

Certificate

Quality Management System EN ISO 13485:2016

Registration No.:

SX 7091956-1

Organization:

CareDx AB

Franzéngatan 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 guality management system is subject to yearly surveillance.

Report No.:

1096030-40

Effective date:

2022-02-11

Expiry date:

2025-02-10

Issue date:

2022-01-21

Akkreditierungsstelle D-ZM-14169-01-02

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