

Declaration of conformity AlleleSEQR HLA Sequencing kits[®] IVD 98/79; Annex II - list B.

Company name : Genome Diagnostics BV
Visiting address : Yalelaan 48
Postal code : 3584 CM
City : Utrecht
Country : The Netherlands
Telephone : +31 (0)30 – 252 3799

The following declaration of conformity is issued under the sole responsibility of Genome Diagnostics B.V.

We hereby declare that the distributed CE marked medical devices listed on the attached "Product List" conform the applicable essential requirements and Annex IV of the "EC-Directive", the Council Directive 98/79/EC of 27 October 1998, concerning in vitro diagnostic medical devices.

The devices listed in the "Product List" are assessed for conformity by Tüv Süd Product Service GmbH, substantiated by CE-certificate V1 102580.

Notified body name : Tüv Süd Product Service GmbH
NB identification code : 0123
Visiting address : Ridlerstrasse 65
Postal code : D-80339
City : München
Country : Germany

In addition, we ensure that the devices listed in the "Product List" are manufactured under a quality management system conform ISO 13485:2016 and EN ISO 13495:2016.

Utrecht
01 August 2019



Name: W. Mulder PhD
Function: Chief Executive Officer

Annex: Product list

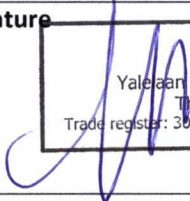
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**Appendix to:
Declaration of conformity AlleleSEQR HLA Sequencing kits®
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PRODUCT LIST

This Product List belongs to the Declaration of Conformity "AlleleSEQR HLA Sequencing kits®", and specifies the products concerned that Genome Diagnostics B.V. intends to distribute. The list identifies the products by product name, version and product number.

Product name	Version	Product number
ALLELESEQR HLA-A PCR/SEQUENCING KIT	25 reactions	08K60-01
	100 reactions	08K60-03
ALLELESEQR HLA-A COMBIKIT	25 reactions	08K60-05
	100 reactions	08K60-06
ALLELESEQR HLA-B PCR/SEQUENCING KIT	25 reactions	08K61-01
	100 reactions	08K61-03
ALLELESEQR HLA-B COMBIKIT	25 reactions	08K61-05
	100 reactions	08K61-06
ALLELESEQR HLA-DRB1 PCR/SEQUENCING KIT	25 reactions	08K63-01
	100 reactions	08K63-03
ALLELESEQR HLA-DRB1 COMBIKIT	25 reactions	08K63-05
	100 reactions	08K63-06

Name	W. Mulder PhD	Signature  GenDx Yalelaan 48 3584 CM Utrecht The Netherlands Trade register: 36202468 VAT: NL814323194B01
Function	Chief Executive Officer	
Place of issue	Utrecht, The Netherlands	
Date of issue	01 August 2019	