T-SPOT.*TB*

Oxford Immunotec

# EC DECLARATION OF CONFORMITY

**T-SPOT.*TB*** **Product Code: TB.300/TB.50**

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.*TB* 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;

Jon Hughes Ph.D., FTOPRA
VP, Regulatory Affairs & Quality Assurance

Date: 7 December 2020

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