

EC Certificate - Full Quality Assurance System

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

No. CE 512756
Issued To: **Integra LifeSciences (Ireland) Ltd**
IDA Business & Technology Park
Sragh
Tullamore, County Offaly
Ireland

In respect of:

Design and Manufacture of Ultrasonic Surgical Aspirators and associated sterile and non-sterile accessories, including flues and tips; Tissue Oxygen Partial Pressure (PtO₂) and Temperature Monitors.
Those aspects of Annex II relating to securing and maintaining sterility in the manufacture of sterile disposable wrench sets.

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):

First Issued: **2007-04-05**

Date: **2021-05-18**

Expiry Date: **2024-05-26**

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Page 1 of 5

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 512756

Issued To:

Integra LifeSciences (Ireland) Ltd
IDA Business & Technology Park
Sragh
Tullamore, County Offaly
Ireland

| Device code | Device name | Intended purpose per IFU |
|------------------|---|--|
| Class IIb | | |
| 44778 | CUSA Excel Ultrasonic Surgical Aspirator System | Ultrasonic Surgical Aspirator System is indicated for use in these surgical procedures where fragmentation, emulsification and aspiration of soft and hard tissue is desirable: Neurosurgery, Gastrointestinal and affiliated organ surgery, Urological surgery, General surgery, Orthopedic surgery, Gynecological surgery, Laparoscopic surgery |
| 44778 | CUSA NXT Ultrasonic Surgical Aspirator System | Ultrasonic Surgical Aspirator System is indicated for use in surgical procedures where fragmentation, emulsification and aspiration of soft and hard (e.g. bone) tissue is desirable, including Neurosurgery, Gastrointestinal and affiliated organ surgery, Urological surgery, General surgery, Orthopedic surgery, Gynecological surgery and Laparoscopic surgery |
| 44778 | CUSA Clarity Ultrasonic Surgical Aspirator System | Ultrasonic Surgical Aspirator System is indicated for use in these surgical procedures where fragmentation, emulsification and aspiration of soft and hard tissue is desirable Neurosurgery, Gastrointestinal and affiliated organ surgery, Urological surgery, General surgery, Orthopedic surgery, Gynecological surgery, Laparoscopic surgery. |

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Page 2 of 5

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| Device code | Device name | Intended purpose per IFU |
|------------------|------------------------|---|
| Class IIb | | |
| 44750 | CUSA Excel Handpiece | Ultrasonic Surgical Aspirator System is indicated for use in these surgical procedures where fragmentation, emulsification and aspiration of soft and hard tissue is desirable: Neurosurgery, Gastrointestinal and affiliated organ surgery, Urological surgery, General surgery, Orthopedic surgery, Gynecological surgery, Laparoscopic surgery |
| 44750 | CUSA Clarity Handpiece | Ultrasonic Surgical Aspirator System is indicated for use in these surgical procedures where fragmentation, emulsification and aspiration of soft and hard tissue is desirable Neurosurgery, Gastrointestinal and affiliated organ surgery, Urological surgery, General surgery, Orthopedic surgery, Gynecological surgery, Laparoscopic surgery. |

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Page 3 of 5

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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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|------------------|---|---|
| Class IIb | | |
| 60974 | Licox PtO2 Monitor | PtO2 Monitor measures oxygen partial pressure (PtO2) and temperature in brain tissue and these parameters are used together as an aid in the determination of the perfusion status of cerebral tissue local to sensor placement. Monitor values are relative within an individual, and should not be used as the sole basis for determining a diagnosis or therapy. It is intended to provide data additional to that obtained by current clinical practice in cases where hypoxia or ischemia are a concern. |
| Class IIa | | |
| MD 1302 | Licox PtO2 monitor Recon | --- |
| MD 1104 | CUSA Excel CEM Nosecone | --- |
| MD 1104 | CUSA Clarity CEM Nosecone | --- |
| MD 0106 | CUSA Excel manifold Tubing | --- |
| MD 0106 | CUSA Clarity Quick Connect Cartridge and Tubing Set | --- |

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Page 4 of 5

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| Device code | Device name | Intended purpose per IFU |
|------------------|---|--------------------------|
| Class IIa | | |
| MD 0106 | CUSA Selector Tubing Kits and accessories | --- |
| Class Is | | |
| MD 0106 | CUSA Excel Torque Wrench | --- |
| MD 0106 | CUSA Clarity Torque Wrench | --- |

