

Doc number	RF-SBTX- 1.12.06_Decl_of_Conformity	
Version	1	Oct 1 st 2020
Page	1 of 2	

Declaration of conformity SBTexcellerator®, IVD 98/79

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

The following declaration of conformity is issued under the sole responsibility of Genome Diagnostics B.V.

We hereby declare that the distributed CE marked medical devices listed on the attached “Product List” conform to the applicable essential requirements of the EC-Directive 98/79/EC of 27 October 1998 on in vitro diagnostic medical devices.

SBTexcellerator® meets the provisions of Annex IV, List B.

The devices listed in the appendix “Product List” are assessed for conformity by TÜV SÜD Product Service GmbH, substantiated by CE-certificate V1 102580 0001 Rev. 02.

Notified body name : TÜV SÜD Product Service GmbH
 NB identification code : 0123
 Visiting address : Ridlerstrasse 65
 Postal code : D-80339
 City : München
 Country : Germany

In addition, we ensure that the devices listed in the “Product List” are manufactured under a quality management system conform ISO 13485:2016 and EN ISO 13485:2016.

Utrecht
10-01-20


 Name: W. Mulder PhD
 Function: Chief Executive Officer

Annex: Product list



Doc number	RF-SBTX- 1.12.06_Decl_of_Conformity	
Version	1	Oct 1 st 2020
Page	2 of 2	

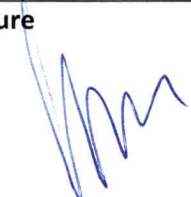
Appendix to declaration of conformity SBTexcellerator®, IVD 98/79: product list

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

This product list belongs to the Declaration of Conformity of SBTexcellerator®, IVD 98/79, 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
4100084	SBTexcellerator® HLA-A Core Kit
4100184	SBTexcellerator® HLA-A Extended Kit
4100284	SBTexcellerator® HLA-A Full kit
4101084	SBTexcellerator® HLA-B Core Kit
4101184	SBTexcellerator® HLA-B Extended Kit
4101284	SBTexcellerator® HLA-B Full Kit
4105084	SBTexcellerator® HLA-DRB1 Core Kit
4105184	SBTexcellerator® HLA-DRB1 Extended Kit
4105284	SBTexcellerator® HLA-DRB1 Full kit
4105384	SBTexcellerator® HLA-DRB3/4/5 Core Kit

Name	W. Mulder PhD	Signature 
Function	Chief Executive Officer	
Place of issue	Utrecht, the Netherlands	
Date of issue	Oct 1 st 2020	