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Declaration of conformity NGSgo® Library Full Kit, IVD 98/79

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

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.

NGSgo Library Full Kit meets the provisions of Annex IV, List B.

The devices listed in the appendix "Product List" are assessed for conformity by Tüv Süd Product Service GmbH, substantiated by CE-certificate V1 102580 0001 Rev. 02.

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
2021-03-29

Name: W. Mulder PhD
Function: Chief Executive Officer

Annex: Product list



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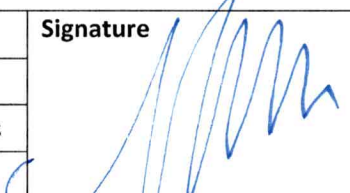
Appendix to declaration of conformity NGSgo® Library Full Kit, IVD 98/79: product list

Company name : Genome Diagnostics B.V.
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This product list belongs to the Declaration of Conformity of NGSgo® Library Full Kit, IVD 98/79, 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 catalogue number.

Cat. No.	Product name
2842156	NGSgo® Library Full Kit
	Library Preparation and Indexing Kit
	<i>For Illumina - IndX plate I</i>
2842256	NGSgo® Library Full Kit
	Library Preparation and Indexing Kit
	<i>For Illumina - IndX plate II</i>
2842356	NGSgo® Library Full Kit
	Library Preparation and Indexing Kit
	<i>For Illumina - IndX plate III</i>
2842456	NGSgo® Library Full Kit
	Library Preparation and Indexing Kit
	<i>For Illumina - IndX plate IV</i>
	Library Preparation and Indexing Kit

Name	W. Mulder PhD	Signature 
Function	Chief Executive Officer	
Place of issue	Utrecht, the Netherlands	
Date of issue	2021-03-29	