

# 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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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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## Supplementary Information to CE 735275

Issued To:

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Number	Device Name	Intended purpose per IFU
<b>Class IIa</b>		
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	---

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Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

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

## 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  
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Falmouth  
Cornwall  
TR11 4TA  
United Kingdom**

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

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

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