EC Certificate

TÜVRheinland®

Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices,
Annex IV excluding (4, 6)

Registration No.: HL 7091956-1

Manufacturer: CareDx AB
Franzéngatan 5
SE-112 51 Stockholm
Sweden

Products: PCR reagents for low/intermediate-resolution typing of HLA-A, HLA-B, HLA-DR

The Notified Body hereby declares that the requirements of Annex IV, excluding section 4 and 6 of the directive 98/79/EC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex IV, section 5 of the aforementioned directive. For placing on the market of List A devices covered by this certificate an EC design-examination certificate according to Annex IV, section 4 and a verification of manufactured products according to section 6 is required.

Report No.: 1111016-10

Effective date: 2021-08-17

Expiry date: 2025-05-26

Issue date: 2022-05-07

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

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TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 98/79/EC concerning in vitro diagnostic medical devices with the identification number 0197.