

Certificate

Quality Management System
EN ISO 13485:2016
EN ISO 13485:2016/AC:2018
EN ISO 13485:2016/A11:2021

Registration No.: SX 1628881-1

Certificate Holder: Revvity chemagen Technologie GmbH
Arnold-Sommerfeld-Ring 2
52499 Baesweiler
Germany

Scope: Design and development, manufacture and distribution of magnetic polymer carriers, kits and reagents for nucleic acids purification used for in vitro diagnostic.

Servicing of instruments used for nucleic acids purification with magnetic polymer carriers for in vitro diagnostic examination.

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.: 1137714-40

Effective date: 2024-12-04

Expiry date: 2027-12-03

Issue date: 2024-12-04



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