Certificate

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

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.:	1175400-10
Effective date:	2025-01-20
Expiry date:	2027-03-31
Issue date:	2025-01-20

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This certificate can be validated on https://www.certipedia.com

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Precisely Right.

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Ratastie 2
FI-01620 Vantaa
Finland

The scope of certification also covers the following sites:

No.	Facility	Scope
/01	c/o Thermo Fisher Scientific Oy Ratastie 2 FI-01620 Vantaa Finland	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 diagnostics medical instruments, liquid handling products and consumables.
/02	c/o Thermo Fisher Scientific Oy Rahtikatu 2 FI-80100 Joensuu Finland	The manufacture and service of in vitro diagnostic liquid handling products and consumables.

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