

Certificate

Quality Management System

EN ISO 13485:2016

EN ISO 13485:2016/AC:2018

EN ISO 13485:2016/A11:2021

Registration No.: SX 1194103-1

Certificate Holder: Ritter GmbH
Kaufbeurer Str. 55
86830 Schwabmünchen
Germany

Scope: Design and development, manufacture and distribution of dialysis cartridges as well as accessories for In-Vitro Diagnostics (other IVD from plastic) and plastic injection moulding articles for medical devices (non-implants).

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices. Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 1192299-100

Effective date: 2025-11-30

Expiry date: 2028-11-29

Issue date: 2025-11-13

Replaces certificate SX 1194103-1 issued 2022-11-25.



Dr. Karsten Kluge
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