

Doc number	CE-SBTX-ANX04-DOC-01	
Version	6	03 June 2020
Page	1 of 4	

Declaration of conformity SBTexcellerator®, IVD 98/79; Annex II; list b.

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 and Annex IV of the "EC-Directive", the Council Directive 98/79/EC of 27 October 1998, concerning in vitro diagnostic medical devices.

The devices listed in the "Product List" are assessed for conformity by Tüv Süd Product Service GmbH, substantiated by CE-certificate V1 102580 0001 Rev. 01.

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 13495:2016.

Utrecht
 03 June 2020



Name: W. Mulder PhD
 Function: Chief Executive Officer

Annex: Product list

Doc number	CE-SBTX-ANX04-DOC-01	
Version	6	03 June 2020
Page	2 of 4	

Appendix to Declaration of conformity SBTexcellerator[®], IVD 98/79 Annex II; list b: Product List

Product list SBTexcellerator[®], IVD 98/79 Annex II list b.

This product list belongs to the Declaration of Conformity SBTexcellerator[®], and specifies the CE marked products concerned that Genome Diagnostics B.V. intends to distribute.

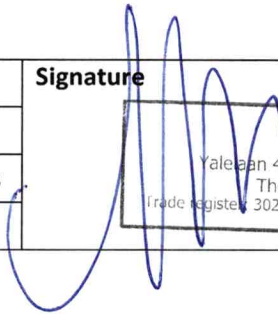
The following list identifies the products by product name, version and product number.

Product name	Version	Product number
SBTexcellerator [®] HLA-A	Core kit	4100084
	Extended kit	4100184
SBTexcellerator [®] HLA-B	Core kit	4101084
	Extended kit	4101184
SBTexcellerator [®] HLA-DRB 1	Core kit	4105084
	Extended kit	4105184
SBTexcellerator [®] HLA-DRB 3/4/5	Core kit	4105384

Doc number	CE-SBTX-ANX04-DOC-01	
Version	6	03 June 2020
Page	3 of 4	

Product name	Product number
SBTexcellerator® Supplement	
SBTexcellerator® HLA-A A13 GSSP (3000199.4)	3000199-A13
SBTexcellerator® HLA-A A14 GSSP (3000199.5)	3000199-A14
SBTexcellerator® HLA-A A15 GSSP (3000199.6)	3000199-A15
SBTexcellerator® HLA-A A16 GSSP (3000199.7)	3000199-A16
SBTexcellerator® HLA-A A17 GSSP (3000199.8)	3000199-A17
SBTexcellerator® HLA-A A18 GSSP (3000199.9)	3000199-A18
SBTexcellerator® HLA-A A19 GSSP (3000199.10)	3000199-A19
SBTexcellerator® HLA-A A20 GSSP (3000199.11)	3000199-A20
SBTexcellerator® HLA-A A21 GSSP (3000199.12)	3000199-A21
SBTexcellerator® HLA-A A22 GSSP (3000199.13)	3000199-A22
SBTexcellerator® HLA-A A23 GSSP (3000199.14)	3000199-A23
SBTexcellerator® HLA-A A24 GSSP (3000199.15)	3000199-A24
SBTexcellerator® HLA-A A25 GSSP (3000199.16)	3000199-A25
SBTexcellerator® HLA-A A26 GSSP (3000199.17)	3000199-A26
SBTexcellerator® HLA-A A27 GSSP (3000199.18)	3000199-A27
SBTexcellerator® HLA-A A28 GSSP (3000199.19)	3000199-A28
SBTexcellerator® HLA-A A29 GSSP (3000199.20)	3000199-A29
SBTexcellerator® HLA-A A30 GSSP (3000199.21)	3000199-A30
SBTexcellerator® HLA-A A31 GSSP (3000199.22)	3000199-A31
SBTexcellerator® HLA-A A32 GSSP (3000199.23)	3000199-A32
SBTexcellerator® HLA-A A33 GSSP (3000199.24)	3000199-A33
SBTexcellerator® HLA-A A34 GSSP (3000199.25)	3000199-A34
SBTexcellerator® HLA-A A35 GSSP (3000199.26)	3000199-A35
SBTexcellerator® HLA-A A36 GSSP (3000199.27)	3000199-A36
SBTexcellerator® HLA-A A37 GSSP (3000199.28)	3000199-A37
SBTexcellerator® HLA-A A38 GSSP (3000199.29)	3000199-A38
SBTexcellerator® HLA-A A39 GSSP (3000199.30)	3000199-A39
SBTexcellerator® HLA-A A40 GSSP (3000199.31)	3000199-A40
SBTexcellerator® HLA-B B9 SEQ 5F (3000299.1)	3000299-B9
SBTexcellerator® HLA-B B10 SEQ 5R (3000299.2)	3000299-B10
SBTexcellerator® HLA-B B12 GSSP (3000299.4)	3000299-B12
SBTexcellerator® HLA-B B14 GSSP (3000299.6)	3000299-B14
SBTexcellerator® HLA-B B16 GSSP (3000299.8)	3000299-B16
SBTexcellerator® HLA-B B18 GSSP (3000299.10)	3000299-B18
SBTexcellerator® HLA-B B19 GSSP (3000299.11)	3000299-B19
SBTexcellerator® HLA-B B22 GSSP (3000299.14)	3000299-B22
SBTexcellerator® HLA-B B23 GSSP (3000299.15)	3000299-B23
SBTexcellerator® HLA-B B26 GSSP (3000299.17)	3000299-B26
SBTexcellerator® HLA-B B27 GSSP (3000299.18)	3000299-B27
SBTexcellerator® HLA-B B28 GSSP (3000299.19)	3000299-B28
SBTexcellerator® HLA-B B29 SEQ 1F (3000299.20)	3000299-B29
SBTexcellerator® HLA-B B30 GSSP (3000299.21)	3000299-B30
SBTexcellerator® HLA-B B31 GSSP (3000299.22)	3000299-B31
SBTexcellerator® HLA-B B32 GSSP (3000299.23)	3000299-B32
SBTexcellerator® HLA-B B33 GSSP (3000299.24)	3000299-B33
SBTexcellerator® HLA-B B34 GSSP (3000299.25)	3000299-B34
SBTexcellerator® HLA-B B35 GSSP (3000299.26)	3000299-B35
SBTexcellerator® HLA-B B36 GSSP (3000299.27)	3000299-B36
SBTexcellerator® HLA-B B37 GSSP (3000299.28)	3000299-B37

