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| Doc number | RF-AlleleSEQR-<br>1.12.06_Decl_of_Conformity-<br>ANNEX III |                          |
| Version    | 1  | Oct 1 <sup>st</sup> 2020 |
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## Declaration of conformity AlleleSEQR products, IVD 98/79; ANNEX III

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

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, other device 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  
10-01-2020

Name: W. Mulder PhD  
Function: Chief Executive Officer

Annex: Product list

### GenDx

Yalelaan 48 | 3584 CM Utrecht  
The Netherlands  
Trade register: 30202468 | VAT: NL814323194B01

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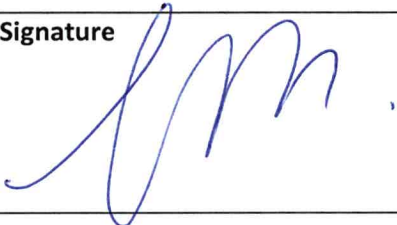
**Appendix to declaration of conformity AlleleSEQR products, IVD 98/79;  
ANNEX III: product list**

Company name : Genome Diagnostics B.V.  
 Visiting address : Yalelaan 48  
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This product list belongs to the Declaration of Conformity of AlleleSEQR products, IVD 98/79, ANNEX III, 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                     |
|----------|----------------------------------|
| 08K62-06 | AlleleSEQR® Combikit HLA-C       |
| 08K62-02 | AlleleSEQR® HLA-C (25)           |
| 08K62-04 | AlleleSEQR® HLA-C (100)          |
| 08K64-01 | AlleleSEQR® HLA-DQB1 (25)        |
| 08K64-03 | AlleleSEQR® HLA-DQB1 (100)       |
| 08K65-01 | AlleleSEQR® HLA-DPB1 (25)        |
| 08K65-03 | AlleleSEQR® HLA-DPB1 (100)       |
| 8K62-22  | AlleleSEQR® MSP HLA-C C3R368C    |
| 8K62-25  | AlleleSEQR® MSP HLA-C C3R486G    |
| 8K62-28  | AlleleSEQR® MSP HLA-C C3R539T    |
| 8K62-31  | AlleleSEQR® MSP HLA-C C3R559A    |
| 8K64-10  | AlleleSEQR® MSP HLA-DQB1 Q2F134C |
| 8K65-10  | AlleleSEQR® MSP HLA-DPB1 P2F194C |
| 8K65-13  | AlleleSEQR® MSP HLA-DPB1 P2R251A |
| 8K65-16  | AlleleSEQR® MSP HLA-DPB1 P2R292A |
| 8K65-19  | AlleleSEQR® MSP HLA-DPB1 P2R313G |
| 8K62-10  | AlleleSEQR® MSP HLA-C C2F105T    |
| 8K62-13  | AlleleSEQR® MSP HLA-C C2F142G    |
| 8K62-16  | AlleleSEQR® MSP HLA-C C2F176G    |
| 8K62-19  | AlleleSEQR® MSP HLA-C C3F361T    |
| 8K62-63  | AlleleSEQR® HLA-C Plus C5F       |
| 8K62-65  | AlleleSEQR® HLA-C Plus C6F       |
| 8K62-67  | AlleleSEQR® HLA-C Plus C7F       |
| 8K62-69  | AlleleSEQR® HLA-C Plus C7R       |
| 8K62-61  | AlleleSEQR® HLA-C Plus C1R       |

|                       |                          |  |
|-----------------------|--------------------------|--|
| <b>Name</b>           | W. Mulder PhD            | <b>Signature</b><br> |
| <b>Function</b>       | Chief Executive Officer  |  |
| <b>Place of issue</b> | Utrecht, the Netherlands |  |
| <b>Date of issue</b>  | Oct 1 <sup>st</sup> 2020 |  |