

# EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

**No.** CE 80978  
Issued To: **Origio Inc.**  
**2400 Hunters Way**  
**Charlottesville**  
**Virginia**  
**22911**  
**USA**

In respect of:

**The manufacture of sterile cryopreservation devices (Cryopette®) and sterile micropipettes/stripper tips intended for the preparation, manipulation and transfer of oocytes, zygotes and embryos during IVF and ICSI procedures**

**Those aspects of Annex V relating to securing and maintaining sterility in the manufacture of Pasteur pipettes for transfer of tissue culture media or other non-body liquids during IVF procedures**

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III certificate is required.

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



Frank Lee, EMEA Compliance & Risk Director

First Issued: **06 April 2004**Date: **04 January 2016**Expiry Date: **05 April 2019**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. 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.

This certificate was issued electronically and is bound by the conditions of the contract.

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## List of Significant Subcontractors

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

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Date: **04 January 2016**  
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<b>Subcontractor:</b>	<b>Service(s) supplied</b>
CooperSurgical Inc., 95 Corporate Drive Trumbull Connecticut 06611 USA	<b>Manufacture Packaging Sterilization</b>
Drummond Scientific 500 Parkway Broomall PA 19008 USA	<b>Manufacture</b>
ORIGIO a/s Knardrupvej 2 Måløv Denmark	<b>EU Representative</b>

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<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Steris Isomedix Services, Inc. 435 Whitney Street Northborough Massachusetts 01532 USA	<b>Sterilization</b>
STERIS Isomedix Services 23 Elizabeth Drive Chester New York 10918 USA	<b>Gamma Sterilization</b>
Steris Isomedix Services 9 Apollo Drive Whippany New Jersey 07981 USA	<b>Sterilization</b>

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Date	Reference Number	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.
18 May 2012	7817823	Change of name, addition of adba names and extension to scope to include plastic tips intended for the manipulation and transfer of oocytes and embryos during IVF and ICSI procedures.
10 May 2013	7915666	Addition of cryopresevation devices (Cryopette®) to certificate scope. Addition of Drummond Scientific and Steris Isomedix, NJ as significant subcontractors.

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Date	Reference Number	Action
14 March 2014	8120225	<p>Certificate renewal.</p> <p>The change of scope from 'The manufacture of cryopreservation devices (Cryopette®), sterile micropipettes and Pasteur pipettes for use in vitro fertilization procedures.</p> <p>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' to</p> <p>'The manufacture of sterile cryopreservation devices (Cryopette®) and sterile micropipettes/stripper tips intended for the preparation, manipulation and transfer of oocytes, zygotes and embryos during IVF and ICSI procedures.</p> <p>Those aspects of Annex V relating to securing and maintaining sterility in the manufacture of Pasteur pipettes for transfer of tissue culture media or other non-body liquids during IVF procedures'.</p>



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Date	Reference Number	Action
12 July 2014	8192019	Removal of ADBA trading names. Addition of Steris Isomedix, New York as gamma sterilisation subcontractor.
04 January 2016	8405607	Addition of CooperSurgical, Inc as manufacturing, packaging, and sterilization subcontractor.

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