SBTexcellerator® HLA-B B38 GSSP (3000299.29)	3000299-B38
SBTexcellerator® HLA-B B39 GSSP (3000299.30)	3000299-B39
SBTexcellerator® HLA-B B40 GSSP (3000299.31)	3000299-B40
SBTexcellerator® HLA-B B41 GSSP (3000299.32)	3000299-B41
SBTexcellerator® HLA-B B42 GSSP (3000299.33)	3000299-B42
SBTexcellerator® HLA-B B43 GSSP (3000299.34)	3000299-B43
SBTexcellerator® HLA-B B44 GSSP (3000299.35)	3000299-B44
SBTexcellerator® HLA-B B45 GSSP (3000299.36)	3000299-B45
SBTexcellerator® HLA-B B46 GSSP (3000299.37)	3000299-B46
SBTexcellerator® HLA-B B47 GSSP (3000299.38)	3000299-B47
SBTexcellerator® HLA-B B48 GSSP (3000299.39)	3000299-B48
SBTexcellerator® HLA-B B49 GSSP (3000299.40)	3000299-B49
SBTexcellerator® HLA-B B50 GSSP (3000299.41)	3000299-B50
SBTexcellerator® HLA-B B51 GSSP (3000299.42)	3000299-B51
SBTexcellerator® HLA-B B52 GSSP (3000299.43)	3000299-B52
SBTexcellerator® HLA-DRB1 R9 SEQ 2Rb (3000699.1)	3000699-R9
SBTexcellerator® HLA-DRB1 R11 GSSP (3000699.3)	3000699-R11
SBTexcellerator® HLA-DRB1 R12 GSSP (3000699.4)	3000699-R12
SBTexcellerator® HLA-DRB1 R13 GSSP (3000699.5)	3000699-R13
SBTexcellerator® HLA-DRB1 R14 GSSP (3000699.6)	3000699-R14
SBTexcellerator® HLA-DRB1 R16 GSSP (3000699.8)	3000699-R16
SBTexcellerator® HLA-DRB1 R17 GSSP (3000699.9)	3000699-R17
SBTexcellerator® HLA-DRB1 R18 GSSP (3000699.10)	3000699-R18
SBTexcellerator® HLA-DRB1 R19 GSSP (3000699.11)	3000699-R19
SBTexcellerator® HLA-DRB1 R20 GSSP (3000699.12)	3000699-R20
SBTexcellerator® HLA-DRB1 R21 GSSP (3000699.13)	3000699-R21
SBTexcellerator® HLA-DRB1 R22 GSSP (3000699.14)	3000699-R22
SBTexcellerator® HLA-DRB1 R23 GSSP (3000699.15)	3000699-R23
SBTexcellerator® HLA-DRB1 R24 GSSP (3000699.16)	3000699-R24
SBTexcellerator® HLA-DRB1 R25 GSSP (3000699.17)	3000699-R25
SBTexcellerator® HLA-DRB1 R26 GSSP (3000699.18)	3000699-R26
SBTexcellerator® HLA-DRB1 R27 GSSP (3000699.19)	3000699-R27
SBTexcellerator® HLA-DRB1 R28 GSSP (3000699.20)	3000699-R28
SBTexcellerator® HLA-DRB1 R29 GSSP (3000699.21)	3000699-R29
SBTexcellerator® HLA-DRB1 R30 GSSP (3000699.22)	3000699-R30
SBTexcellerator® HLA-DRB1 R31 GSSP (3000699.23)	3000699-R31

Name	W. Mulder PhD	Signature  
Function	Chief Executive Officer	
Place of issue	Utrecht, The Netherlands	
Date of issue	03 June 2020	