

Certificate

Certificate No.: MD 1087672-40

Manufacturer: **CareDx AB**
Franzégatan 5
SE-112 51 Stockholm
Sweden

REPs Facility ID: F004744

Certification criteria: ISO 13485:2016
Australia Therapeutic Goods (Medical Devices) Regulations, 2002,
Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance
Procedure
Canada Medical Device Regulation – 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 software
and in vitro diagnostics based on molecular genetic testing and flow
cytometry used in the fields of tissue typing, transplant genetics and
crossmatch tests

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.: 1087672-40

Issue Date: 2021-08-23

Effective Date: 2021-08-23

Expiry Date: 2022-02-10



Certification officer: Dipl.-Ing. (FH) D. Wiedemuth
TUV Rheinland of North America, Inc.

The validity of the certificate can be verified on https://www.certipedia.com/quality_marks/9000015611?locale=en
or calling 1-888-743-4652.