

Certificate

Production Quality Assurance



No. CE 80978

Issued to:

ORIGIO Humagen Pipets
2400 Hunters Way
Charlottesville
Virginia
22911
USA

In respect of:

The manufacture of sterile micropipettes and Pasteur pipettes for use in vitro fertilization procedures

on the basis of our examination under the requirements of Council Directive 93/42/EEC, Annex V, Section 3.2.

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

A handwritten signature in black ink, appearing to read 'D. Ford', written over a horizontal line.

David Ford, Director, Healthcare and Testing Services

First Issued: **6 Apr 2004**

Date: **21 Jan 2010**

Expiration Date: **5 Apr 2014**

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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.

Certificate

List of Significant Subcontractors

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

Certificate No. **CE 80978**
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Charlottesville
USA

Subcontractor	Service(s) supplied
Origio A/S Gate A Mollehaven 12 DK-4040 Jyllinge Denmark	EU Representative
Steris Isomedix Services 435 Whitney Street Northborough MA 01532 USA	Sterilization

Certificate

History of Quality Assurance Certificate

Certificate No: CE 80978
Issue Date: 21 Jan 2010
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Charlottesville
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Date	Customer Reference	Action
06 April 2004		First issue
02 April 2009	7160149	Certificate renewal and Steris Isomedix Sterilization location change
21 January 2010	7479496	Company name change from Humagen Fertility Diagnostics to ORIGIO Humagen Pipets and addition of EU representative