By Royal Charter

EC Certificate - Full Quality Assurance System

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

No. **CE 543007**

Issued To: **IRIDEX Corporation**
1212 Terra Bella Avenue
Mountain View
California
94043-1824
USA

In respect of:

The design and manufacture of solid-state laser systems for use in ophthalmology and ENT; and in ophthalmology, sterile single use devices for illumination, irrigation and aspiration.

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: **2008-10-10** Date: **2021-05-18** Expiry Date: **2024-05-26**

...making excellence a habit.™

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 543007

Issued To:

IRIDEX Corporation
1212 Terra Bella Avenue
Mountain View
California
94043-1824
USA

GMDN Code	Device description	Intended Purpose Per IFU
Class IIb		
60341	OcuLight SL/SLx Laser Console PN: 12731/12730 PN: 13030/13030-220	Indicated for retinal photocoagulation, laser trabeculoplasty, transscleral cyclophotocoagulation, transscleral retinal photocoagulation, iridotomy, and other diode laser treatments.
60341	Cyclo G6 Laser Console PN: 66245-1 / 66245	For the treatment of Glaucoma, including: Primary Open Angle Glaucoma; Closed angle Glaucoma; Refractory Glaucoma (recalcitrant/uncontrolled)
60341	IQ 810 Laser Console PN: 60001-1/2/3	IQ 810 Laser Systems hand pieces, delivery devices & accessories that are used with them to deliver laser energy in either CW-pulse, MicroPulse™ or LongPulse™ mode. The IQ 810 is indicated for transpupillary, transscleral retinopathy, retinal photocoagulation, laser trabeculoplasty, iridotomy and transscleral cyclophotocoagulation.
36150	OcuLight GL Laser Console PN: 33004-1 / 33004	The OcuLight GL is indicated for retinal Photocoagulation, Laser Trabeculoplasty, Iridotomy, Iridoplasty.
36150	OcuLight GLx Laser Console PN: 33005-1 / 33005	OcuLight GLx is indicated for retinal Photocoagulation, Laser Trabeculoplasty, Iridotomy, Iridoplasty, stapedectomy, and stapedotomy.

First Issued: **2008-10-10** Date: **2021-05-18** Expiry Date: **2024-05-26**

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 543007

Issued To:

IRIDEX Corporation
1212 Terra Bella Avenue
Mountain View
California
94043-1824
USA

GMDN Code	Device description	Intended Purpose Per IFU
Class IIb		
36150	OcuLight TX Laser Console PN: 32100 / 32000-1 / 32000-4	Otolaryngology. The OcuLight TX is intended to be used in ENT surgery for tissue incision, excision, coagulation, vaporization, ablation and vessel hemostasis. Indications for use include, but are not limited to Stapedectomy, Stapedotomy, Myringotomy, Lysis of adhesions, control of bleeding, removal of Acoustic Neuromas, Soft Tissue Adhesion in Micro/Macro Otologic procedures. Ophthalmology. The OcuLight TX is intended to photocoagulate ocular tissue in ophthalmic procedures. Indications for use include: Retinal Photocoagulation, Laser Trabeculoplasty, Iridotomy, Iridoplasty
36150	IQ 532 Laser Console PN: 65500 / 65500-08 IQ 532XP Laser Console PN: 66120 MicroPulse Mode Upgrade for IQ532 PN: 66200-G	Ear, Nose and Throat (ENT)/Otolaryngology Intended for soft and fibrous tissue, including osseous tissue incision, excision, coagulation, vaporization, ablation and vessel hemostasis, otosclerotic hearing loss and/or diseases of the inner ear: Stapedectomy, Stapedotomy, Myringotomies, Lysis of adhesions, Control of bleeding, Removal of acoustic, neuromas, Soft tissue adhesion in micro/macro otologic procedures. Ophthalmology Indicated for use in photocoagulation of both anterior and posterior segments including retinal photocoagulation, panretinal photocoagulation and intravitreal endophotocoagulation of vascular and structural abnormalities of the retina and choroids, iridotomy, iridoplasty in angle closure glaucoma, and trabeculoplasty in open angle glaucoma.

