By Royal Charter

EC Certificate - Full Quality Assurance System

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

No. **CE 735275**

Issued To: **Research Instruments Limited**
Bickland Industrial Park
Falmouth
Cornwall
TR11 4TA
United Kingdom

In respect of:

Design, manufacture and final inspection of Integra micromanipulation system, Saturn laser systems, electrically heated plates and temperature control units for use in RI Witness systems, and sterile single-use plastic pipettes (EZ-Range) for use in Assisted Reproductive Techniques (ART).

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: **2021-04-01** Date: **2021-04-01** Expiry Date: **2024-05-26**

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Supplementary Information to CE 735275

Issued To:

Research Instruments Limited
Bickland Industrial Park
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Number	Device Name	Intended purpose per IFU
Class IIa		
MD 1110	RI Integra Micromanipulator	---
MD 1110	RI Saturn Laser System	---
MD 1110	RI Witness Embryology Heated Plate	---
MD 0109	RI EZ-Range (RI EZ-Tip, RI EZ-Strip, RI EZ-Squeeze) sterile single-use plastic pipettes	---

First Issued: **2021-04-01** Date: **2021-04-01** 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 735275**
Date:	**2021-04-01**
Issued To:	**Research Instruments Limited** **Bickland Industrial Park** **Falmouth** **Cornwall** **TR11 4TA** **United Kingdom**

Subcontractor:	**Service(s) supplied**
CooperSurgical Distribution B.V Celsiusweg 35 5928 PR Venlo The Netherlands	**EU Representative**
Europlaz Technologies Ltd The Maltings Industrial Estate Hall Road Southminster CM0 7EQ UK	**Assembly**
FISBA AG Rorschacher Strasse 268 9016 St. Gallen Switzerland	**Crucial Supplier**
Swann-Morton (Services) Limited Owlerton Green Sheffield S6 2BJ United Kingdom	**Radiation (Gamma Sterilization)**

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Issued To:	**Research Instruments Limited** **Bickland Industrial Park** **Falmouth** **Cornwall** **TR11 4TA** **United Kingdom**

Subcontractor:	**Service(s) supplied**
Transluminal SARL 65 Boulevard de la Moselle Pompey 54340 France	**Manufacture**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 735275**

Date: **2021-04-01**

Issued To: **Research Instruments Limited**
Bickland Industrial Park
Falmouth
Cornwall
TR11 4TA
United Kingdom

Date	Reference Number	Action
Current	3279829	First Issue. Transfer from SGS (NB 1639).

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