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## ***EC Declaration of Conformity SBTengine®***

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 / -fax : +31 (0)30 – 252 3799 / +31 (0)30 – 254 2611

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


Product group : HLA Typing Software  
 Make : SBTengine®  
 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**

<b>Name</b>	W. Mulder PhD	<b>Signature</b>  <b>GenDx</b> Yalelaan 48   3584 CM Utrecht The Netherlands Trade register: 30202468   VAT: NL814323194B01
<b>Function</b>	Managing Director	
<b>Place of issue</b>	Utrecht, The Netherlands	
<b>Date of issue</b>	28 April 2016	

## Appendix to EC Declaration of Conformity SBTengine®.

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### Product list SBTengine®, 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 SBTengine.


Device name	Variants		Product number
SBTengine	Standard Entry <sup>1</sup>	1 license	4109931
SBTengine	Standard Entry <sup>1</sup>	2 licenses	4109932
SBTengine	Standard Entry <sup>1</sup>	3 licenses	4109933
SBTengine	Standard Entry <sup>1</sup>	4 licenses	4109934
SBTengine	Standard Entry <sup>1</sup>	5 licenses	4109935
SBTengine	Standard Entry <sup>1</sup>	6 licenses	4109936
SBTengine	Standard Entry <sup>1</sup>	7 licenses	4109937
SBTengine	Standard Entry <sup>1</sup>	8 licenses	4109938
SBTengine	Standard Entry <sup>1</sup>	9 licenses	4109939
SBTengine	Standard Entry <sup>1</sup>	custom	4109930
SBTengine	One Year Standard Extension	1 license	4109731
SBTengine	One Year Standard Extension	2 licenses	4109732
SBTengine	One Year Standard Extension	3 licenses	4109733
SBTengine	One Year Standard Extension	4 licenses	4109734
SBTengine	One Year Standard Extension	5 licenses	4109735
SBTengine	One Year Standard Extension	6 licenses	4109736
SBTengine	One Year Standard Extension	7 licenses	4109737
SBTengine	One Year Standard Extension	8 licenses	4109738
SBTengine	One Year Standard Extension	9 licenses	4109739
SBTengine	One Year Standard Extension	custom	4109730

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SBTEngine	Premium Entry <sup>2</sup>	1 license	4109831
SBTEngine	Premium Entry <sup>2</sup>	2 licenses	4109832
SBTEngine	Premium Entry <sup>2</sup>	3 licenses	4109833
SBTEngine	Premium Entry <sup>2</sup>	4 licenses	4109834
SBTEngine	Premium Entry <sup>2</sup>	5 licenses	4109835
SBTEngine	Premium Entry <sup>2</sup>	6 licenses	4109836
SBTEngine	Premium Entry <sup>2</sup>	7 licenses	4109837
SBTEngine	Premium Entry <sup>2</sup>	8 licenses	4109838
SBTEngine	Premium Entry <sup>2</sup>	9 licenses	4109839
SBTEngine	Premium Entry <sup>2</sup>	custom	4109830
SBTEngine	Five Year Premium Extension	1 license	4109631
SBTEngine	Five Year Premium Extension	2 licenses	4109632
SBTEngine	Five Year Premium Extension	3 licenses	4109633
SBTEngine	Five Year Premium Extension	4 licenses	4109634
SBTEngine	Five Year Premium Extension	5 licenses	4109635
SBTEngine	Five Year Premium Extension	6 licenses	4109636
SBTEngine	Five Year Premium Extension	7 licenses	4109637
SBTEngine	Five Year Premium Extension	8 licenses	4109638
SBTEngine	Five Year Premium Extension	9 licenses	4109639
SBTEngine	Five Year Premium Extension	custom	4109630

<sup>1</sup> One Year

<sup>2</sup> Five Year

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