



EC Certificate - Production Quality Assurance

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

No. CE 611370
Issued To: Clinical Innovations, LLC
747 West 4170 South
Murray
Utah
84123
USA

In respect of:

The manufacture of Uterine Manipulators, Intrauterine, Urodynamic and Gastrointestinal Pressure Measurement Devices, Vacuum Assisted Fetal Delivery Systems, Monitoring Electrodes for Fetal Scalp Heart Beat including a Reusable Cable, Vacuum Assisted devices for Organ Manipulation in Laparoscopic Procedures.
Those aspects of Annex V concerned with metrology of latitude calibrator.
Those aspects of Annex V relating to securing and maintaining sterility in the manufacture of Vent tube for fetal head release.

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):

Gary Fenton, Global Assurance Director

First Issued: **30 April 2014**

Date: **30 April 2014**

Expiry Date: **01 May 2019**

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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.



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List of Significant Subcontractors

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

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Subcontractor:	Service(s) supplied
Pelican Feminine Healthcare Limited Cardiff Business Park Llanishen CF14 5FW United Kingdom	EU Representative
STERIS Isomedix Services Inc 9120 South 150 East Sandy Utah 84070 USA	Sterilization

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EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 611370**
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Date	Reference Number	Action
30 April 2014	8120332	First issue, transfer from Dekra certificates number: CI 76981CE 01, CI 76981CE 02, CI 76981CE 03, CI 76981CE 04, CI 76981CE 05.

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