Certificate

Certificate No.:	MD 1060415-1-2
Manufacturer:	**Fujirebio Diagnostics AB** Gemenskapens Gata 7 SE-431 53 Mölndal Sweden
REPs Facility ID:	F007055
Certification criteria:	ISO 13485:2016 Canada Medical Devices Regulations – Part 1 – SOR 98/282 United States 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 – Subparts A to D
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.

TUV Rheinland of North America, Inc., an MDSAP recognized Auditing Organization, certifies that the quality management system of the Manufacturer has been audited against and found to conform the Certification criteria for the Scope contained in this certificate. The quality management system is subject to annual surveillance audit(s).

Project No.:	1172202-690
Issue Date:	2025-07-09
Effective Date:	2025-07-09
Expiry Date:	2026-10-07

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Certification officer: M. Sc. Irene Carraretto
TUV Rheinland of North America, Inc.

The validity of the certificate can be verified on https://www.certipedia.com or calling 1-888-743-4652.

TUV Rheinland of North America, Inc., 400 Beaver Brook Road, Boxborough, MA 01719, USA
Tel: (925) 249-9123, Fax: (925) 249-9124