First Issued: **2008-10-10** Date: **2021-05-18** Expiry Date: **2024-05-26**

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 543007

Issued To:

IRIDEX Corporation
1212 Terra Bella Avenue
Mountain View
California
94043-1824
USA

GMDN Code	Device description	Intended Purpose Per IFU
Class IIb		
36150	IQ 577 Laser Console PN: 65600-01 / 65600-02 / 65600-08 MicroPulse Mode Upgrade for IQ577 PN: 66200-Y	Indicated for use in photocoagulation of both anterior and posterior segments, including retinal photocoagulation, panretinal photocoagulation (PR) and intravitreal endophotocoagulation of vascular and structural abnormalities of the retina and choroids, iridotomy, iridoplasty in angle closure glaucoma, and trabeculoplasty in open angle glaucoma
36150	TxCell Scanning Laser Delivery System PN: TxCell™ Scanning Laser Delivery System – IQ532 / TxCell™ Scanning Laser Delivery System – IQ577 / 70057 70058 /70059 / 70067 / 70068 / 70069 / 70060 70292 / 70293 / 70295 70400 / 70296 / 70297 70298 / 70300	When the TxCell Scanning Laser Delivery System is connected to the IQ 532 (532 nm) or the IQ 577 (577 nm) Laser Console, from the IRIDEX Family of IQ Laser Systems and used to deliver laser energy in CW- Pulse, MicroPulse or LongPulse mode, it is intended to be used by a trained ophthalmologist for the treatment of ocular pathology of both the anterior and posterior segments of the eye.

First Issued: **2008-10-10** Date: **2021-05-18** Expiry Date: **2024-05-26**

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 543007

Issued To:

IRIDEX Corporation
1212 Terra Bella Avenue
Mountain View
California
94043-1824
USA

GMDN Code	Device description	Intended Purpose Per IFU
Class IIb		
36336	Footswitch PN: 12167 / 60638 / 31703 / 31824 / 31808	The Iridex Lasers may be operated with a wireless footswitch or wired footswitch (that plugs into the system via the footswitch connection at the rear of the laser console). Depression of the footswitch activates the delivery of laser energy. Releasing the footswitch stops the laser.
44731	IQ Personal Interface / Remote Control PN: 60600 / 65777	The remote control, which mirrors the main Iridex Laser console display, is capable of controlling the same treatment functions as the main console and also has the same color graphic user interface (GUI). The remote control may be used in place of, or concurrently with, the front panel controls.

First Issued: **2008-10-10** Date: **2021-05-18** Expiry Date: **2024-05-26**

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 543007

Issued To:

IRIDEX Corporation
1212 Terra Bella Avenue
Mountain View
California
94043-1824
USA

NBOG Code	Device description	Intended Purpose Per IFU
Class IIa		
MD 1104	OtoProbe, Long Angle, RFID PN: 65975-1 / 65975	--
MD 1104	OtoProbe, Short Angle, RFID PN: 65978-1 / 65978	--
MD 1104	OtoProbe, Long Angle PN: 14310-1 / 14310	--
MD 1104	Oto Probe, Short Angle PN: 14320-1 / 14320	--
MD 1104	EndoProbe, Stepped, 23 Gauge, 45" Angled, RFID PN: 65698-1 / 65698	--
MD 1104	EndoProbe, 20 Gauge, Angled 45 PN: 10547-1 / 10547	--
MD 1104	EndoProbe, 20 Gauge, Straight PN: 10562-1 / 10562	--
MD 1104	EndoProbe, 23 Gauge, Straight PN: 14390-1 / 14390	--
MD 1104	EndoProbe, 25 Gauge, Straight PN: 13920-1 / 13920	--
MD 1104	EndoProbe, 20-24 Gauge, Stepped Angled 45° PN: 14030-1 / 14030	--
MD 1104	EndoProbe, 25-30 Gauge, Stepped Angled 45° PN:14120-1 / 14120	--

First Issued: **2008-10-10** Date: **2021-05-18** Expiry Date: **2024-05-26**

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 543007

Issued To:

IRIDEX Corporation
1212 Terra Bella Avenue
Mountain View
California
94043-1824
USA

NBOG Code	Device description	Intended Purpose Per IFU
Class IIa		
MD 1104	EndoProbe, 23-27 Gauge, Stepped Angled 45° PN:14400-1 / 14400	--
MD 1104	EndoProbe, Britelight™ Illuminating 19.5 Gauge, Straight PN:13900-1 / 13900	--
MD 1104	EndoProbe, Britelight™ Illuminating 19.5 Gauge, Angled 45° PN:13930-1 / 13930	--
MD 1104	Endo Probe, Britelight™ Illuminating 19.5 Gauge, Angled 30° PN:14020-1 / 14020	--
MD 1104	EndoProbe, Fluted, 20 Gauge, Straight PN:11473-1 / 11473	--
MD 1104	EndoProbe, Illuminating (Bayonet) 20 Gauge, Angled 30° PN:14410-1 / 14410	--
MD 1104	EndoProbe, Britelight™ Illuminating 25 Gauge, Straight PN:14490-1 / 14490	--
MD 1104	EndoProbe, Britelight™ Illuminating 23 Gauge, Straight PN:14540-1 / 14540	--
MD 1104	EndoProbe, Britelight™ Illuminating 23-27 Gauge, Angled 45° PN:14545-1 / 14545	--
MD 1104	EndoProbe, Britelight™ Illuminating 25-27 Gauge, Angled 20° PN:14560-1 / 14560	--
MD 1104	EndoProbe, Britelight™ Illuminating 20-24 Gauge, Angled 45° PN:14550	--

