

Declaration of conformity NGSgo®-AmpX, IVD 98/79

Company name : Genome Diagnostics BV
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®-AmpX loci and their applicable annex combine as follows:

- HLA-A, -B, -DRB1 and -DRB3/4/5 meet the provisions of Annex IV.
- HLA-C, -DPB1, -DQB1, -DQA1, -DPA1, and -G 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
01 August 2019



Name: W. Mulder PhD
Function: Chief Executive Officer

Annex: Product list

Doc number	CE-NGSGA-ANX04-DOC-01	
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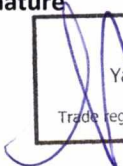
Appendix to declaration of conformity NGSgo[®]-AmpX, IVD 98/79: product list

Company name : Genome Diagnostics BV
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This product list belongs to the Declaration of Conformity of NGSgo[®]-AmpX, IVD 98/79, and specifies the CE marked products concerned that Genome Diagnostics BV intends to distribute.

The following list identifies the products by product name and product number.

Product name	Number of reactions	Product number
NGSgo [®] -AmpX HLA-A, B, C, DRB1, DQB1	24	2841102
NGSgo [®] -AmpX HLA-DPA1, DPB1, DQA1, DRB3/4/5	24	2841502
NGSgo [®] -AmpX HLAGeneSuite	24	2841602
NGSgo [®] -AmpX HLA-A	24	2840102
NGSgo [®] -AmpX HLA-B	24	2840202
NGSgo [®] -AmpX HLA-C	24	2840302
NGSgo [®] -AmpX HLA-DPB1	24	2840402
NGSgo [®] -AmpX HLA-DQB1	24	2840502
NGSgo [®] -AmpX HLA-DRB1	24	2840602
NGSgo [®] -AmpX HLA-DRB3/4/5	24	2840702
NGSgo [®] -AmpX HLA-DQA1	24	2840802
NGSgo [®] -AmpX HLA-DPA1	24	2840902
NGSgo [®] -AmpX HLA-G	24	2841002
NGSgo [®] -AmpX HLA-A, B, C, DRB1, DQB1	96	2841162
NGSgo [®] -AmpX HLA-DPA1, DPB1, DQA1, DRB3/4/5	96	2841562
NGSgo [®] -AmpX HLAGeneSuite	96	2841662
NGSgo [®] -AmpX HLA-A	96	2840162
NGSgo [®] -AmpX HLA-B	96	2840262
NGSgo [®] -AmpX HLA-C	96	2840362
NGSgo [®] -AmpX HLA-DPB1	96	2840462
NGSgo [®] -AmpX HLA-DQB1	96	2840562
NGSgo [®] -AmpX HLA-DRB1	96	2840662
NGSgo [®] -AmpX HLA-DRB3/4/5	96	2840762
NGSgo [®] -AmpX HLA-DQA1	96	2840862
NGSgo [®] -AmpX HLA-DPA1	96	2840962

Name	W. Mulder PhD	Signature  GenDx Yalelaan 48 3584 CM Utrecht The Netherlands Trade register: 30202468 VAT: NL814323194B01
Function	Chief Executive Officer	
Place of issue	Utrecht, the Netherlands	
Date of issue	01 August 2019	