

## EC DECLARATION OF CONFORMITY

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

**Product Name:** T-SPOT®.CMV

**Product Code(s):** CMV.400

**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** 23rd January 2018

**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:** 23<sup>rd</sup> May 2024

Revision number	Date of Issue DD MMM YYYY	Reason for change
1-9		Details available upon request from Oxford Immunotec
10	23 <sup>rd</sup> Nov 2021	Periodic Review. Update to BS EN ISO 15223-1:2021
11	23 <sup>rd</sup> Jun 2022	Update for change of address and update to template format Template SOP
12	08 <sup>th</sup> Dec 2023	Removal of 'a PerkinElmer company' from logo
13	14 <sup>th</sup> Mar 2024	New document number and template format. Addition of 'Date of First CE marking' and revision history table
14	23 <sup>rd</sup> May 2024	Update to align with current branding.