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Page 5 of 5

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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 512756**
 Date: **2021-05-18**
 Issued To: **Integra LifeSciences (Ireland) Ltd**
IDA Business & Technology Park
Sragh
Tullamore, County Offaly
Ireland

| Subcontractor: | Service(s) supplied |
|--|----------------------------|
| Edwards Lifesciences Technology Sàrl State Road 402, Km 1.4 Industrial Park Añasco 00610-1577 Puerto Rico | ETO Sterilization |
| Integra LifeSciences Burlington MA, Inc. 85 Rangeway Road Billerica Massachusetts 01862 USA | Design |
| Integra LifeSciences Corporation 4900 Charlemer Drive Bldg A. Cincinnati Ohio 45227 USA | Manufacture |

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Subcontractor:

Service(s) supplied

Integra NeuroSciences
State Road 402, Km 1.2
Añasco 00610
Puerto Rico

Control of Sterilization
Manufacture
Packaging

Integra Pain Management
3498 West 2400 South #1050
West Valley City
Utah
84119
USA

Control of Sterilization
Packaging

Sterigenics US, LLC
5725 W. Harold Gatty Drive
Salt Lake City
Utah
84116
USA

ETO Sterilization

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| Date | Reference Number | Action |
|-------------------|------------------|--|
| 5 April 2007 | | First Issue. |
| 20 August 2009 | 7433926 | Re-issue due to additional sterilization sub-contractor, 'Sterigenics International, Inc.' |
| 27 May 2010 | 7523808 | Re-issue due to addition of 'Edwards Lifesciences Technology Sàrl, Puerto Rico' to list of significant subcontractors for 'ETO Sterilization'. |
| 30 March 2012 | 7816212 | Certificate renewal and subcontractor name change from 'Integra Radionics Inc.' to 'Integra Burlington MA, Inc.' |
| 10 August 2012 | 7831080 | Re-issue to extension to scope to include Intracranial Pressure and Temperature Monitors. |
| 26 September 2013 | 8015515 | Reissue due to extension to scope to include Tissue oxygen Partial Pressure (PtO2) and Temperature Monitors; and Intracranial Pressure, Temperature and Oxygen Partial Pressure (PtO2) Monitors. Also removal of significant subcontractor Steri-Tech, Inc. |

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| 13 April 2015 | 8294071 | Removal of subcontractor Integra Neurosciences, Andover. Addition of 'manufacture' against Integra NeuroSciences, Puerto Rico. |
| 02 February 2016 | 8412743 | Reissue due to extension to scope to include, ', including flues and tips'. Addition of subcontractor, 'Integra NeuroSciences Implants (France) S.A.S.' for Packaging Addition of subcontractor, 'Sterigenics, France' for ETO Sterilisation. |
| 16 March 2016 | 8483345 | Addition of subcontractor, 'Integra LifeSciences Corporation, 4900 Charlemer Drive Bldg A., Cincinnati, Ohio 45227, USA' for manufacture. Removal of subcontractor, 'Sterigenics International, Inc., New York 12804' for ETO Sterilization. Change of subcontractor address from, 'Integra Burlington MA, Inc., Massachusetts 01803' to 'Integra Burlington MA, Inc., 85 Rangeway Road, Billerica, Massachussets 01862, USA', and removal of "manufacture" against this subcontractor. |

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Page 2 of 3

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| 21 March 2017 | 8673694 | Renewal of CE 512756. Extension of scope to include products covered by CE 517843; 'Those aspects of Annex II relating to securing and maintaining sterility in the manufacture of sterile disposable wrench sets.' Changes to activities listed for Integra Neurosciences Implants, addition of 'Control of Sterilization and Manufacture'. |
| 11 May 2017 | 8575383 | Addition of subcontractors 'Integra Pain Management' for packaging and control of sterilization and 'Sterigenics US, LLC' In Salt Lake City, Utah, USA for ETO Sterilization. |
| 12 March 2019 | 7780263 | Traceable to NB 0086. |
| Current | 3275203 | Re-Issued-Certificate Renewal Amended – Removed two Critical Subcontractors Integra Neurosciences Implants (France) S.A.S and Sterigenics France. Added Device Schedule. Updated name for Burlington, MA site. Restricted – Removed "Intracranial Pressure, Temperature and Oxygen Partial Pressure (PtO2) Monitors" from scope. |