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## Declaration of conformity SBTexcellerator<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 SBTexcellerator<sup>®</sup> products as specified in the product list belonging to this declaration.

Utrecht  
10-01-20

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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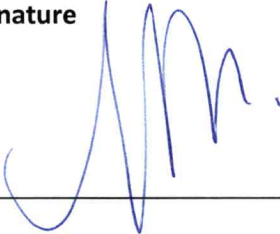
### Appendix to declaration of conformity SBTexcellerator®, IVD 98/79; ANNEX III: product list

Company name : Genome Diagnostics B.V.  
 Visiting address : Yalelaan 48  
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This product list belongs to the Declaration of Conformity of SBTexcellerator®, 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
4102084	SBTexcellerator® HLA-C Core Kit
4102184	SBTexcellerator® HLA-C Extended Kit
4102284	SBTexcellerator® HLA-C Full Kit
4106384	SBTexcellerator® HLA-DQA1 Full Kit
4104084	SBTexcellerator® HLA-DQB1 Core Kit
4104184	SBTexcellerator® HLA-DQB1 Extended Kit
4104284	SBTexcellerator® HLA-DQB1 Full Kit
4107384	SBTexcellerator® HLA-DPA1 Full Kit
4103084	SBTexcellerator® HLA-DPB1 Core Kit
4103184	SBTexcellerator® HLA-DPB1 Extended Kit
4103284	SBTexcellerator® HLA-DPB1 Full Kit
4108084	SBTexcellerator® HLA-G Core Kit

<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	