Certificate

Certificate No.:	MD 1060415-1-1
Manufacturer:	**Fujirebio Diagnostics AB** Gemenskapens Gata 7 SE-431 53 Mölndal Sweden
REPs Facility ID:	F007055
Certification criteria:	ISO 13485:2016 Brazil RDC ANVISA n. 16/2013, RDC ANVISA n. 23/2012, RDC ANVISA n. 67/2009 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 test kits used for the determination of cancer and other disease state biomarkers for diagnosis and management of patients with cancer and other disease states.

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.:	1140250-230
Issue Date:	2023-09-27
Effective Date:	2023-10-08
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/quality_marks/0000058941?locale=en or calling 1-888-743-4652.

TUV Rheinland of North America, Inc., 295 Foster St. Suite 100, Littleton, MA 01460, USA
Tel: (925) 249-9123, Fax: (925) 249-9124

Certificate

Certificate No.: MD 1060415-1-1

Manufacturer: **Fujirebio Diagnostics AB**

Gemenskapens Gata 7
SE-431 53 Mölndal
Sweden

The scope of certification includes the following sites:

No.	Location	Scope
/01	Fujirebio Diagnostics AB Gemenskapens Gata 7 SE-431 53 Mölndal Sweden REPs Facility ID: F007055	Design and Development, Manufacture and Distribution.
/02	Fujirebio Diagnostics AB Elof Lindälvs gata 13 SE-414 58 Göteborg Sweden REPs Facility ID: F001608	Manufacture and Distribution.

Project No.: 1140250-230

Issue Date: 2023-09-27

Effective Date: 2023-10-08

Expiry Date: 2026-10-07

MDSAP
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