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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  
 2022-05-06



Name: W. Mulder PhD  
 Function: Chief Executive Officer

Annex: Product list

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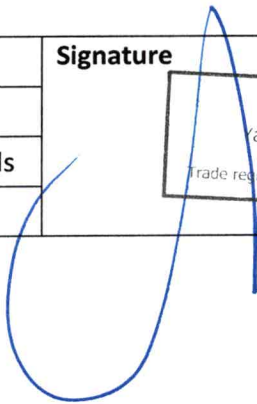

## Appendix to declaration of conformity NGSgo®-MX11-3, REGULATION (EU) 2017/746: product list

Company name : Genome Diagnostics B.V.  
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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

<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>	2022-05-06	