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Declaration of conformity NGSgo®-AmpX V2, 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 NGSgo-AmpX v2 products as specified in the product list belonging to this declaration.

Utrecht
4 June 2020



Name: W. Mulder PhD
 Function: Chief Executive Officer

Annex: Product list

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Appendix to declaration of conformity NGSgo®-AmpX v2, IVD 98/79; ANNEX III: product list

Company name : Genome Diagnostics B.V.
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This product list belongs to the Declaration of Conformity of NGSgo®-AmpX v2, 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
7870362	NGSgo-AmpX v2 HLA-C (96)
7870562	NGSgo-AmpX v2 HLA-DQB1 (96)
7870462	NGSgo-AmpX v2 HLA-DPB1 (96)
7870862	NGSgo-AmpX v2 HLA-DQA1 (96)
7870962	NGSgo-AmpX v2 HLA-DPA1 (96)
7871062	NGSgo-AmpX v2 HLA-G (96)

Name	W. Mulder PhD	Signature  GenDx Yalelaan 48 3584 CM Utrecht The Netherlands Trade register: 30202468 VAT: NL8143231941001
Function	Chief Executive Officer	
Place of issue	Utrecht, the Netherlands	
Date of issue	4 june 2020	