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Declaration of conformity NGSgo® workflow compatible with Illumina, IVD 98/79/EC.

Company name : Genome Diagnostics BV
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", the Council Directive 98/79/EC of the council of 27 October 1998, concerning in vitro diagnostic medical devices.

The NGSgo workflow compatible with Illumina consists of a three-component workflow for the amplification and library preparation of human genomic DNA:
NGSgo®-AmpX, NGSgo®-LibrX compatible with Illumina and NGSgo-IndX compatible with Illumina.

NGSgo® workflow configurations and their applicable Directive-annex combine as follows:

- HLA-A, -B, -DRB1 and -DRB3/4/5 meet the provisions of Annex IV.
- HLA-C, -DPB1, -DQB1, -DQA1, and -DPA1 meet the provisions of Annex III.

The devices listed in the "Product List" that meet the provisions of Annex IV are assessed for conformity by TÜV SÜD Product Service GmbH, substantiated by CE-certificate V1 102580.

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
01 August 2019



Name: W. Mulder PhD
Function: Chief Executive Officer

Annex: Product list

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Appendix to the Declaration of conformity NGSgo® compatible with Illumina: Product list

Company name : Genome Diagnostics BV
 Visiting address : Yalelaan 48
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This product list belongs to the Declaration of Conformity of NGSgo® workflow compatible with Illumina, and specifies the CE marked products concerned that Genome Diagnostics BV intends to distribute. The list identifies the products by product name, format and product number.

Name of device, components, parts and/or accessories as per product label	Σ	Catalogue number	
NGSgo Workflow compatible with Illumina HLA-A, B, C, DRB1, DQB1	4x24	2842129	
	2x96	2842139	
NGSgo Workflow compatible with Illumina HLAGeneSuite	4x24	2842629	
	2x96	2842639	
NGSgo-AmpX Amplification primers HLA-A, B, C, DRB1, DQB1	24	2841102	
NGSgo-AmpX Amplification primers HLA-DPA1, DPB1, DQA1, DRB3/4/5		2841502	
NGSgo-AmpX Amplification primers HLAGeneSuite		2841602	
NGSgo-AmpX Amplification primers HLA-A		2840102	
NGSgo-AmpX Amplification primers HLA-B		2840202	
NGSgo-AmpX Amplification primers HLA-C		2840302	
NGSgo-AmpX Amplification primers HLA-DRB1		2840602	
NGSgo-AmpX Amplification primers HLA-DQB1		2840502	
NGSgo-AmpX Amplification primers HLA-DPB1		2840402	
NGSgo-AmpX Amplification primers HLA-DPA1		2840902	
NGSgo-AmpX Amplification primers HLA-DQA1		2840802	
NGSgo-AmpX Amplification primers HLA-DRB3/4/5		2840702	
NGSgo-AmpX Amplification primers HLA-A, B, C, DRB1, DQB1		96	2841162
NGSgo-AmpX Amplification primers HLA-DPA1, DPB1, DQA1, DRB3/4/5			2841562
NGSgo-AmpX Amplification primers HLAGeneSuite	2841662		
NGSgo-AmpX Amplification primers HLA-A	2840162		
NGSgo-AmpX Amplification primers HLA-B	2840262		
NGSgo-AmpX Amplification primers HLA-C	2840362		
NGSgo-AmpX Amplification primers HLA-DRB1	2840662		
NGSgo-AmpX Amplification primers HLA-DQB1	2840562		
NGSgo-AmpX Amplification primers HLA-DPB1	2840462		
NGSgo-AmpX Amplification primers HLA-DPA1	2840962		
NGSgo-AmpX Amplification primers HLA-DQA1	2840862		
NGSgo-AmpX Amplification primers HLA-DRB3/4/5	2840762		

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NGSgo-AmpX Amplification primers HLA-A, B, C, DRB1, DQB1		2841152
NGSgo-AmpX Amplification primers HLA-DPA1, DPB1, DQA1, DRB3/4/5		2841552
NGSgo-AmpX Amplification primers HLAGeneSuite		2841652
NGSgo-AmpX Amplification primers HLA-A		2840152
NGSgo-AmpX Amplification primers HLA-B		2840252
NGSgo-AmpX Amplification primers HLA-C		2840352
NGSgo-AmpX Amplification primers HLA-DRB1	192	2840652
NGSgo-AmpX Amplification primers HLA-DQB1		2840552
NGSgo-AmpX Amplification primers HLA-DPB1		2840452
NGSgo-AmpX Amplification primers HLA-DPA1		2840952
NGSgo-AmpX Amplification primers HLA-DQA1		2840852
NGSgo-AmpX Amplification primers HLA-DRB3/4/5		2840752
NGSgo-LibrX Library preparation kit compatible with Illumina	48	2842805
NGSgo-LibrX Library preparation kit compatible with Illumina	96	2842605
NGSgo-LibrX Library preparation kit compatible with Illumina	192	2842505
NGSgo-LibrX Library preparation kit compatible with Illumina	384	2842405
NGSgo-IndX Adapter & indices set A compatible with Illumina		2842203
NGSgo-IndX Adapter & indices set B compatible with Illumina	4x24	2842303
NGSgo-IndX Adapter & indices set C compatible with Illumina		2842403
NGSgo-IndX Adapter & indices set D compatible with Illumina		2842503
NGSgo-IndX Adapter & indices set A+B compatible with Illumina	2x96	2842603
NGSgo-IndX Adapter & indices set C+D compatible with Illumina	2x96	2842703
NGSgo-IndX Adapter & indices set A+B+C+D compatible with Illumina	1x384	2842803

Σ = amount of tests that can be performed with this kit/component

Name	W. Mulder PhD	Signature  GenDx Yalelaan 18 3584 CM Utrecht The Netherlands Trade register: 30.02468 VAT: NL814323194B01
Function	Chief Executive Officer	
Place of issue	Utrecht, The Netherlands	