bsi.

By Royal Charter

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 cryopresevation 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**

...making excellence a habit.™

bsi.

By Royal Charter

EC Certificate - Production Quality Assurance

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

List of Significant Subcontractors

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

Certificate No:	**CE 80978**
Date:	**04 January 2016**
Issued To:	**Origio Inc.** **2400 Hunters Way** **Charlottesville** **Virginia** **22911** **USA**

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

...making excellence a habit.™

bsi.

By Royal Charter

EC Certificate - Production Quality Assurance

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

List of Significant Subcontractors

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

Certificate No:	**CE 80978**
Date:	**04 January 2016**
Issued To:	**Origio Inc.** **2400 Hunters Way** **Charlottesville** **Virginia** **22911** **USA**

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

...making excellence a habit.™