bsi.

Certificate

Full Quality Assurance System

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

No. CE 577859

Issued to:

Oxoid Ltd
Wade road
Basingstoke
RG24 8PW
United Kingdom

In respect of:

The design and manufacture of immunoassay reagent kits 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 the IVDD Annex IV.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):

Gary Fenton, Global Assurance Director

First Issued: **4 Jan 2012** Date: **17 Jul 2013**

Expiration Date: **27 Jul 2018**

Conditions of Approval
Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive.
This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.
For the placing on the market of List A devices covered by this certificate, an EC Design-Examination Certificate according to IVDD Annex IV (4) is required. Surveillance as referred to in Annex IV(5) is required.

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Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: +44 (0)845 080 9000

BSI/1023/MD/1112/BLD