

EC DECLARATION OF CONFORMITY

T-SPOT.CMV

Product Code:

CMV.400

We: **Oxford Immunotec Ltd.,**

Address: 94C Innovation Drive,
Milton Park,
Abingdon,
Oxfordshire,
OX14 4RZ,
United Kingdom

Declare on our own responsibility that the *in vitro* diagnostic device: the T-SPOT.CMV test meets the essential requirements of the EC Council Directive 98/79/EC and is 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:

- ISO 13485:2003, COR1:2009
- BS EN ISO 14971:2012
- BS EN ISO 23640:2015
- BS EN ISO 18113-2:2011
- BS EN ISO 9001:2008
- BS EN 13641:2002
- BS EN ISO 15223-1:2016

Oxford Immunotec has a certified Quality Management System in place based on the ISO13485:2003 standard. This has been certified by Underwriters Laboratories LLC.

Signed by the Company's designated representative;

Dr Jan Pullen

Director, Quality and Regulatory

Date:

