



EC Declaration of Conformity

Lumenis Ltd.
Yokneam Industrial Park
Hakidma Street 6,
Yokneam 2069204, Israel

Does hereby declare under our sole responsibility that the **AcuPulse Family of Surgical & Aesthetic CO2 Laser Systems and accessories**, which includes device catalog numbers referenced in the attached list, meets the provisions and essential requirements of the Council Directive 93/42/EEC concerning medical devices (MDD) as transposed in the national laws of the Member States.

Device Classification: **Is, Rule: 5, Annex VIII**
Ila, Rule: 6, Annex IX
Ilb, Rule: 9, Annex IX

The regulatory route demonstrating the conformity is based on the criteria of Annex II of the MDD with the exemption of section 4, audited by **mdc medical device certification GmbH NB: 0483**, located in **Kriegerstrasse 6, 70191 STUTTGART, Germany**, as an appointed Notified Body.

Initial manufacturing date of the system: **2002.**
EC certificate number: **D1368200005**
DOC certificate number: **1008513**

Authorized European Representative: Lumenis (Germany) GmbH
Heinrich-Hertz-Str. 3
Dreieich Dreieichenhain D-63303, Germany
Tel: +49 (0)6103-8335-0

Dan O'Callaghan
QA/RA Director.
Boston Scientific Ltd, Lumenis Surgical

13-Apr-22

Name & Title

Date

Dan O'Callaghan

12-Apr-23

Declaration Validity Date



List of Products

System

Product Number	Product Name	Device Type	Classification MDD
GA-0000070	AcuPulse	Laser System	IIb, Rule: 9, Annex IX
GA-1000000	AcuPulse DUO	Laser System	IIb, Rule: 9, Annex IX
GA-0000140	AcuPulse 40WG	Laser System	IIb, Rule: 9, Annex IX
GA-0000070CN	AcuPulse CHINA	Laser System	IIb, Rule: 9, Annex IX
GA-1000000CN	AcuPulse DUO CHINA	Laser System	IIb, Rule: 9, Annex IX
GA-0000140CN	AcuPulse 40WG CHINA	Laser System	IIb, Rule: 9, Annex IX
RG-1000000	Refurbish AcuPulse Duo	Laser System	IIb, Rule: 9, Annex IX
RG-0000070	Refurbish AcuPulse	Laser System	IIb, Rule: 9, Annex IX
RG-0000140	Refurbish AcuPulse 40WG	Laser System	IIb, Rule: 9, Annex IX

Sterile Accessories

Product Number	Product Name	Device Type	Classification MDD
AC-1148100	Micro-G™ Otology Kit	Accessory	IIb, Rule:9, Annex IX
AC-1148090	Micro-H™ Otology Kit	Accessory	IIb, Rule:9, Annex IX
AC-1059590	FiberLase™ CO2 Fiber	Accessory	IIb, Rule: 9, Annex IX
AC-1094030	FiberLase™ Endoscope Protection Sheath	Accessory	Is, Rule: 5, Annex VIII
AC-1148110	FiberLase™ ENDURE CO2 Fiber	Accessory	IIb, Rule: 9, Annex IX
AC-2005212	FemTouch™ Fine Focus Disposable Tip	Accessory	IIb, Rule: 9, Annex IX



Product Number	Product Name	Device Type	Classification MDD
AC-2005210	FemTouch™ Fine Panoramic Disposable Tip	Accessory	IIb, Rule: 9, Annex IX
AC-2005211	FemTouch™ Standard Focus Disposable Tip	Accessory	IIb, Rule: 9, Annex IX
AC-2005209	FemTouch™ Standard Panoramic Disposable	Accessory	IIb, Rule: 9, Annex IX
AC-2003748	OtoLase Starter Kit	Accessory	IIa, Rule: 6, Annex IX
AC-2003612	OtoLase Straight HP	Accessory	IIa, Rule: 6, Annex IX
AC-2003613	OtoLase Curved HP	Accessory	IIa, Rule: 6, Annex IX
AC-20055380	OtoLase Straight Tips Package	Accessory	IIa, Rule: 6, Annex IX
AC-20055390	OtoLase Curved Tips Package	Accessory	IIa, Rule: 6, Annex IX
AC-0001300	FiberLase™ Robotic Drop-In Guide	Accessory	IIb, Rule: 9, Annex IX
SA-1115060	FiberLase™ Robotic Drop-In Guide	Accessory	IIb, Rule: 9, Annex IX

