



**EU Quality Management System Certificate**  
**Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III**  
**Certificate No. MDR-0039**

Issued to: UTK Solution GmbH  
Sedanstrasse 16, 58507 Lüdenscheid  
Germany

SRN of the manufacturer: DE-MF-000013399

EU authorised representative: Not applicable

SRN of EU authorised  
representative: Not applicable

SIQ has audited the quality management system in accordance with MDR Annex IX and found that the above-mentioned Manufacturer's quality management system meets the requirements of the Regulation (EU) 2017/745 concerning medical devices Annex IX. Devices covered by the Manufacturer's quality management system are listed on the page(s) below.  
This certificate is based on

**Audit reports No.:**

OSV 00543/2023, 2023-05-31	OSV 00781/2024, 2024-06-28	OSV 00530/2025, 2025-04-30
OSV 00830/2023, 2023-08-07	OSV 00667/2024, 2024-08-19	OSV 00680/2025, 2025-05-27
OSV 01285/2023, 2023-12-21	OSV 01350/2024, 2024-10-22	OSV 00833/2025, 2025-06-19
OSV 00483/2024, 2024-04-15	OSV 00318/2025, 2025-03-28	OSV 00361/2025, 2025-03-31
OSV 00602/2024, 2024-04-30	OSV 00360/2025, 2025-03-31	OSV 00498/2026, 2026-04-13
OSV 00599/2024, 2024-05-09	OSV 00645/2025, 2025-05-27	

See also decision of NB's commission for medical devices.

This certificate remains valid as long as the Manufacturer's quality management system is subject to periodical surveillance as referred to in Regulation (EU) 2017/745 concerning medical devices Annex IX and continues to meet the above requirements.

**Reference to any previous certificate: /**

Certification date: 2026-04-13  
Issue: 01/ 2026-04-13  
Valid until: 2031-04-12



Managing Director of SIQ  
Gregor Schoss



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Device: Various devices not included in other classes – other  
EMDN: V9099  
Intended purpose: /  
Classification: IIa  
Specific conditions for or  
provisions or  
limitations to the  
validity of certificate: /

Certification date: 2026-04-13  
Issue: 01/ 2026-04-13  
Valid until: 2031-04-12



Managing Director of SIQ

Gregor Schoss