



EC Certificate - Production Quality Assurance

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

No.

Issued To:

CE 80978

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."

Page 1 of 1

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.

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 845 080 9000 BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK, A member of BSI Group of Companies.





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

~			
S. I I	naan	ITPO	ctor:
\sim u	DCOL	ıtıa	CLUIS

Service(s) supplied

CooperSurgical Inc., 95 Corporate Drive Trumbull Connecticut 06611 Manufacture Packaging Sterilization

Drummond Scientific

500 Parkway Broomall PA 19008

USA

USA

Manufacture

ORIGIO a/s Knardrupvej

2 Måløv Denmark **EU Representative**

...making excellence a habit."





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

Sterilization

STERIS Isomedix Services 23 Elizabeth Drive

Gamma Sterilization

Chester

New York 10918

USA

USA

Steris Isomedix Services

Sterilization

9 Apollo Drive Whippany New Jersey

07981 USA

...making excellence a habit."