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EC Declaration of Conformity NGSengine®

The undersigned,

Company name : Genome Diagnostics BV
 Visiting address : Yalelaan 48
 Postal address : n/a
 Post code : 3584 CM
 City : Utrecht
 Country : The Netherlands
 Telephone : +31 (0)30 – 252 3799

being manufacturer, declares under his sole responsibility that the medical device

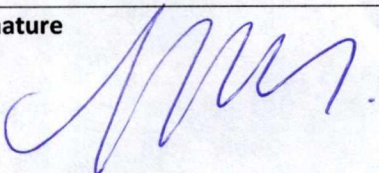
Product group : HLA Typing Software
 Make : NGSengine®
 Model/type/category : n/a
 Other references : n/a

to which this declaration relates are in conformity with the provisions of the

In Vitro Diagnostic Medical Devices Directive (IVDD) 98/78/EC

which apply to them, following the procedure set out in Annexe(s):

Annex III

Name	W. Mulder PhD	Signature 
Function	Managing Director	
Place of issue	Utrecht, The Netherlands	
Date of issue	January 10 th 2019	

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Appendix to EC Declaration of Conformity NGSengine®.

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Product list NGSengine®, IVD 98/79; Annex III

This product list belongs to the Declaration of Conformity, and specifies the CE marked products concerned that Genome Diagnostics BV intends to distribute in conformity with the provisions of the Council Directive 98/79/EC 27 October 1998, concerning in vitro diagnostic medical devices.

The following list identifies the products by product name, version and product number.

Table 1. The different product numbers belonging to NGSengine.

Device name	Variants	Product number
NGSengine	Standard Entry ¹	4849940
NGSengine	One Year Standard Extension	4849740
NGSengine	Premium Entry ²	4849840
NGSengine	Five Year Premium Extension	4849640

¹ One Year

² Five Year

Name	W. Mulder PhD	Signature 
Function	Managing Director	
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