First Issued: **2008-10-10** Date: **2021-05-18** Expiry Date: **2024-05-26**

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 543007

Issued To:

IRIDEX Corporation
1212 Terra Bella Avenue
Mountain View
California
94043-1824
USA

NBOG Code	Device description	Intended Purpose Per IFU
Class IIa		
MD 1104	EndoProbe, Adjustable & Intuitive, Thumb Adjust 20 Gauge PN:14572T-1 / 14572T	--
MD 1104	EndoProbe, Adjustable & Intuitive, Finger Adjust 20 Gauge PN:14572F-1 / 14572F	--
MD 1104	EndoProbe, Adjustable & Intuitive, Thumb Adjust 23 Gauge PN:14573T-1 / 14573T	--
MD 1104	EndoProbe, Adjustable & Intuitive, Finger Adjust 23 Gauge PN:14573F-1 / 14573F	--
MD 1104	EndoProbe, Adjustable & Intuitive, Thumb Adjust 25 Gauge PN:14574T-1 / 14574T	--
MD 1104	EndoProbe, Adjustable & Intuitive, Finger Adjust 25 Gauge PN:14574F-1 / 14574F	--
MD 1104	XR EndoProbe, Adjustable & Intuitive, Finger Adjust 20 Gauge PN:15905F-1 / 15905F	--
MD 1104	XR EndoProbe, Adjustable & Intuitive, Thumb Adjust 23 Gauge PN:15906T-1 / 15906T	--
MD 1104	XR EndoProbe, Adjustable & Intuitive, Finger Adjust 23 Gauge PN:15906F-1 / 15906F	--
MD 1104	XR EndoProbe, Adjustable & Intuitive, Thumb Adjust 25 Gauge PN:15907T-1 / 15907T	--
MD 1104	XR Endo Probe, Adjustable & Intuitive, Finger Adjust 25 Gauge PN:15907F-1 / 15907F	--

First Issued: **2008-10-10** Date: **2021-05-18** Expiry Date: **2024-05-26**

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 543007

Issued To:

IRIDEX Corporation
1212 Terra Bella Avenue
Mountain View
California
94043-1824
USA

NBOG Code	Device description	Intended Purpose Per IFU
Class IIa		
MD 0106	DioPexy with tray PN: 11454-1	--
MD 0106	G-Probe PN: 11256-1 / 11256	--
MD 0106	G-Probe RFID PN: 15980 / 15980-1	--
MD 0106	G-Probe Short Handle PN: 12044-1 / 12044	--
MD 0106	G-Probe Illuminate PN: 16200 / 16200-1	--
MD 0106	MicroPulse P3 Device PN: 15522 / 15522-1	--
MD 1104	ENT Probe, FlexFiber 200 PN: 15702-1 / 15702	--
MD 1104	ENT Probe, FlexFiber 300 PN: 15703-1 / 15703	--
MD 1104	ENT Probe, FlexFiber 400 PN: 15704-1 / 15704	--

First Issued: **2008-10-10** Date: **2021-05-18** Expiry Date: **2024-05-26**

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 543007

Issued To:

IRIDEX Corporation
1212 Terra Bella Avenue
Mountain View
California
94043-1824
USA

NBOG Code	Device description	Intended Purpose Per IFU
Class IIa		
MD 1104	ENT Probe, FlexFiber 600 PN: 15706-1 / 15706	--
MD 1104	ENT Probe, FlexFiber 200 RFID PN: 15735-1 / 15735	--
MD 1104	ENT Probe, FlexFiber 300 RFID PN: 15738-1 / 15738	--
MD 1104	ENT Probe, FlexFiber 400 RFID PN: 15741 -1 / 15741	--
MD 1104	ENT Probe, FlexFiber 600 RFID PN: 15744-1 / 15744	--

First Issued: **2008-10-10** Date: **2021-05-18** Expiry Date: **2024-05-26**

By Royal Charter

EC Certificate - Full Quality Assurance System

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 543007**
Date:	**2021-05-18**
Issued To:	**IRIDEX Corporation** **1212 Terra Bella Avenue** **Mountain View** **California** **94043-1824** **USA**

