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## EC Declaration of Conformity: Chimerism Monitoring Workflow

Company name : Genome Diagnostics BV  
 Visiting address : Yalelaan 48  
 Postal address : n/a  
 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 of the "EC-Directive", the Council Directive 98/79/EC of 27 October 1998, concerning in vitro diagnostic medical devices.

The Chimerism Monitoring Workflow consists of a three-component workflow by means of qPCR to genotype both recipient and donor(s) before transplantation and subsequently monitor the chimeric status over time after transplantation:  
 KMRtype®, KMRtrack® and KMRassay™.

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 Chimerism Monitoring Workflow products as specified in the product list belonging to this declaration.

Name: W. Mulder PhD  
 Function: Chief Executive Officer



Annex: Product list Chimerism Monitoring Workflow, IVD 98/79; Annex III

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## Appendix to EC Declaration of Conformity Chimerism Monitoring Workflow

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### Product list Chimerism Monitoring Workflow, IVD 98/79; Annex III

The products listed in Table 1 belong to the Declaration of Conformity of the Chimerism Monitoring Workflow 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.

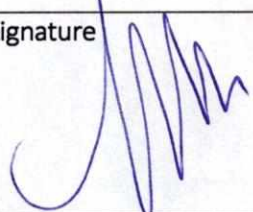
Table 1. *Components of the Chimerism Monitoring Workflow*

Component name	Purpose	Rxn	Description	Cat. No.
KMRtype	Genotyping	24	KMRtype Genotyping kit	8841781
KMRtrack	Monitoring	48	KMRtrack Monitoring kit	8842982
			KMRtrack KMR004	8844342-04
			KMRtrack KMR009	8844342-09
			KMRtrack KMR010	8844342-10
			KMRtrack KMR011	8844342-11
			KMRtrack KMR013	8844342-13
			KMRtrack KMR014	8844342-14
			KMRtrack KMR016	8844342-16
			KMRtrack KMR017	8844342-17
			KMRtrack KMR019	8844342-19
			KMRtrack KMR020	8844342-20
			KMRtrack KMR028	8844342-28
			KMRtrack KMR029	8844342-29
			KMRtrack KMR030	8844342-30
			KMRtrack KMR031	8844342-31
			KMRtrack KMR033	8844342-33
KMRtrack KMR034	8844342-34			
KMRtrack KMR035	8844342-35			
KMRtrack KMR036	8844342-36			
KMRtrack KMR037	8844342-37			



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			KMRtrack KMR038	8844342-38
			KMRtrack KMR039	8844342-39
			KMRtrack KMR040	8844342-40
			KMRtrack KMR041	8844342-41
			KMRtrack KMR042	8844342-42
			KMRtrack KMR043	8844342-43
			KMRtrack KMR044	8844342-44
			KMRtrack KMR045	8844342-45
			KMRtrack KMR046	8844342-46
			KMRtrack KMR047	8844342-47
			KMRtrack KMR048	8844342-48
			KMRtrack KMR049	8844342-49
			KMRtrack KMR050	8844342-50
			KMRtrack KMR051	8844342-51
			KMRtrack KMR052	8844342-52
			KMRtrack KMR053	8844342-53
			KMRtrack KMR054	8844342-54
			KMRtrack KMR055	8844342-55
			KMRtrack KMR056	8844342-56
			KMRtrack KMR057	8844342-57
KMRassay	Genotyping and monitoring	288	KMRassay qPCR Buffer & Enzyme	8843283
			KMRassay Reference Assay 901	8843284
Rxn = amount of reactions.				

Name	W. Mulder PhD	Signature 
Function	Chief Executive Officer	
Place of issue	Utrecht, The Netherlands	
Date of issue	18 December 2017	