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Declaration of conformity NGSgo-AmpX v2, REGULATION (EU) 2017/746

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
 SRN : NL-MF-000000453

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 REGULATION (EU) 2017/746 of the European parliament and of the council of 5 April 2017 on in vitro diagnostic medical devices. NGSgo-AmpX v2 meets the provisions of a Class C IVD under Annex VIII, Rule 2.

The devices listed in the appendix “Product List” are assessed for conformity by Tüv Süd Product Service GmbH, substantiated by CE-certificate No. V12 102580 0004 Rev. 00. Conformity assessment is based on Annex IX chapters I and III of the REGULATION (EU) 2017/746.

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
2022-05-06



Name: W. Mulder PhD
 Function: Chief Executive Officer

Annex: Product list

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Appendix to declaration of conformity NGSgo-AmpX v2, REGULATION (EU) 2017/746: product list

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This product list belongs to the Declaration of Conformity of NGSgo-AmpX v2, REGULATION (EU) 2017/746, 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.	Basic UDI-DI	Product name + Trade name
7971462	871846936ngsgo-ampxv2F4	NGSgo-AmpX v2 HLA-A, B, C, DRB1, DQB1, DPB1 (96)
7971662	871846936ngsgo-ampxv2F4	NGSgo-AmpX v2 HLA-A, B, C, DRB1, DQB1, DPB1, DPA1, DQA1, DRB3/4/5 (96)
7970162	871846936ngsgo-ampxv2F4	NGSgo-AmpX v2 HLA-A (96)
7970262	871846936ngsgo-ampxv2F4	NGSgo-AmpX v2 HLA-B (96)
7970362	871846936ngsgo-ampxv2F4	NGSgo-AmpX v2 HLA-C (96)
7970662	871846936ngsgo-ampxv2F4	NGSgo-AmpX v2 HLA-DRB1 (96)
7970762	871846936ngsgo-ampxv2F4	NGSgo-AmpX v2 DRB3/4/5 (96)
7970562	871846936ngsgo-ampxv2F4	NGSgo-AmpX v2 HLA-DQB1 (96)
7970862	871846936ngsgo-ampxv2F4	NGSgo-AmpX v2 HLA-DQA1 (96)
7970462	871846936ngsgo-ampxv2F4	NGSgo-AmpX v2 HLA-DPB1 (96)

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Cat. no.	Basic UDI-DI	Product name + Trade name
7970962	871846936ngsgo-ampxv2F4	NGSgo-AmpX v2 HLA-DPA1 (96)

Name	W. Mulder PhD	Signature  GenDx Yalelaan 48 3534 CM Utrecht The Netherlands Trade register: 30002468 VAT: NL014323194B01
Function	Chief Executive Officer	
Place of issue	Utrecht, the Netherlands	
Date of issue	2022-05-06	