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## Declaration of conformity NGSengine®, 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. NGSengine® 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



Name: M. Penning PhD  
Function: General Manager

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Annex: Product list

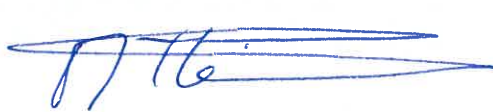
## Appendix to declaration of conformity NGSengine®, REGULATION (EU) 2017/746: product list

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This product list belongs to the Declaration of Conformity of NGSengine®, 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
4949940	871846936ngsengineX5	NGSengine® Standard Entry, one year
4949740	871846936ngsengineX5	NGSengine® One Year Standard Extension
4949840	871846936ngsengineX5	NGSengine® Premium Entry, five years
4949640	871846936ngsengineX5	NGSengine® Five Year Premium Extension

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