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Declaration of conformity NGSgo®-MX11-3, 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®-MX11-3 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
 2023-10-25

GenDx
 Yalelaan 48 | 3584 CM Utrecht
 The Netherlands
 Trade register: 30202468 | VAT: NL814332194191

Name: M. Penning PhD
 Function: General Manager

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Annex: Product list


Appendix to declaration of conformity NGSgo®-MX11-3, REGULATION (EU) 2017/746: product list

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This product list belongs to the Declaration of Conformity of NGSgo®-MX11-3, 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
7971864	871846936ngsgo-mx11-3ST	NGSgo®-MX11-3

Name	M. Penning PhD	Signature 
Function	General Manager	
Place of issue	Utrecht, the Netherlands	
Date of issue	2023-10-25	