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Declaration of conformity NGSgo®-AmpX, 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 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



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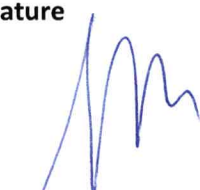
Appendix to declaration of conformity NGSgo[®]-AmpX, IVD 98/79; ANNEX III: product list

Company name : Genome Diagnostics B.V.
 Visiting address : Yalelaan 48
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This product list belongs to the Declaration of Conformity of NGSgo[®]-AmpX, 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
2840302	NGSgo [®] -AmpX HLA-C (24)
2840362	NGSgo [®] -AmpX HLA-C (96)
2840802	NGSgo [®] -AmpX HLA-DQA1 (24)
2840862	NGSgo [®] -AmpX HLA-DQA1 (96)
2840502	NGSgo [®] -AmpX HLA-DQB1 (24)
2840562	NGSgo [®] -AmpX HLA-DQB1 (96)
2840902	NGSgo [®] -AmpX HLA-DPA1 (24)
2840962	NGSgo [®] -AmpX HLA-DPA1 (96)
2840402	NGSgo [®] -AmpX HLA-DPB1 (24)
2840462	NGSgo [®] -AmpX HLA-DPB1 (96)
2841002	NGSgo [®] -AmpX HLA-G (24)

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