

Certificate

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

Registration No.: SX 1127267-1

Certificate Holder: FUJIFILM Wako Chemicals Europe GmbH
Fuggerstr. 12
41468 Neuss
Germany

Scope: Manufacture and distribution of in vitro diagnostic reagents for clinical chemistry, installation and service of clinical analyzers

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.: 1163069-10

Effective date: 2024-11-26

Expiry date: 2026-12-07

Issue date: 2024-11-26

Replaces certificate SX 1127267-1 issued 2023-12-04



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