

Certificate

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

Registration No.: SX 7091956-1
Certificate Holder: CareDx AB
Franzégatan 5
SE-112 51 Stockholm
Sweden

Scope: Design and development, manufacture and distribution of in vitro diagnostic software and reagents based on molecular genetic testing used in the fields 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.: 1154558-40
Effective date: 2025-02-11
Expiry date: 2028-02-10
Issue date: 2025-02-05
Replaces certificate SX 7091956-1 issued 2022-01-21



Dr. Matthias Fischer
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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