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

NGSgo<sup>®</sup>-AmpX meets 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

<p><b>GenDx</b>          Yalelaan 48   3584 CM Utrecht          The Netherlands          Trade register: 30202468   VAT: NL814323194B01</p>
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## Appendix to declaration of conformity NGSgo<sup>®</sup>-AmpX, 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 NGSgo<sup>®</sup>-AmpX, 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
2841602	NGSgo <sup>®</sup> -AmpX HLA GeneSuite (24)
2841662	NGSgo <sup>®</sup> -AmpX HLA GeneSuite (96)
2841102	NGSgo <sup>®</sup> -AmpX HLA-A, B, C, DRB1, DQB1 (24)
2841162	NGSgo <sup>®</sup> -AmpX HLA-A, B, C, DRB1, DQB1 (96)
2841502	NGSgo <sup>®</sup> -AmpX HLA-DPA1, DPB1, DQA1, DRB3/4/5 (24)
2841562	NGSgo <sup>®</sup> -AmpX HLA-DPA1, DPB1, DQA1, DRB3/4/5 (96)
2840102	NGSgo <sup>®</sup> -AmpX HLA-A (24)
2840162	NGSgo <sup>®</sup> -AmpX HLA-A (96)
2840202	NGSgo <sup>®</sup> -AmpX HLA-B (24)
2840262	NGSgo <sup>®</sup> -AmpX HLA-B (96)
2840602	NGSgo <sup>®</sup> -AmpX HLA-DRB1 (24)
2840662	NGSgo <sup>®</sup> -AmpX HLA-DRB1 (96)
2840702	NGSgo <sup>®</sup> -AmpX HLA-DRB3/4/5 (24)
2840762	NGSgo <sup>®</sup> -AmpX HLA-DRB3/4/5 (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>	Oct 1 <sup>st</sup> 2020	