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 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 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2004-04-06** Date: **2019-04-04** Expiry Date: **2024-04-05**

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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:	**2019-04-04**
Issued To:	**Origio Inc.** **2400 Hunters Way** **Charlottesville** **Virginia** **22911** **USA**

Subcontractor:	**Service(s) supplied**
Cooper Medical SRL Edificio N° B49, 51 Ave 0 Parque Industrial Zona Franca Coyol LaGuarita, Alajuela Costa Rica	**Manufacture**
CooperSurgical Inc. 95 Corporate Drive Trumbull Connecticut 06611 USA	**Dry Heat Sterilization** **Manufacture** **Packaging**
Drummond Scientific 500 Parkway Broomall PA 19008 USA	**Crucial Supplier**

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

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Subcontractor:	**Service(s) supplied**
Origio a/s Knardrupvej 2 2760 Måløv Denmark	**EU Representative**

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bsi.

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EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 80978**

Date: **2019-04-04**

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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 cryopreservation 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	Certificate renewal. The change of scope from 'The manufacture of cryopreservation devices (Cryopette®), sterile micropipettes and Pasteur pipettes for use in vitro fertilization procedures. 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 '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'.

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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.
14 August 2018	8992910	Addition of Cooper Medical, SRL as manufacturing subcontractor. Added sterilization methods utilized to subcontractors.
15 March 2019	9719742	Traceable to NB 0086.
Current	9685433	Certificate renewal. Removal of Cryopette from scope. Update of Drummond activity to crucial supplier Steris subcontractors name change to Isomedix Operations Inc.