Subcontractor:	**Service(s) supplied**
Emergo Europe Prinsessegracht 20 2514 AP The Hague The Netherlands	**EU Representative**
Isomedix Operations, Inc 3459 South Clinton Avenue South Plainfield New Jersey 07080 USA	**ETO Sterilization**
Parter Sterilization Services A Division of Parter Medical Products 17115 Kingsview Avenue Carson California 90746 USA	**ETO Sterilization**

...making excellence a habit.™

By Royal Charter

EC Certificate - Full Quality Assurance System

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 543007**
Date:	**2021-05-18**
Issued To:	**IRIDEX Corporation** **1212 Terra Bella Avenue** **Mountain View** **California** **94043-1824** **USA**

Subcontractor:	**Service(s) supplied**
Peregrine Surgical Ltd. 51 Britain Drive New Britain PA 18901 USA	**Control of Sterilization** **Manufacture**
Sparqtron Corporation 5079 Brandin Court Fremont California 94538 USA	**Manufacture**

...making excellence a habit.™

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 543007**

Date: **2021-05-18**

Issued To: **IRIDEX Corporation**
1212 Terra Bella Avenue
Mountain View
California
94043-1824
USA

Date	Reference Number	Action
10 October 2009	7283975	First Issue - based on certificate CE 525874
08 January 2010	7466996	Re-issue to include IQ 577 laser system on supplementary page and EU Representative on the list of significant sub-contractors -DCA
21 March 2010	7505188	Addition of IQS32 Laser System and 25-27 G Illuminating Endoprobe to supplementary pages. Correction of EU Representative to MDCI Ltd., Arundel House, 1 Liverpool Gardens, Worthing. Correction to Parter Sterilization Services title to match ISO 13485 certificate. Certificate re-issue.
14 October 2010	7600143	Re-issue to expand scope to include, in ophthalmology, sterile single use devices for illumination, irrigation, aspiration and humidification. Associated addition of subcontractors Peregrine Surgical Ltd. and Steris Isomedix Services. Change of EU Representative from MDCI to Emerge Europe.
30 July 2013	7973706	Re-issue to add sub-contractor for sterile manufacture Madhu Instruments, India Update of product list.
25 November 2013	8080122	Reissue to update the product list.
24 March 2015	8315374	Update of product list and certificate renewal.

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 543007**

Date: **2021-05-18**

Issued To: **IRIDEX Corporation**
1212 Terra Bella Avenue
Mountain View
California
94043-1824
USA

Date	Reference Number	Action
15 January 2016	8439291	Update of product list. - To include Cyclo G6 Laser Console. - Removal of 57 devices.
23 February 2018	8843601	Addition of Significant Subcontractor 'Sparqtron Corporation' for Manufacture. Changes to the EU Rep address details Update to the product list in CE 543007; Removal of 8 items in the pages 5, 8 and 13 Addition of 3 items (Cyclo G6 laser console and G-Probe) in the page 7 Removal of Peregrine Surgical Ltd., Madhu Instruments and STERIS Applied Sterilization Technologies from the significant subcontractor list. Addition of part number 32000-4, OcuLight (R)TX to the list in page 2
18 March 2019	7782034	Traceable to NB 0086.

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 543007**

Date: **2021-05-18**

Issued To: **IRIDEX Corporation**
1212 Terra Bella Avenue
Mountain View
California
94043-1824
USA

Date	Reference Number	Action
02 April 2020	3159196	Renewal. Scope reduction to remove 'dermatology' and 'humidification' from scope. Addition of Significant Subcontractor Isomedix Operations, Inc for ETO Sterilization. Addition of Significant Subcontractor Peregrine Surgical Ltd. for Manufacture and Control of Sterilization. Amendment of Parter Sterilization Services name. Update of product list. Removal of 48 products including: -IQ 532™ XP (532nm) -Remote Control for TX -TxCell™ Scanning Laser Delivery System - CSO, (577 nm) -TxCell™ Scanning Laser Delivery System - CSO, (532 nm) -Transscleral 600µ Probe (81 Onm) Vet -MoistAir Humidifier Chamber -GreenTip Membrane Scraper Addition of 3 products -IQ 532 Console -IQ 577 Console -MicroPulse P3 Device

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 543007**

Date: **2021-05-18**

Issued To: **IRIDEX Corporation**
1212 Terra Bella Avenue
Mountain View
California
94043-1824
USA

Date	Reference Number	Action
Current	3446181	Supplemented – Added IQ 532XP laser console to device table