

EC CERTIFICATE

Number: 2135186CE01

Full Quality Assurance System

Directive 98/79/EC on In Vitro Diagnostic Medical Devices, Annex IV excluding (4,6)
(List A, B and devices for self-testing)

Manufacturer:

Genome Diagnostics B.V.

Yalelaan 48
3584 CM Utrecht
The Netherlands

For the product category(ies)

**High resolution HLA-typing reagents for the determination of the following groups;
HLA-A, HLA-B HLA-DRB1 and HLA-DRB345.**

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EC-Directive which apply to them:

0344

Documents, that form the basis of this certificate:

Certification Notice 2119985CN, initially dated 10 February 2011
Addendum, initially dated 20 July 2011

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant provisions of 'Besluit in-vitro diagnostica', the Dutch transposition of the Council Directive 98/79/EC of October 27, 1998 concerning In vitro diagnostic medical devices, including all subsequent amendments. The manufacturer has implemented a quality assurance system for design, manufacture and final inspection for the above mentioned product category in accordance to the provisions of Annex IV of Council Directive 98/79/EC of October 27, 1998 and is subject to periodical surveillance. For placing on the market of List A devices an additional EC design examination certificate according to Annex IV (4) is mandatory.

The necessary information related to the quality assurance system of the manufacturer, including facilities and the reference to the relevant documentation, of the products concerned and the assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 1 August 2020
Issued for the first time: 20 July 2011
Reissued: 1 August 2017

DEKRA Certification B.V.



drs. G.J. Zoetbrood
Managing Director



ing. A.A.M. Laan
Certification Manager

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DEKRA Certification B.V. is Notified Body with ID no 0344

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ADDENDUM

Belonging to certificate: 2135186CE01

1/1

CE MARKING OF CONFORMITY IN VITRO DIAGNOSTIC MEDICAL DEVICES

High resolution HLA-typing reagents for the determination of the following groups; HLA-A, HLA-B HLA-DRB1 and HLA-DRB345.

Issued to:

Genome Diagnostics B.V.

Yalelaan 48
3584 CM Utrecht
The Netherlands

This certificate covers the following product(s):

- SBTexcellerator® HLA-A
- SBTexcellerator® HLA-B
- SBTexcellerator® HLA-DRB1
- SBTexcellerator® HLA-DRB3/4/5
- NGSgo®-AmpX HLA-A, -B, -DRB1
- NGSgo®-AmpX HLA-DRB3/4/5
- AlleleSEQR® HLA-A PCR/Sequencing kit (25 typings and 100 typings)
- AlleleSEQR® HLA-B PCR/Sequencing kit (25 typings and 100 typings)
- AlleleSEQR® HLA- DRB1 PCR/Sequencing kit (25 typings and 100 typings)
- AlleleSEQR® HLA-A COMBIKIT (25 and 100 typings)
- AlleleSEQR® HLA-B COMBIKIT (25 and 100 typings)
- AlleleSEQR® HLA-DRB1 COMBIKIT (25 and 100 typings)
- NGSgo® Workflow Compatible with Illumina (HLA-A, -B, -DRB1, -DRB3/4/5)

Initial date: 20 July 2011

Revision date: 23 September 2016

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drs. G.J. Zoetbrood
Managing Director



ing. A.A.M. Laan
Certification Manager

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