

# EU DECLARATION OF CONFORMITY

Declaration No.: 11-2026

**Manufacturer:** UTK Solution GmbH  
Sedanstr. 16  
58507 Lüdenscheid  
Germany

**Product Name:** BlueLavage®

**Product category:** Surgical rinsing and suction system

**Model / Type:** -

**Basis UDI-DI:** 426075025011211BL2D

**UDI DI:**

4260750250001	4260750250087	4260750250155	4260750250223	4260750250292
4260750250018	4260750250094	4260750250162	4260750250230	4260750250308
4260750250025	4260750250100	4260750250179	4260750250247	4260750250315
4260750250032	4260750250117	4260750250186	4260750250254	
4260750250049	4260750250124	4260750250193	4260750250261	
4260750250063	4260750250131	4260750250209	4260750250278	
4260750250070	4260750250148	4260750250216	4260750250285	

**Classification:** IIa (Annex VIII, Rule 12)

**SRN Number:** DE-MF-000013399

**EMDN Code:** V9099

**UTK SOLUTION HEREBY STATES, UNDER ITS SOLE RESPONSIBILITY, THAT ABOVE MENTIONED PRODUCT(S) COMPLY(IES) WITH THE GENERAL SAFETY AND PERFORMANCE REQUIREMENTS OF MEDICAL DEVICE REGULATION 2017/745.**

**The product was a subject of conformity assessment procedure described in Annex IX (Full quality assurance system).**

**Standards applied:**

EN ISO 13485:2021	EN ISO 11135: 2019
EN ISO 14971:2019	EN 62366-1: 2015
EN ISO 15223-1: 2021	IEC 60601-1: 2005
EN ISO 10993-1: 2020	IEC 60601-1-2: 2014
EN ISO 11737-1: 2018	

**Relevant Union legislation:** RoHS 2011/65/EU

**Notified body:** SIQ, Slovenian Institute of Quality and Metrology  
Mašera - Spasičeva ulica 10  
1000 Ljubljana, SLOVENIA  
Notified Body No. 1304

**EU Certificate:** No: 1304-MDD-138  
Issue: 01/2019-09-02  
Valid until: 2024-05-27/ end of transition time  
Transition time until: 2028-12-31

Lüdenscheid, 2026-04-27

Olaf Thiessies



Director