

Certificate

Certificate No.: MD 1041072-1-1

Manufacturer: **CareDx Pty Ltd**
20 Collie St.
Fremantle WA 6160
Australia

REPs Facility ID: F003515

Certification criteria: ISO 13485:2016

Australia Therapeutic Goods (Medical Devices) Regulations, 2002,
Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance
Procedure

Brazil RDC ANVISA n. 665/2022, RDC ANVISA n. 551/2021, RDC
ANVISA n. 67/2009

Scope: Design and development, manufacture and distribution of molecular
genetic IVD's and software in the field of tissue typing and transplant
genetics

TÜV Rheinland[®]

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.: 1116608-60

Issue Date: 2022-12-14

Effective Date: 2022-12-17

Expiry Date: 2024-12-16



Certification officer: Dipl.-Ing. S. Pane
TUV Rheinland of North America, Inc.

The validity of the certificate can be verified on https://www.certipedia.com/quality_marks/9000009353?locale=en
or calling 1-888-743-4652.