By Royal Charter

EC Certificate - Full Quality Assurance

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV, excluding Sections 4 and 6

No. **CE 577859**

Issued To: **Oxoid Ltd**
Wade Road
Basingstoke
RG24 8PW
United Kingdom

In respect of:

Design and manufacture of immunoassay reagent kits and controls for detection of Chlamydia.

on the basis of our examination under the requirements of Council Directive 98/79/EC, Annex IV, the quality system was found to meet the requirements of 98/79/EC Annex IV.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2012-01-04** Date: **2020-12-21** Expiry Date: **2023-07-27**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive. For the placing on the market of List A devices covered by this certificate, an EC Design-Examination Certificate according to 98/79/EC Annex IV Section 4 is required and a letter releasing each batch according to Annex IV Section 6.
This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780
BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
A member of BSI Group of Companies.

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Supplementary Information to CE 577859

Issued To:

Oxoid Ltd
Wade Road
Basingstoke
RG24 8PW
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Number	Device Name	Intended use per IFU
Annex II List B		
IVD0305	IMAGEN Chlamydia	The IMAGEN Chlamydia is a qualitative direct immunofluorescence test for the detection of Chlamydia in human urogenital and ophthalmic specimens and for the confirmation of Chlamydia in cell culture.
	IMAGEN Chlamydia Positive Control Slides	The IMAGE Chlamydia Control Slides are for use as a control for the IMAGEN Chlamydia test (Code No. K610111-2)

First Issued: **2012-01-04** Date: **2020-12-21** Expiry Date: **2023-07-27**

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List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 577859**
Date:	**2020-12-21**
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Subcontractor:	**Service(s) supplied**
Remel Europe Limited Remel House Clipper Boulevard West Crossways Dartford DA2 6PT United Kingdom	**Manufacture**
Thermo Fisher Diagnostics B.V Scheepsbouwersweg 1 B 1121 PC Landsmeer The Netherlands	**EU Representative**

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EC Certificate - Full Quality Assurance Certificate History

Certificate No: **CE 577859**
Date: **2020-12-21**
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Date	Reference Number	Action
04 January 2012	7718270	First Issue – Transfer from another Notified Body
17 July 2013	7984854	Certificate renewal
19 July 2018	8959253	Certificate Renewal and amendment of scope to include controls
26 February 2019	8879737	Traceable to NB 0086.
Current	3338426	Addition of EU Representative