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Declaration of conformity AlleleSEQR products, IVD 98/79

Company name : Genome Diagnostics B.V.
 Visiting address : Yalelaan 48
 Post 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 to the applicable essential requirements of the EC-Directive 98/79/EC of 27 October 1998 on in vitro diagnostic medical devices.

AlleleSEQR products meet the provisions of Annex IV, List B.

The devices listed in the appendix "Product List" are assessed for conformity by TÜV SÜD Product Service GmbH, substantiated by CE-certificate V1 102580 0001 Rev. 02.

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 13485:2016.

Utrecht
 10-01-2020

Name: W. Mulder PhD
 Function: Chief Executive Officer

Annex: Product list



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Appendix to declaration of conformity AlleleSEQR products, IVD 98/79: product list

Company name : Genome Diagnostics B.V.
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This product list belongs to the Declaration of Conformity of AlleleSEQR products, IVD 98/79, and specifies the CE marked products concerned that Genome Diagnostics B.V. intends to distribute.

The following list identifies the products by product name and product number.

Cat. no.	Product name
08K60-06	AlleleSEQR® Combikit HLA-A
08K61-06	AlleleSEQR® Combikit HLA-B
08K63-06	AlleleSEQR® Combikit HLA-DRB1
08K60-01	AlleleSEQR® HLA-A (25)
08K60-03	AlleleSEQR® HLA-A (100)
08K61-01	AlleleSEQR® HLA-B (25)
08K61-03	AlleleSEQR® HLA-B (100)
08K63-01	AlleleSEQR® HLA-DRB1 (25)
08K63-03	AlleleSEQR® HLA-DRB1 (100)
8K63-10	AlleleSEQR® MSP HLA-DRB1 R2F124C
8K63-13	AlleleSEQR® MSP HLA-DRB1 R2F124T
8K63-16	AlleleSEQR® MSP HLA-DRB1 R2F197A
8K63-19	AlleleSEQR® MSP HLA-DRB1 R2R256A
8K63-22	AlleleSEQR® MSP HLA-DRB1 R2R286A
8K60-13	AlleleSEQR® MSP HLA-A A2F98T
8K60-16	AlleleSEQR® MSP HLA-A A2F144A
8K60-19	AlleleSEQR® MSP HLA-A A2F261C
8K60-22	AlleleSEQR® MSP HLA-A A2R311T
8K60-25	AlleleSEQR® MSP HLA-A A3F363A
8K60-28	AlleleSEQR® MSP HLA-A A3F363G
8K60-31	AlleleSEQR® MSP HLA-A A3F414C
8K60-34	AlleleSEQR® MSP HLA-A A2F203G
8K61-10	AlleleSEQR® MSP HLA-B B2F106A
8K61-13	AlleleSEQR® MSP HLA-B B2F144C
8K61-16	AlleleSEQR® MSP HLA-B B2F206C
8K61-19	AlleleSEQR® MSP HLA-B B2R311T
8K61-22	AlleleSEQR® MSP HLA-B B3F357C
8K61-25	AlleleSEQR® MSP HLA-B B3F357G
8K61-28	AlleleSEQR® MSP HLA-B B3R559A
8K61-31	AlleleSEQR® MSP HLA-B B3R603G
8K60-10	AlleleSEQR® MSP HLA-A A2F98A

Name	W. Mulder PhD	Signature 
Function	Chief Executive Officer	
Place of issue	Utrecht, the Netherlands	
Date of issue	Oct 1 st 2020	