

Certificate


Quality Management System EN ISO 13485:2016

Registration No.	SX 1060415-1
Certificate Holder	Fujirebio Diagnostics AB Gemenskapens Gata 7 SE-431 53 Mölndal Sweden
Scope	Design and development, manufacture and distribution of in-vitro diagnostic test kits and reagents used for the determination of cancer and other disease state biomarkers for diagnosis and management of patients with cancer and other disease states.

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.	1140250-40
Effective date	2023-10-12
Expiry date	2026-10-11
Issue date	2023-09-27
Replaces certificate SX 1060415-1 issued 2022-12-01	

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


M. Sc. Irene Carraretto
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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Registration No. SX 1060415-1
Certificate Holder Fujirebio Diagnostics AB
Gemenskapens Gata 7
SE-431 53 Mölndal
Sweden

The scope of certification also covers the following sites:

No.	Facility	Scope
/01	c/o Fujirebio Diagnostics AB Gemenskapens Gata 7 SE-431 53 Mölndal Sweden	Design and development, manufacture and distribution.
/02	c/o Fujirebio Diagnostics AB Elof Lindälvs gata 13 SE-414 58 Göteborg Sweden	Manufacture and distribution.

Report No. 1140250-40
Effective date 2023-10-12
Expiry date 2026-10-11
Issue date 2023-09-27

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Irene Carraretto

M. Sc. Irene Carraretto
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany