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## Declaration of conformity NGSgo<sup>®</sup>-MX6-1, 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.

The NGSgo<sup>®</sup>-MX6-1 loci and their applicable annex combine as follows:


- HLA-A, -B, and -DRB1 meet the provisions of Annex IV.
- HLA-C, -DPB1, and -DQB1 meet the provisions of Annex III.

The devices listed in the appendix “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  
3 December 2019



Name: W. Mulder PhD  
Function: Chief Executive Officer

Annex: Product list

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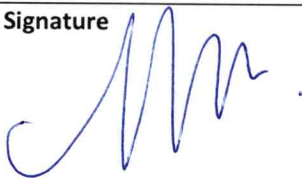
## Appendix to declaration of conformity NGSgo®-MX6-1, IVD 98/79: product list

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This product list belongs to the Declaration of Conformity of NGSgo®-MX6-1, 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
7871464	NGSgo-MX6-1 (96)

<b>Name</b>	W. Mulder PhD	<b>Signature</b> 
<b>Function</b>	Chief Executive Officer	
<b>Place of issue</b>	Utrecht, the Netherlands	
<b>Date of issue</b>	3 December 2019	