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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 in-vitro fertilization media with or without antibiotic and protein supplementation, for use in assisted reproduction processes up to and including embryo/blastocyst implantation stage and vacuum pumps for aspiration (Pioneer Pro Pump)

Those aspects of Annex II related to securing and maintaining sterility in the manufacture of laboratory dishware and labware for assisted reproduction techniques and IVF laboratory use

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 0086):

Stewart Brain, Head of Compliance & Risk - Medical Devices

First Issued: **2010-04-23** Date: **2017-08-29** Expiry Date: **2020-04-22**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 550877**

Date: **2017-08-29**

Issued To: **LifeGlobal Group, LLC**
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393 Soundview Road
Guilford, CT 06437
USA

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.
Current	8789185	Addition of media with protein supplementation. Addition of Octapharma AB, Sweden as crucial supplier.

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