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| Doc number | ALSEQR-RF-DC2B |              |
| Version    | 7              | 03 June 2020 |
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## Declaration of conformity AlleleSEQR HLA Sequencing kits<sup>®</sup> IVD 98/79; Annex II - list B.

Company name : Genome Diagnostics B.V.  
 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.

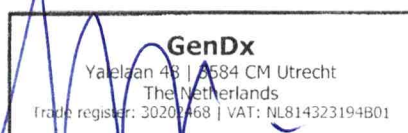
We hereby declare that the distributed CE marked medical devices listed on the attached "Product List" conform the applicable essential requirements and Annex IV of the "EC-Directive", the Council Directive 98/79/EC of 27 October 1998, concerning in vitro diagnostic medical devices.

The devices listed in the "Product List" are assessed for conformity by Tüv Süd Product Service GmbH, substantiated by CE-certificate V1 102580 0001 Rev. 01.

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  
 03 June 2020



Name: W. Mulder PhD  
 Function: Chief Executive Officer

Annex: Product list

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

**PRODUCT LIST**

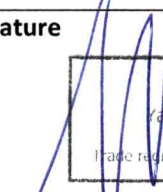
This Product List belongs to the Declaration of Conformity “AlleleSEQR HLA Sequencing kits®”, and specifies the products concerned that Genome Diagnostics B.V. intends to distribute.  
The list identifies the products by product name, version and product number.

| 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       |

| Product name         | Version | Product number |
|----------------------|---------|----------------|
| ALLELESEQR MSP HLA-A | A2F98A  | 25 reactions   |
|                      |         | 100 reactions  |
|                      |         | 500 reactions  |
|                      | A2F98T  | 25 reactions   |
|                      |         | 100 reactions  |
|                      |         | 500 reactions  |
|                      | A2F144A | 25 reactions   |
|                      |         | 100 reactions  |
|                      |         | 500 reactions  |
|                      | A2F261C | 25 reactions   |
|                      |         | 100 reactions  |
|                      |         | 500 reactions  |
|                      | A2R311T | 25 reactions   |
|                      |         | 100 reactions  |
|                      |         | 500 reactions  |
|                      | A3F363A | 25 reactions   |
|                      |         | 100 reactions  |
|                      |         | 500 reactions  |
|                      | A3F363G | 25 reactions   |
|                      |         | 100 reactions  |
|                      |         | 500 reactions  |
|                      | A3F414C | 25 reactions   |
|                      |         | 100 reactions  |
|                      |         | 500 reactions  |
|                      | A2F203G | 25 reactions   |
|                      |         | 100 reactions  |
|                      |         | 500 reactions  |

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| Product name            | Version |               | Product number |
|-------------------------|---------|---------------|----------------|
| ALLELESEQR MSP HLA-B    | B2F106A | 25 reactions  | 8K61-10        |
|                         |         | 100 reactions | 8K61-11        |
|                         |         | 500 reactions | 8K61-12        |
|                         | B2F144C | 25 reactions  | 8K61-13        |
|                         |         | 100 reactions | 8K61-14        |
|                         |         | 500 reactions | 8K61-15        |
|                         | B2F206C | 25 reactions  | 8K61-16        |
|                         |         | 100 reactions | 8K61-17        |
|                         |         | 500 reactions | 8K61-18        |
|                         | B2R311T | 25 reactions  | 8K61-19        |
|                         |         | 100 reactions | 8K61-20        |
|                         |         | 500 reactions | 8K61-21        |
|                         | B3F357C | 25 reactions  | 8K61-22        |
|                         |         | 100 reactions | 8K61-23        |
|                         |         | 500 reactions | 8K61-24        |
|                         | B3F357G | 25 reactions  | 8K61-25        |
|                         |         | 100 reactions | 8K61-26        |
|                         |         | 500 reactions | 8K61-27        |
|                         | B3R559A | 25 reactions  | 8K61-28        |
|                         |         | 100 reactions | 8K61-29        |
|                         |         | 500 reactions | 8K61-30        |
|                         | B3R603G | 25 reactions  | 8K61-31        |
|                         |         | 100 reactions | 8K61-32        |
|                         |         | 500 reactions | 8K61-33        |
| ALLELESEQR MSP HLA-DRB1 | R2F124C | 25 reactions  | 8K63-10        |
|                         |         | 100 reactions | 8K63-11        |
|                         |         | 500 reactions | 8K63-12        |
|                         | R2F124T | 25 reactions  | 8K63-13        |
|                         |         | 100 reactions | 8K63-14        |
|                         |         | 500 reactions | 8K63-15        |
|                         | R2F197A | 25 reactions  | 8K63-16        |
|                         |         | 100 reactions | 8K63-17        |
|                         |         | 500 reactions | 8K63-18        |
|                         | R2R256A | 25 reactions  | 8K63-19        |
|                         |         | 100 reactions | 8K63-20        |
|                         |         | 500 reactions | 8K63-21        |
|                         | R2R286A | 25 reactions  | 8K63-22        |
|                         |         | 100 reactions | 8K63-23        |
|                         |         | 500 reactions | 8K63-24        |

|                       |                          |   |
|-----------------------|--------------------------|---|
| <b>Name</b>           | W. Mulder PhD            | <b>Signature</b><br> <div data-bbox="853 1664 1260 1792" data-label="Text"> <p><b>GenDx</b><br/> Valenien 48   3584 CM Utrecht<br/> The Netherlands<br/> Trade register: 30202468   VAT: NL814323194B01</p> </div> |
| <b>Function</b>       | Chief Executive Officer  |   |
| <b>Place of issue</b> | Utrecht, The Netherlands |   |
| <b>Date of issue</b>  | 03 June 2020             |   |