

Certificate

Production Quality Assurance



No. CE 61894

Issued to:

**ORIGIO MidAtlantic Devices
77 Elbo Lane
Mount Laurel
New Jersey
08054
USA**

In respect of:

Manufacture of cryopreservation devices (Cryopette®)

Those aspects of Annex V relating to securing and maintaining sterility in the manufacture of plastic tips intended for the manipulation and transfer of oocytes and embryos during IVF and ICSI 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', with a horizontal line underneath.

David Ford, Director, Healthcare and Testing Services

First Issued: 15 Jul 2002

Date: 26 Feb 2010

Expiration Date: 14 Jul 2012

Page: 1 of 1

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.

List of Significant Subcontractors

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

Certificate No. **CE 61894**
Date: **26 Feb 2010**
Issued to: **ORIGIO MidAtlantic Devices**
Mount Laurel
USA

Subcontractor	Service(s) supplied
STERIS Isomedix Services, Inc. 9 Apollo Drive Whippany New Jersey 07981 USA	Gamma Irradiation
Drummond Scientific 500 Parkway Broomall PA 19008 USA	Manufacture

History of Quality Assurance Certificate

Certificate No: CE 61894
Issue Date: 26 Feb 2010
Issued to: ORIGIO MidAtlantic Devices
Mount Laurel
USA

Date	Customer Reference	Action
15 July 2002		First Issue
12 October 2005		Reissue in new format
27 September 2006		Company address change
13 July 2007		Certificate renewal. Amendment to subcontractors name, STERIS Isomedix Services, Inc. Removal of Consumer Product Testing and Embryotech Laboratory from the list of significant subcontractors
February 2010	7482020	Extension to scope for Cryopette® device. Change to company name from Mid-Atlantic Diagnostics, Inc. to ORIGIO MidAtlantic Devices