Non sterile Accessories

Product Number	Product Name	Device Type	Classification MDD
AA2775200	SurgiTouch™ Scanning Handpiece Set	Accessory	IIb, Rule: 9, Annex IX
AA2814900	SurgiTouch™ Scanning Handpiece 125mm	Accessory	IIb, Rule: 9, Annex IX
AA2778200	SurgiTouch™ Scanning Handpiece 200mm	Accessory	IIb, Rule: 9, Annex IX
AA2782600	SurgiTouch™ Scanning Handpiece 260mm	Accessory	IIb, Rule: 9, Annex IX
SPN-1028780	Surgitouch Upgrade Kit For Acupulse DUO, replacement	Accessory	IIb, Rule: 9, Annex IX
AA0632600	AcuPulse Incisional Handpiece 125 mm	Accessory	IIb, Rule: 9, Annex IX
UG-1145830	AcuPulse Combo & StretchTouch Modes UG	Accessory	IIb, Rule: 9, Annex IX
KT-1001618	AcuPulse DUO HW Upgrade kit AcuPulse 40WG to DUO	Accessory	IIb, Rule: 9, Annex IX



Product Number	Product Name	Device Type	Classification MDD
KT-1001616	AcuPulse DUO HW Upgrade kit AcuPulse to DUO Model: Kit with prolonged arm	Accessory	IIb, Rule: 9, Annex IX
KT-1001617	AcuPulse DUO HW Upgrade Kit AcuPulse to DUO Model: Kit without prolonged arm	Accessory	IIb, Rule: 9, Annex IX
UG-0000580	AcuPulse Upgrade Kit 40AES-F to 40AES-R	Accessory	IIb, Rule: 9, Annex IX
UG-0000360	AcuPulse Upgrade Kit 40AES-R To 40AES-A	Accessory	IIb, Rule: 9, Annex IX
UG-0000350	AcuPulse Upgrade Kit 40ST to 40 AES-A	Accessory	IIb, Rule: 9, Annex IX
UG-0000340	AcuPulse Upgrade Kit 30 To 30ST	Accessory	IIb, Rule: 9, Annex IX
UG-0000390	AcuPulse Upgrade Kit 40 To 40AES-A	Accessory	IIb, Rule: 9, Annex IX
UG-0000370	AcuPulse Upgrade Kit 40 to 40AES-R	Accessory	IIb, Rule: 9, Annex IX
UG-0000320	AcuPulse Upgrade Kit 40 to 40F	Accessory	IIb, Rule: 9, Annex IX
UG-0000300	AcuPulse Upgrade Kit 40 to 40ST	Accessory	IIb, Rule: 9, Annex IX
UG-0000380	AcuPulse Upgrade Kit 40AES-F to 40AES-A	Accessory	IIb, Rule: 9, Annex IX
UG-1149910	AcuPulse Upgrade Kit to AES-A 4 Modes Upgrade	Accessory	IIb, Rule: 9, Annex IX
UG-1149920	AcuPulse Upgrade Kit to AES-R 4 Modes Upgrade	Accessory	IIb, Rule: 9, Annex IX
SPN-1028790	AcuScan 120 Microscanner Kit, replacement	Accessory	IIb, Rule: 9, Annex IX
KT-1034490	AcuScan 120 Microscanner	Accessory	IIb, Rule: 9, Annex IX
KT-1037270	AcuScan 120 Microscanner Kit	Accessory	IIb, Rule: 9, Annex IX
KT-1001731	AcuScan 120 Microscanner Upgrade Kit	Accessory	IIb, Rule: 9, Annex IX
KT-1037260	AcuScan 120 Upgrade Kit	Accessory	IIb, Rule: 9, Annex IX
KT-1042800	Digital AcuBlade Upgrade kit for AcuPulse Model: Kit for AB09	Accessory	IIb, Rule: 9, Annex IX



