

EC DECLARATION OF CONFORMITY

Declaration of Conformity No.: TB-DC(EC)-UK-0001

Product Name: T-SPOT®.TB

Product Code(s): TB.300 / TB.50

Manufacturer: Oxford Immunotec Limited
143 Park Drive East
Milton Park
Abingdon
Oxfordshire
United Kingdom
OX14 4SE

Authorised Representative: Oxford Immunotec (Ireland) Limited
Unit 3d North Point House,
North Point Business Park,
New Mallow Road,
Cork
Republic of Ireland
T23 AT2P

Date of First CE Marking 26th June 2004

Conformity Assessment Route: In Vitro-Diagnostic Medical Devices Directive
98/79/EC Annex III

Risk Classification: General IVD

Oxford Immunotec Limited hereby declare that the above-mentioned device is in conformity with the In Vitro-Diagnostic Medical Devices Directive 98/79/EC.

This declaration of conformity is issued under the sole responsibility of, and signed on behalf of the manufacturer, Oxford Immunotec Limited.

Signature:



Name: Chris Dark
Position: Head of Regulatory Affairs
Place: Oxfordshire, OX14 4SE, United Kingdom
Issued: 23rd May 2024

| Revision number | Date of Issue DD MMM YYYY | Reason for change |
|-----------------|------------------------------|---|
| 1-20 | | Details available upon request from Oxford Immunotec |
| 21 | 23 rd Nov 2021 | Periodic Review. Update to BS EN ISO 15223-1:2021 |
| 22 | 23 rd Jun 2022 | Update for change of address and update to template format Template SOP |
| 23 | 08 th Dec 2023 | Removal of 'a PerkinElmer company' from logo |
| 24 | 14 th Mar 2024 | New document number and template format. Addition of 'Date of First CE marking' and revision history table |
| 25 | 23 rd May 2024 | Update to align with current branding. |