By Royal Charter

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 550877**

Issued To: **LifeGlobal Group, LLC**
a.d.b.a LifeGlobal
393 Soundview Road
Guilford, CT 06437
USA

In respect of:

The design, development and manufacture of sterile medical devices for Assisted Reproductive Technology (ART) procedures;
Media with antibiotic and/or protein supplementation for gamete and embryo retrieval, micromanipulation, culture, maintenance, transfer and preservation.
Oil for overlay of ART media during gamete and embryo culture and micromanipulation.
Plastic dishes for gamete and embryo culture and micromanipulation.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 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: **2010-04-23** Date: **2021-03-05** Expiry Date: **2024-05-26**

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Supplementary Information to CE 550877

Issued To:

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Number	Device Name	Intended purpose per IFU
Class III		
---	LG Global	See CE 549386
---	LG Global for Fertilization	
---	LG Global w/ HEPES	
---	LG Global Collect	
---	Global Blastocyst Fast Freeze Thawing Kit	
---	Global total LP	
---	Global total LP w/HEPES	
---	Global total LP for Fertilization	
---	HSA	
Class IIa		
SMD 0109	IVF Media (Oil)	---
SMD 0109	ART Dishes	---

First Issued: **2010-04-23** Date: **2021-03-05** Expiry Date: **2024-05-26**

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List of Significant Subcontractors

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

Certificate No:	**CE 550877**
Date:	**2021-03-05**
Issued To:	**LifeGlobal Group, LLC** **a.d.b.a LifeGlobal** **393 Soundview Road** **Guilford, CT 06437** **USA**

Subcontractor:	**Service(s) supplied**
CooperSurgical Canada 24 Norwich St. E Guelph Ontario N1H 2G6 Canada	**Manufacture**
CooperSurgical, Inc. 95 Corporate Drive Trumbull Connecticut 06611 USA	**Manufacture**
CooperSurgical, Inc. 75 Corporate Drive Trumbull Connecticut 06611 USA	**Regulatory Compliance**

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Subcontractor:	**Service(s) supplied**
CooperSurgical, Inc. 50 Corporate Drive Trumbull Connecticut 06611 USA	**Design** **Regulatory Compliance**
Fagron Belgium NV Venecoweg 20 A Nazareth 9810 Belgium	**Crucial Supplier**
FertiPro N.V. Industriepark Noord 32 8730 Beernem Belgium	**Manufacture**

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Subcontractor:	**Service(s) supplied**
Fujian Fukang Pharmaceutical Co. ,Ltd No. 6 Gaogang Avenue Jiangyin Industrial Estate Fuqing Fuzhou 350309 Fujian China	**Medicinal Substances**
LifeGlobal Europe Rue de la Presse 4 1000 Brussels Belgium	**EU Representative**
Octapharma AB Lars Forssells gata 23 112 75 Stockholm Sweden	**Crucial Supplier**

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Subcontractor:	**Service(s) supplied**
Origio a/s Knardrupvej 2 2760 Måløv Denmark	**Design**
Thermo Fisher Scientific Inc. 75 Panorama Creek Drive Rochester New York 14625-2385 USA	**Manufacture**

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EC Certificate - Full Quality Assurance System Certificate History

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Date	Reference Number	Action
23 April 2010	7374717	First issue.
02 December 2011	7374715	Extension of Certificate Scope to include devices containing ancillary antibiotic.
28 May 2013	7804078	Scope extension to include Pioneer Pro-Pump for Aspiration.
01 October 2013	8067356	Change of company name from 'genX International Inc' to 'LifeGlobal, LLC, a wholly owned subsidiary of LifeGlobal Group, LLC. Change of name of genX Scientific LLC, Ontario to Lifeglobal LLC.
27 March 2014	8123787	Change of company name from 'LifeGlobal, LLC, a wholly owned subsidiary of LifeGlobal Group, LLC' to 'LifeGlobal Group, LLC, a.d.b.a LifeGlobal'.
18 November 2014	8239163	Change of EU Representative name 'IVFonline Europe' to 'LifeGlobal Europe'. Removal of significant subcontractor 'Embryotech Laboratories, Inc.' and 'design' added to the activities of significant subcontractor 'LifeGlobal, LLC'.
07 April 2015	8292497	Certificate renewal. Addition of 'Fagron Industry, 8790 Waregem' as significant subcontractor.

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Date	Reference Number	Action
07 June 2017	8728102	Addition of laboratory dishware and labware to scope. Addition of Thermo Fisher Scientific as a significant subcontractor.
29 August 2017	8789185	Addition of media with protein supplementation. Addition of Octapharma AB, Sweden as crucial supplier.
19 February 2019	9719698	Administrative Subcontractor Service wording update from 'Sterile Manufacture' to 'Manufacture' for Thermo Fisher Scientific Inc., New York 15625-2385, USA. Traceable to NB 0086.
09 May 2019	9658394	Addition of subcontractor CooperSurgical, Inc., Trumbull, Connecticut, USA for manufacture of vacuum pumps. Correction to LifeGlobal Guelph address.
11 December 2019	3095439	Name change from LifeGlobal, LLC, Guelph, Canada, to CooperSurgical Canada, Guelph, Canada. Removal of design activity from Guelph Canada facility.

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Date	Reference Number	Action
11 May 2020	9770430	Certificate renewal. Name and address updated for crucial supplier Fagron Industry. Address updated for crucial supplier Octapharma AB. Fujian Fukang Pharmaceutical Co.,Ltd added as significant subcontractor (Medicinal substances) as the manufacturer of gentamicin sulphate Removal of vacuum pumps for aspiration (Pioneer Pro Pump) from scope. Removal of class Is dishware and labware from scope. Removal of media without antibiotic and protein supplementation from scope. Added plastic dishes for gamete and embryo culture or micromanipulation to scope. The scope has been reformatted to better reflect the certified devices.
Current	3389475	Addition of CooperSurgical, Inc. (50 Corporate Drive), CooperSurgical, Inc. (75 Corporate Drive) and Origio a/s as significant subcontractors.