

## EC DECLARATION OF CONFORMITY

**T-SPOT.COVID**

**Product Code: COV.435/200 / COV.435/300**

We: **Oxford Immunotec Ltd.,**  
Address: 94C Innovation Drive  
Milton Park  
Abingdon  
Oxfordshire  
OX14 4RZ  
United Kingdom

Through our Authorised Representative in Europe,

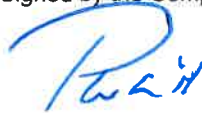
**Oxford Immunotec (Ireland) Ltd**  
Unit 3d North Point House,  
North Point Business Park,  
New Mallow Road,  
Cork,  
Republic of Ireland

Declare on our own responsibility that the *in vitro* diagnostic device: the T-SPOT.COVID test is classified as General IVD and meets the essential requirements of the EC Council Directive 98/79/EC in accordance with the relevant requirements of Annex I and III of the IVD Directive, and is compliant with the legislation of the United Kingdom. The product/system conforms to the following harmonised standards:

- BS EN ISO 13485:2016
- BS EN ISO 14971:2019
- BS EN ISO 23640:2015
- BS EN ISO 18113-2:2011
- BS EN ISO 15223-1:2016
- BS EN 13641:2002

Oxford Immunotec has a certified Quality Management System in place based on the BS EN ISO 13485:2016 standard. This has been certified by Underwriters Laboratories LLC.

Signed by the Company's designated representative;



Dr. Peter Wrighton-Smith  
Chief Executive Officer

Date: 5<sup>th</sup> MAY 2021



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