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 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
2023-10-24

Name: M. Penning PhD
Function: General Manager

Annex: Product list

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)
7970962	871846936ngsgo-ampxv2F4	NGSgo®-AmpX v2 HLA-DPA1 (96)

Name	M. Penning PhD	**Signature** 
Function	General Manager	
Place of issue	Utrecht, the Netherlands	
Date of issue	2023-10-24	