T-Cell *Select*™

Oxford Immunotec

EC DECLARATION OF CONFORMITY

T-Cell *Select* **Product Code: TSK.910 /TSK.960**

We: **Oxford Immunotec Ltd.,**

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

Through our Authorised Representative in Europe,

Oxford Immunotec (Ireland) Ltd
Unit 3d North Point House,
North Point Business Park,
New Mallow Road,
Cork,
Republic of Ireland

Declare on our own responsibility that the *in vitro* diagnostic device: the T-Cell *Select* kit is classified as General IVD and meets the essential requirements of the EC Council Directive 98/79/EC 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:

- BS EN ISO 13485:2016
- BS EN ISO 14971:2019
- BS EN ISO 23640:2015
- BS EN ISO 18113-2:2011
- BS EN ISO 15223-1:2021
- BS EN 13641:2002

Oxford Immunotec has a certified Quality Management System in place based on the BS EN ISO 13485:2016 standard. This has been certified by Underwriters Laboratories LLC.

Signed by the Company's designated representative;

Jon Hughes Ph.D., FTOPRA
VP, Regulatory Affairs & Quality Assurance

Date: 23 Nov. 2021

CE