

Doc number	RF-IL- 1.12.06_Decl_of_Conformity	
Version	1	Oct 1 <sup>st</sup> 2020
Page	1 of 2	

## Declaration of conformity NGSgo® workflow, 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® workflow 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  
 10-01-2020

Name: W. Mulder PhD  
 Function: Chief Executive Officer

Annex: Product list



Doc number	RF-IL-1.12.06_Decl_of_Conformity	
Version	1	Oct 1 <sup>st</sup> 2020
Page	2 of 2	

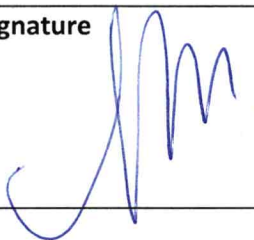
## Appendix to declaration of conformity NGSgo<sup>®</sup> workflow, IVD 98/79: product list

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

This product list belongs to the Declaration of Conformity of NGSgo<sup>®</sup> workflow, 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 product number.

Cat. no.	Product name
2842129	NGSgo <sup>®</sup> Workflow A, B, C, DRB1, DQB1 (4x24)
2842139	NGSgo <sup>®</sup> Workflow A, B, C, DRB1, DQB1 (2x96)
2842629	NGSgo <sup>®</sup> Workflow HLA Genesuite (4x24)
2842639	NGSgo <sup>®</sup> Workflow HLA Genesuite (2x96)

<b>Name</b>	W. Mulder PhD	<b>Signature</b> 
<b>Function</b>	Chief Executive Officer	
<b>Place of issue</b>	Utrecht, the Netherlands	
<b>Date of issue</b>	Oct 1 <sup>st</sup> 2020	