

Certificate



Quality Management System EN ISO 13485:2016

Registration No.: SX 7091956-1

Organization: CareDx AB
Franzégatan 5
SE-112 51 Stockholm
Sweden

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.

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.: 1087672-10
Effective date: 2021-08-17
Expiry date: 2022-02-10
Issue date: 2021-08-17

A handwritten signature in blue ink is written over a circular seal. The seal contains the TÜV Rheinland logo and the text 'TÜV Rheinland LGA Products GmbH' and 'Zertifizierungsstelle'.

Katja Mierisch
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

