

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
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T23 AT2P

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:

A handwritten signature in blue ink, appearing to be "Chris Dark", written over a light blue horizontal line.

Name: Chris Dark

Position: Head of Regulatory Affairs

Place: Oxford Immunotec Limited, 143 Park Drive,
Milton Park, Abingdon, Oxfordshire, OX14 4SE, United Kingdom

Date: 08Dec2023

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