 2026FS20F  
Process No.: QS – 2026  
Certificate No.: 2026GB415181130

Hamburg, 30 November 2018



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