


### EC DECLARATION OF CONFORMITY

Legal Manufacturer:	Agilent Technologies Singapore (International) Pte Ltd. No. 1 Yishun Avenue 7 Singapore, 768923	
European Representative:	Agilent Technologies Denmark ApS Produktionsvej 42 DK-2600 Glostrup Denmark	
Manufacturing Site:	Agilent Technologies Denmark ApS Produktionsvej 42 DK-2600 Glostrup Denmark	
Product: Code:	Polyclonal Rabbit Anti-Human IgM/FITC, Rabbit F(ab') <sub>2</sub> F0058	
Classification:	<input type="checkbox"/> Annex II, List B <input checked="" type="checkbox"/> Self-Declaration	
Conformity Assessment Route:	<input type="checkbox"/> Annex IV <input checked="" type="checkbox"/> Annex III	
GMDN Code and Product Term:	57318 Total immunoglobulin M (IgM total) IVD, antibody	
<p>This declaration of conformity is issued under the sole responsibility of the manufacturer. We herewith declare that the above-mentioned product meets the provisions of the Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices. All supporting documentation is retained at the premises of the manufacturer.</p> <p>This declaration is based upon a review that the specific requirements concerning:</p> <ol style="list-style-type: none"> <li>1. The preparation of the required technical documentation;</li> <li>2. The implementation of the specified principles of quality assurance, and;</li> <li>3. The implementation of a systematic procedure for Post-Market Vigilance and Surveillance;</li> </ol> <p>have been satisfactorily fulfilled and that the product is not intended for self-testing.</p>		
List of <b>Harmonised Standards</b> used in full or part:	<ul style="list-style-type: none"> <li>• EN ISO 13485</li> <li>• EN ISO 14971</li> <li>• EN ISO 18113-1</li> <li>• EN ISO 18113-2</li> <li>• EN ISO 15223-1</li> <li>• EN ISO 23640</li> <li>• EN ISO 62366-1</li> </ul>	
Notified Body:	(Applies only for Annex II, List B products)	
(EC) Certificate:	(Applies only for Annex II, List B products)	
Place:	Glostrup, Denmark	
Signed for and on the behalf of Agilent Technologies Singapore (International) Pte Ltd. Signature:		Name: Lars Hansen  Position: Senior RA Specialist  Date: 2020DEC01