Product Number	Product Name	Device Type	Classification MDD
KTCE03300	Digital AcuBlade Upgrade Kit	Accessory	Iib, Rule: 9, Annex IX
AC-1007415	FemTouch™, Focus Tip	Accessory	Iib, Rule: 9, Annex IX
SPSA-20002590	FemTouch™ Focus Tip	Accessory	Iib, Rule: 9, Annex IX
AC-2006500	FemTouch™ Fine 3rd Lens Holder Upgrade	Accessory	Iib, Rule: 9, Annex IX
AC-2009595	FemTouch Adapter Kit	Accessory	Iib, Rule: 9, Annex IX
AC-2009596	FemTouch Standard Focus Tip	Accessory	Iib, Rule: 9, Annex IX
AC-2009597	FemTouch Standard Panoramic Tip	Accessory	Iib, Rule: 9, Annex IX
AC-2009598	FemTouch Fine Focus Tip	Accessory	Iib, Rule: 9, Annex IX
AC-2009599	FemTouch Fine Panoramic Tip	Accessory	Iib, Rule: 9, Annex IX
AC-1148120	MicroLase™ Fiber	Accessory	Iib, Rule: 9, Annex IX
AC-20055370	OtoLase Fiber	Accessory	Iib, Rule: 9, Annex IX
SA-1023230	SurgiTouch Scanner	Accessory	Iib, Rule: 9, Annex IX
KT-1000100	SurgiTouch Scanner Model: kit for AcuPulse and AcuPulse DUO	Accessory	Iib, Rule: 9, Annex IX
KT-1023140	SurgiTouch Scanner Model: Upgrade kit for AcuPulse 30/40 to 30/40 ST	Accessory	Iib, Rule: 9, Annex IX
AA0198800	120° Mirror Tip for Multi-Application Handpiece	Accessory	Iib, Rule: 9, Annex IX
AA0198900	90° Mirror Tip for Multi-Application Handpiece	Accessory	Iib, Rule: 9, Annex IX
AA3042000	AcuSpot 712 L Micromanipulator	Accessory	Iib, Rule: 9, Annex IX
AA2630000	AcuSpot 712 Micromanipulator	Accessory	Iib, Rule: 9, Annex IX
AC-0020170	AcuSpot 712 Z Micromanipulator	Accessory	Iib, Rule: 9, Annex IX
AA2330500	BeamAlign Laparoscope Coupler 200mm	Accessory	Iib, Rule: 9, Annex IX



Product Number	Product Name	Device Type	Classification MDD
AA2330600	BeamAlign Laparoscope Coupler 300mm	Accessory	Iib, Rule: 9, Annex IX
AA0852000	ColpoSlad 725 Micromanipulator	Accessory	Iib, Rule: 9, Annex IX
AA0631700	ColpoSlad 726 Micromanipulator	Accessory	Iib, Rule: 9, Annex IX
AA2891800	Fiber Inserts for Laryngeal Probes (3 pk) Model: 14621	Accessory	Iib, Rule: 9, Annex IX
AA2756300	Fiber Inserts for Nasal Probes (3 pk) Model: 14620	Accessory	Iib, Rule: 9, Annex IX
AC-1083940	FiberLase HP-M 140 mm malleable	Accessory	Iia, Rule: 6, Annex IX
AC-1083950	FiberLase HP-M 240 mm malleable	Accessory	Iia, Rule: 6, Annex IX
AC-0001200	FiberLase HP-M 300 mm malleable	Accessory	Iia, Rule: 6, Annex IX
AC-0001100	FiberLase HP-M 90 mm malleable	Accessory	Iia, Rule: 6, Annex IX
AC-1083980	FiberLase HP-R 140 mm bent, straight tip	Accessory	Iia, Rule: 6, Annex IX
AC-1063940	FiberLase HP-R 140 mm straight, curved tip	Accessory	Iia, Rule: 6, Annex IX
AC-1063960	FiberLase HP-R 180 mm straight, curved tip	Accessory	Iia, Rule: 6, Annex IX
AC-1063970	FiberLase HP-R 180 mm straight, straight tip	Accessory	Iia, Rule: 6, Annex IX
AC-1063980	FiberLase HP-R 240 mm bent, curved tip	Accessory	Iia, Rule: 6, Annex IX
AC-1083970	FiberLase HP-R 240 mm bent, straight tip	Accessory	Iia, Rule: 6, Annex IX
AC-1063920	FiberLase HP-R 60 mm straight, curved tip	Accessory	Iia, Rule: 6, Annex IX
AC-1063930	FiberLase HP-R 60mm straight, straight tip	Accessory	Iia, Rule: 6, Annex IX
KT-1064910	FiberLase™ Accessory Starter Kit with FiberLase Fiber	Accessory	Iia, Rule: 6, Annex IX
AC-1083960	FiberLase™ Handpiece Malleable Kit	Accessory	Iia, Rule: 6, Annex IX
KT-1064920	FiberLase™ Accessory Starter Kit with Endure Fiber	Accessory	Iia, Rule: 6, Annex IX



