

Certificate

Quality Management System

EN ISO 13485:2016

EN ISO 13485:2016/AC:2018

EN ISO 13485:2016/A11:2021

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 reagents and in-vitro diagnostic test kits used in the diagnosis, management and detection of cancer disease status, neurological disease and fertility testing.

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.: 1172202-100

Effective date: 2025-07-09

Expiry date: 2026-10-11

Issue date: 2025-07-09

Replaces certificate SX 1060415-1 issued 2023-09-27



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