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## Declaration of conformity NGSengine<sup>®</sup>, IVD 98/79; ANNEX III

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

We hereby declare that the distributed CE marked medical devices, listed on the attached product list, conform to the required technical documentation, in accordance with Annex III, other device of the EC-Directive, the Council Directive 98/79/EC of 27 October 1998, concerning in vitro diagnostic medical devices.

In addition, we ensure and declare that the distributed CE marked medical devices meet the provisions of the EC-Directive which apply to them.

This Declaration of Conformity covers the NGSengine<sup>®</sup> products as specified in the product list belonging to this declaration.

Utrecht  
10-01-2020

Name: W. Mulder PhD  
Function: Chief Executive Officer

Annex: Product list

<p><b>GenDx</b> Yalelaan 48   3584 CM Utrecht The Netherlands Trade register: 30202468   VAT: NL814323194B01</p>
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## Appendix to declaration of conformity NGSengine<sup>®</sup>, IVD 98/79; ANNEX III: product list

Company name : Genome Diagnostics B.V.  
 Visiting address : Yalelaan 48  
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This product list belongs to the Declaration of Conformity of NGSengine<sup>®</sup>, IVD 98/79, ANNEX III, 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
4849940	NGSengine <sup>®</sup> Standard Entry (1 year)
4849740	NGSengine <sup>®</sup> Standard Extension (+1 year)
4849840	NGSengine <sup>®</sup> Premium Entry (5 years)
4849640	NGSengine <sup>®</sup> Premium Extension (+5 years)

<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	