Product Number	Product Name	Device Type	Classification MDD
KT-1061370	FiberLase™ Handpiece Rigid Kit	Accessory	Ila, Rule: 6, Annex
AA2891500	Laryngeal Probe with Straight Tip and Smoke Evacuation Channel Model: 14732	Accessory	Ilb, Rule: 9, Annex IX
AA2891400	Laryngeal Probe with Straight Tip Model: 14731	Accessory	Ilb, Rule: 9, Annex IX
AA2891700	Laryngeal Probe with Straight Tip, 90 Degree Left Mirror and Smoke Evacuation Channel Model: 14734	Accessory	Ilb, Rule: 9, Annex IX
AA2891600	Laryngeal Probe with Straight Tip, 90 Degree Right Mirror and Smoke Evacuation Channel Model: 14733	Accessory	Ilb, Rule: 9, Annex IX
AA0886700	MicroSlad 715 Micromanipulator	Accessory	Ilb, Rule: 9, Annex IX
AA0400400	MicroSlad 717/718 Lens Slide 200 mm Model: 19106	Accessory	Ilb, Rule: 9, Annex IX
AA0402500	MicroSlad 717/718 Lens Slide 250 mm Model: 19107	Accessory	Ilb, Rule: 9, Annex IX
AA0590400	MicroSlad 717/718 Lens Slide 275 mm Model: 19120	Accessory	Ilb, Rule: 9, Annex IX
AA0222800	MicroSlad 717/718 Lens Slide 300 mm Model: 19108	Accessory	Ilb, Rule: 9, Annex IX
AA0192700	MicroSlad 717/718 Lens Slide 400 mm Model: 19110	Accessory	Ilb, Rule: 9, Annex IX
AA0252800	MicroSlad 717/718 Lens Slide 350 mm Model: 19109	Accessory	Ilb, Rule: 9, Annex IX
AA0192900	MicroSlad 719 Lens Slide 200 mm Model: 19101	Accessory	Ilb, Rule: 9, Annex IX
AA0192800	MicroSlad 719 Lens Slide 250 mm Model: 19102	Accessory	Ilb, Rule: 9, Annex IX
AA0590500	MicroSlad 719 Lens Slide 275 mm Model: 19119	Accessory	Ilb, Rule: 9, Annex IX



