

Certificate

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

Registration No.: SX 1070846-1

Certificate Holder: Thermo Fisher Scientific Oy
Ratastie 2
FI-01620 Vantaa
Finland

Scope: The design and development, manufacturing, service, installation and distribution of in vitro diagnostic medical devices including clinical chemistry analysing systems, laboratory automation and diagnostic assays and reagents.

The design and development, manufacture, distribution and service of in vitro diagnostic medical instruments, liquid handling products and consumables.

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.: 1206918-20

Effective date: 2026-03-27

Expiry date: 2027-03-31

Issue date: 2026-03-27

Replaces certificate SX 1070846-1 issued 2025-01-20



Dr. Matthias Fischer
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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