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Declaration of conformity NGSgo[®]-AmpX v2, 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[®]-AmpX v2 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



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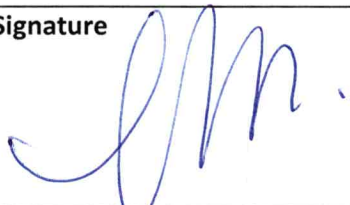
Appendix to declaration of conformity NGSgo[®]-AmpX v2, IVD 98/79: product list

Company name : Genome Diagnostics B.V.
 Visiting address : Yalelaan 48
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This product list belongs to the Declaration of Conformity of NGSgo[®]-AmpX v2, 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
7871462	NGSgo-AmpX v2 HLA-A, B, C, DRB1, DQB1, DPB1
7871662	NGSgo [®] -AmpX v2 HLAGeneSuite
7870162	NGSgo-AmpX v2 HLA-A
7870262	NGSgo-AmpX v2 HLA-B
7870662	NGSgo-AmpX v2 HLA-DRB1
7870762	NGSgo-AmpX v2 DRB3/4/5

Name	W. Mulder PhD	Signature 
Function	Chief Executive Officer	
Place of issue	Utrecht, the Netherlands	
Date of issue	Oct 1 st 2020	