

## Declaration of conformity SBT*excellerator*<sup>®</sup>, IVD 98/79; Annex III; non list 2b.

Company name : Genome Diagnostics BV  
Visiting address : Yalelaan 48  
Post code : 3584 CM  
City : Utrecht  
Country : The Netherlands  
Telephone / -fax : +31 (0)30 – 252 3799 / +31 (0)30 – 254 2611

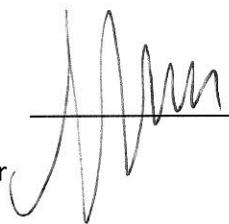
We hereby declare that the distributed CE marked medical devices, listed on the attached product list, conform to the required technical documentation, in accordance with Annex III of the "EC-Directive", the Council Directive 98/79/EC of 27 October 1998, concerning in vitro diagnostic medical devices.

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 SBT*excellerator*<sup>®</sup> products as specified in the product list belonging to this declaration.

Utrecht  
27 March 2015

Name: W. Mulder PhD  
Function: Managing Director



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Annex: Product list

## Appendix to Annex III; non list 2b.

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### Product list SBTexcellerator<sup>®</sup>, IVD 98/79; Annex III; non list 2b.

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.

Product name	Version	Product number
SBTexcellerator <sup>®</sup> HLA-C	Core kit	4102084
	Extended kit	4102184
SBTexcellerator <sup>®</sup> HLA-DPB1	Core kit	4103084
	Extended kit	4103184
SBTexcellerator <sup>®</sup> HLA-DQB1	Core kit	4104084
	Extended kit	4104184
SBTexcellerator <sup>®</sup> HLA-DQA1	Full kit	4106384
SBTexcellerator <sup>®</sup> HLA-DPA1	Full kit	4107384
SBTexcellerator <sup>®</sup> HLA-G	Core kit	4108084

