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Declaration of conformity KMR products, 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 KMR products as specified in the product list belonging to this declaration.

Utrecht
2023-09-19



Name: Maarten Penning
Function: General Manager

Annex: Product list

Appendix to declaration of conformity KMR products, IVD 98/79; ANNEX III:

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product list


Company name : Genome Diagnostics B.V.
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This product list belongs to the Declaration of Conformity of KMR products, 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
8841781	KMRtype® Genotyping Kit
8842982	KMRtrack® Monitoring Kit
8844342-04	KMRtrack® KMR004
8844342-09	KMRtrack® KMR009
8844342-10	KMRtrack® KMR010
8844342-11	KMRtrack® KMR011
8844342-13	KMRtrack® KMR013
8844342-14	KMRtrack® KMR014
8844342-16	KMRtrack® KMR016
8844342-17	KMRtrack® KMR017
8844342-19	KMRtrack® KMR019
8844342-20	KMRtrack® KMR020
8844342-28	KMRtrack® KMR028
8844342-29	KMRtrack® KMR029
8844342-30	KMRtrack® KMR030
8844342-31	KMRtrack® KMR031
8844342-33	KMRtrack® KMR033
8844342-34	KMRtrack® KMR034
8844342-35	KMRtrack® KMR035
8844342-36	KMRtrack® KMR036
8844342-37	KMRtrack® KMR037
8844342-38	KMRtrack® KMR038
8844342-39	KMRtrack® KMR039
8844342-40	KMRtrack® KMR040
8844342-41	KMRtrack® KMR041
8844342-42	KMRtrack® KMR042
8844342-43	KMRtrack® KMR043
8844342-44	KMRtrack® KMR044
8844342-45	KMRtrack® KMR045
8844342-46	KMRtrack® KMR046
8844342-47	KMRtrack® KMR047
8844342-48	KMRtrack® KMR048
8844342-49	KMRtrack® KMR049
8844342-50	KMRtrack® KMR050
8844342-51	KMRtrack® KMR051
8844342-52	KMRtrack® KMR052
8844342-53	KMRtrack® KMR053
8844342-54	KMRtrack® KMR054
8844342-55	KMRtrack® KMR055
8844342-56	KMRtrack® KMR056
8844342-57	KMRtrack® KMR057
8843283	KMRassay™ qPCR Buffer & Enzyme
8843284	KMRassay™ Reference Assay 901
4849951	KMRengine® Standard Entry (1 year)
4849751	KMRengine® Standard Extension (+1 year)
4849851	KMRengine® Premium Entry (5 years)
4849651	KMRengine® Premium Extension (+5 years)

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Name	Maarten Penning	Signature 
Function	General Manager	
Place of issue	Utrecht, the Netherlands	
Date of issue	2023-09-19	