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## EC Declaration of Conformity: KMREngine®

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.

Product group : KMREngine®  
Make : KMREngine®

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 KMREngine® products as specified in the product list belonging to this declaration.

Name: W. Mulder PhD  
Function: Managing Director



Appendix: Product list KMREngine®, IVD 98/79; Annex III

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## Appendix to EC Declaration of Conformity KMEngine®

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 Telephone / -fax : +31 (0)30 – 252 3799 / +31 (0)30 – 254 2611

### Product list KMEngine®, IVD 98/79; Annex III

This product list belongs to the Declaration of Conformity, 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. The different product numbers belonging to KMEngine.

Device name	Variants	Product number
KMEngine	Standard Entry	4849951
KMEngine	One Year Standard Extension	4849751
KMEngine	Premium Entry	4849851
KMEngine	Five Year Premium Extension	4849651

<sup>1</sup> One Year

<sup>2</sup> Five Year

Name	W. Mulder PhD	Signature 
Function	Managing Director	
Place of issue	Utrecht, The Netherlands	
Date of issue (dd-mm-yyyy)	25-01-2018	