Product Number	Product Name	Device Type	Classification MDD
AA0252700	MicroSlad 719 Lens Slide 350 mm Model: 19104	Accessory	IIb, Rule: 9, Annex IX
AA0205000	MicroSlad 719 Lens Slide 400 mm Model: 19105	Accessory	IIb, Rule: 9, Annex IX
AA0631900	MicroSlad 719 Micromanipulator	Accessory	IIb, Rule: 9, Annex IX
AA0193000	MicroSlad Lens Slide 300 mm Model: 19103	Accessory	IIb, Rule: 9, Annex IX
KT-1044100	MicroSwitch Joystick	Accessory	IIb, Rule: 9, Annex IX
ACCE06000	MicroSwitch Joystick Model: Replacement kit	Accessory	IIb, Rule: 9, Annex IX
AA2377300	Multi-Application Handpiece Set	Accessory	IIb, Rule: 9, Annex IX
AA2757200	Nasal Probe with Bent Tip and Smoke Evacuation Channel Model: 14640	Accessory	IIb, Rule: 9, Annex IX
AA2757100	Nasal Probe with Bent Tip Model: 14639	Accessory	IIb, Rule: 9, Annex IX
AA2756700	Nasal Probe with Straight Tip and 90 Degree Left Mirror Model: 14633	Accessory	IIb, Rule: 9, Annex IX
AA2756600	Nasal Probe with Straight Tip and 90 Degree Right Mirror Model: 14632	Accessory	IIb, Rule: 9, Annex IX
AA2756800	Nasal Probe with Straight Tip and Smoke Evacuation Channel Model: 14634	Accessory	IIb, Rule: 9, Annex IX
AA2756500	Nasal Probe with Straight Tip Model: 14631	Accessory	IIb, Rule: 9, Annex IX
AA2756900	Nasal Probe with Straight Tip, 90 Degree Right Mirror and Smoke Evacuation Channel Model: 14635	Accessory	IIb, Rule: 9, Annex IX
AA2757000	Nasal Probe with Straight Tip, 90 Degree Left Mirror and Smoke Evacuation Channel Model: 14636	Accessory	IIb, Rule: 9, Annex IX
AA5051100	Optional side-entry port for MicroSlad micromanipulator	Accessory	IIb, Rule: 9, Annex IX
AA2940000	OtoScan Ear Aeration System Model: NTSC camera	Accessory	IIb, Rule: 9, Annex IX



Product Number	Product Name	Device Type	Classification MDD
AC-2083940	SS FiberLase HP-M 140 mm malleable	Accessory	Ila, Rule: 6, Annex IX
AC-2083950	SS FiberLase HP-M 240 mm malleable	Accessory	Ila, Rule: 6, Annex IX
AC-2001200	SS FiberLase HP-M 300 mm malleable	Accessory	Ila, Rule: 6, Annex IX
AC-2001100	SS FiberLase HP-M 90 mm malleable	Accessory	Ila, Rule: 6, Annex IX
AC-2083980	SS FiberLase HP-R 140 mm bent, straight tip	Accessory	Ila, Rule: 6, Annex IX
AC-2063940	SS FiberLase HP-R 140 mm straight, curved tip	Accessory	Ila, Rule: 6, Annex IX
AC-2063960	SS FiberLase HP-R 180 mm straight, curved tip	Accessory	Ila, Rule: 6, Annex IX
AC-2063970	SS FiberLase HP-R 180 mm straight, straight tip	Accessory	Ila, Rule: 6, Annex IX
AC-2063980	SS FiberLase HP-R 240 mm bent, curved tip	Accessory	Ila, Rule: 6, Annex IX
AC-2083970	SS FiberLase HP-R 240 mm bent, straight tip	Accessory	Ila, Rule: 6, Annex IX
AC-2063920	SS FiberLase HP-R 60 mm straight, curved tip	Accessory	Ila, Rule: 6, Annex IX
AC-2063930	SS FiberLase HP-R 60mm straight, straight tip	Accessory	Ila, Rule: 6, Annex IX
KT-2064920	SS FiberLase™ Accessory Starter Kit with Endure Fiber	Accessory	Ila, Rule: 6, Annex IX
KT-2064910	SS FiberLase™ Accessory Starter Kit with FiberLase Fiber	Accessory	Ila, Rule: 6, Annex IX
AC-2083960	SS FiberLase™ Handpiece-M Kit	Accessory	Ila, Rule: 6, Annex IX
KT-2061370	SS FiberLase™ Handpiece Rigid Kit	Accessory	Ila, Rule: 6, Annex IX