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Declaration of conformity NGSgo® Library Full Kit, 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 Library Full Kit 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,
2023-10-25


**GenDx**
Yalelaan 48 | 3584 CM Utrecht
The Netherlands
Trade register: 30202468 | VAT: NL81432319-1801

Name: M. Penning PhD
Function: General Manager

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Annex: Product list


Appendix to declaration of conformity NGSgo® Library Full Kit, REGULATION (EU) 2017/746: product list

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This product list belongs to the Declaration of Conformity of NGSgo® Library Full Kit, 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
2842156	871846936libraryfullkit79	NGSgo® Library Full Kit Library Preparation and Indexing Kit <i>For Illumina - IndX plate I</i>
2842256	871846936libraryfullkit79	NGSgo® Library Full Kit Library Preparation and Indexing Kit <i>For Illumina - IndX plate II</i>
2842356	871846936libraryfullkit79	NGSgo® Library Full Kit Library Preparation and Indexing Kit <i>For Illumina - IndX plate III</i>
2842456	871846936libraryfullkit79	NGSgo® Library Full Kit Library Preparation and Indexing Kit <i>For Illumina - IndX plate IV</i>

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