


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:	EasyLyse, Erythrocyte-Lysing Reagent S2364		
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:	61165 Blood cell lysis reagent IVD		
<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"> 1. The preparation of the required technical documentation; 2. The implementation of the specified principles of quality assurance, and; 3. The implementation of a systematic procedure for Post-Market Vigilance and Surveillance; <p>have been satisfactorily fulfilled and that the product is not intended for self-testing.</p>			
List of Harmonised Standards used in full or part:	<ul style="list-style-type: none"> • EN ISO 13485 • EN ISO 14971 • EN ISO 18113-2 • EN ISO 15223-1 • EN ISO 23640 		
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