



CERTIFICATE OF REGISTRATION

Oxford Immunotec Ltd

143 Park Drive East
Milton Park
Abingdon
Oxfordshire OX14 4SE UNITED KINGDOM

Facility ID: F001418

UL Medical Regulatory Services of UL LLC®(UL) issues this certificate to the Firm named above, after auditing the Firm’s quality management system and finding it in conformance per the defined scope with respect to:

ISO 13485:2016

with additional regulatory requirements listed on final page of this certificate.

The design, development and manufacture of in-vitro diagnostic devices, including immunological detection assay kits, software, reagents and culture mediums used as aids in the diagnosis of infectious diseases or determination of patient immune status. The servicing and installation of instruments for the isolation of mononuclear immune cells from whole blood samples.

With additional locations listed on Addendum: 1



Authorized by

Paul Hilgeman
Director & Global Industry Leader, Medical
CMIT – Medical Regulatory



Check Certificate Status:
[here](#)

File Number	A13242	Cycle Start Date	April 12, 2022
Certificate Number	1466.220523	Effective Date	May 23, 2022
Initial Issue Date	September 7, 2018	Expiry Date	April 11, 2025

This quality system registration is included in UL’s Directory of Registered Firms and applies to the provision of goods and/or services as specified in the scope of registration from the address(es) shown above. By issuance of this certificate the firm represents that it will maintain its registration in accordance with the applicable requirements. This certificate is not transferable and remains the property of UL Medical and Regulatory Services of UL LLC. Certificates may be verified by visiting the Online Certifications Directory on UL.com.



**UL Medical and Regulatory
Services UL, LLC is an
MDSAP Recognized
Auditing Organization**

UL LLC
333 Pfingsten Road
Northbrook, IL 60062-2096 USA



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Addendum 1

1-1

Facility ID: **F001418**

Oxford Immunotec Ltd
143 Park Drive East, Milton Park
Abingdon OX14 4SE UNITED KINGDOM

Performing: Design, development, manufacturing of in-vitro diagnostic devices; Servicing and installation of instruments; marketing, sales, purchasing.

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Facility ID: **F001418**

Oxford Immunotec Ltd
120C Olympic Avenue , Milton Park
Abingdon, Oxfordshire OX14 4SA UNITED KINGDOM

Performing: Ambient cold storage and distribution.

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Facility ID: **F001418**

Oxford Immunotec Ltd
Unit 2B Trident Park , Basil Hill Rd.
Didcot OX11 7HJ UNITED KINGDOM

Performing: Warehouse.

1-6

Facility ID: **F001418**

Oxford Immunotec Ltd
94C Innovation Drive, Milton Park
Abingdon OX14 4RZ UNITED KINGDOM

Performing: Design, development, manufacturing of in-vitro diagnostic devices; Servicing and installation of instruments; marketing, sales, purchasing

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Additional Regulatory Requirements

Australia:

- Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure

Brazil:

- RDC ANVISA n. 16/2013
- RDC ANVISA n. 23/2012
- RDC ANVISA n. 67/2009

Canada:

- Medical Devices Regulations – Part 1- SOR 98/282

Japan:

- MHLW Ministerial Ordinance 169, Article 4 to Article 68
- PMD Act (,as applicable)

United States:

- 21 CFR 820
- 21 CFR 803
- 21 CFR 806
- 21 CFR 807 – Subparts A to D
- 21 CFR 821 (where applicable)

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