

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

Company name : Genome Diagnostics BV
Visiting address : Yalelaan 48
Post code : 3584 CM
City : Utrecht
Country : The Netherlands
Telephone / -fax : +31 (0)30 – 252 3799 / +31 (0)30 – 254 2611

We hereby declare that the distributed CE marked medical devices, listed on the attached product list, conform to the required technical documentation, in accordance with Annex III of the "EC-Directive", the Council Directive 98/79/EC of 27 October 1998, concerning in vitro diagnostic medical devices.

In addition, we ensure and declare that the distributed CE marked medical devices meet the provisions of the EC-Directive which apply to them.

This Declaration of Conformity covers the AlleleSEQR[®] products as specified in the product list belonging to this declaration.

Utrecht
4 May 2016



Name: W. Mulder PhD
Function: Managing Director

Annex: Product list

Declaration of conformity
 2 MAY 2018
 1013

GENDX


Declaration of conformity AlleSTOR M.A. sequencing kits
 IVD 9873; NON-Annex II

Company name : Genome Diagnostics BV
 Mailing address : Yalstein 48
 Post code : 3584 CM
 City : Utrecht
 Country : The Netherlands
 Telephone / fax : +31 (0)30 - 252 3399 / +31 (0)30 - 252 3311

We hereby declare that the distributed CE marked medical devices listed on the attached product list conform to the relevant technical documentation. In accordance with Annex II of the EU Directive, the Council Directive 98/79/EC of 27 October 1998, concerning in vitro diagnostic medical devices.

In addition, we ensure and declare that the distributed CE marked medical devices meet the provisions of the EC Directives which apply to them.

The Declaration of Conformity covers the AlleSTOR products as specified in the product list belonging to this declaration.


GenDx
 Yalstein 48 | 3584 CM Utrecht
 The Netherlands
 Your product: IVD 9873; NON-Annex II

Utrecht
 4 May 2018

Name: W. Mulder, PhD
 Function: Managing Director

Annex Product list

Declaration of conformity AlleSTOR M.A. sequencing kits
 IVD 9873; NON-Annex II
 2 MAY 2018
 1013

**Appendix to:
Declaration of conformity AlleleSEQR HLA Sequencing kits[®]
IVD 98/79; NON-Annex II**

PRODUCT LIST[®]

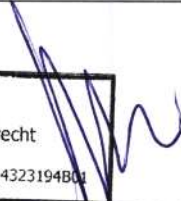
This product list belongs to the Declaration of Conformity, and specifies the products concerned that Genome Diagnostics BV intends to distribute. The list identifies the products by product name, version and product number.

Product name	Version	Product number
ALLELESEQR C PLUS PCR/SEQUENCING KIT	25 reactions	08K62-02
	100 reactions	08K62-04
ALLELESEQR C COMBIKIT	25 reactions	08K62-05
	100 reactions	08K62-06
ALLELESEQR DQB1 PCR/SEQUENCING KIT	25 reactions	08K64-01
	100 reactions	08K64-03
ALLELESEQR DQB1 COMBIKIT	25 reactions	08K64-05
	100 reactions	08K64-06
ALLELESEQR DPB1 PCR/SEQUENCING KIT	25 reactions	08K65-01
	100 reactions	08K65-03
ALLELESEQR DPB1 COMBIKIT	25 reactions	08K65-05
	100 reactions	08K65-06

Product name	Version	Product number	
ALLELESEQR MSP HLA-C	C2F105T	25 reactions	8K62-10
		100 reactions	8K62-11
		500 reactions	8K62-12
	C2F142G	25 reactions	8K62-13
		100 reactions	8K62-14
		500 reactions	8K62-15
	C2F176G	25 reactions	8K62-16
		100 reactions	8K62-17
		500 reactions	8K62-18
	C3F361T	25 reactions	8K62-19
		100 reactions	8K62-20
		500 reactions	8K62-21
	C3R368C	25 reactions	8K62-22
		100 reactions	8K62-23
		500 reactions	8K62-24
	C3R486C	25 reactions	8K62-25
		100 reactions	8K62-26
		500 reactions	8K62-27
	C3R539T	25 reactions	8K62-28
		100 reactions	8K62-29
		500 reactions	8K62-30
C3R559A	25 reactions	8K62-31	
	100 reactions	8K62-32	
	500 reactions	8K62-33	

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Product name	Version		Product number
ALLELESEQR HLA-C PLUS SEQUENCING MIXES FOR ADDITIONAL EXONS	C1R	25 reactions	8K62-61
		100 reactions	8K62-62
	C5F	25 reactions	8K62-63
		100 reactions	8K62-64
	C6F	25 reactions	8K62-65
		100 reactions	8K62-66
	C7F	25 reactions	8K62-67
		100 reactions	8K62-68
	C7R	25 reactions	8K62-69
		100 reactions	8K62-70
ALLELESEQR MSP HLA-DQB1	Q2F134C	25 reactions	8K64-10
		100 reactions	8K64-11
		500 reactions	8K64-12
ALLELESEQR MSP HLA-DPB1	P2F194C	25 reactions	8K65-10
		100 reactions	8K65-11
		500 reactions	8K65-12
	P2R251C	25 reactions	8K65-13
		100 reactions	8K65-14
		500 reactions	8K65-15
	P2R292A	25 reactions	8K65-16
		100 reactions	8K65-17
		500 reactions	8K65-18
	P2R313G	25 reactions	8K65-19
		100 reactions	8K65-20
		500 reactions	8K65-21

Name	W. Mulder PhD	Signature  GenDx Yalelaan 48 3584 CM Utrecht The Netherlands Trade register: 30202468 VAT: NL814323194B01
Function	Managing Director	
Place of issue	Utrecht, The Netherlands	
Date of issue	4 May 2016	