

### EC DECLARATION OF CONFORMITY

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|---|--|--|--|
| Legal Manufacturer:   | Agilent Technologies Singapore (International) Pte Ltd.<br>No. 1 Yishun Avenue 7<br>Singapore, 768923  |  |  |
| European Representative:  | Agilent Technologies Denmark ApS<br>Produktionsvej 42<br>DK-2600 Glostrup<br>Denmark   |  |  |
| Manufacturing Site:   | Agilent Technologies Denmark ApS<br>Produktionsvej 42<br>DK-2600 Glostrup<br>Denmark   |  |  |
| Product:<br>Code:   | Ig Reagent Rabbit F(ab') <sub>2</sub> /FITC<br>X0929   |  |  |
| Classification:   | <input type="checkbox"/> Annex II, List B<br><input checked="" type="checkbox"/> Self-Declaration  |  |  |
| Conformity Assessment Route:  | <input type="checkbox"/> Annex IV<br><input checked="" type="checkbox"/> Annex III   |  |  |
| GMDN Code and Product Term:   | 41353 Total immunoglobulin G (IgG total) IVD, control  |  |  |
| <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 18113-2</li> <li>• EN ISO 15223-1</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.<br>Signature:   | Name: Lars Hansen<br>Position: Senior RA Specialist<br>Date: 2020DEC01   |  |  |