

Certificate

Quality Management System
EN ISO 13485:2016
EN ISO 13485:2016/AC:2018
EN ISO 13485:2016/A11:2021


Registration No.: SX 1041072-1
Certificate Holder: CareDx Pty Ltd
20 Collie St.
Fremantle WA 6160
Australia

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

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.: 1171377-100
Effective date: 2024-12-17
Expiry date: 2027-12-16
Issue date: 2024-12-05
Replaces certificate SX 1041072-1 issued 2024-12-14

This certificate can be validated on <https://www.certipedia.com>


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