

EC CERTIFICATION

FULL QUALITY ASSURANCE SYSTEM

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

We hereby declare that an examination of the under mentioned full quality assurance system has been carried out following the requirements of the Swedish national legislation LVFS 2003:11 to which the undersigned is subjected, transposing Annex II (with the exemption of section 4) of the Directive 93/42/EEC on medical devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive, and the result entitles the organization to use the CE 0413 marking on those products listed below.

Organization:

Elliquence, LLC

Main Site: 2455 Grand Avenue, Baldwin, New York 11510, United States

Product Category:

- Radio Surgical Equipment
- Endoscope

For further identification of the products covered, see the MDD product list/product schedule.

Certificate Number:

41316578-03

Initial Certification Date:

18 February 2009

Certificate Valid from:

15 March 2019

Certificate Expiry Date:

17 February 2024




Peter Nermander

Certification Authority MDD
Intertek Semko AB, Kista, Sweden

15 March 2019

Signed Date

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The certification is subject to the organization maintaining their system in compliance with the regulations stated in this certificate, allowing regular assessments and following the contracted requirements of the Notified Body.

Intertek Semko AB is a Notified Body according to Directive 93/42/EEC on medical devices, with identification number 0413.



Products included in the certificate no: 41316578-03
 Issued to: **Elliquence, LLC**
 2455 Grand Avenue
 Baldwin, New York 11510
 United States

Product category	Type/Model designation	Class	Sterile	GMDN code (not mandatory)	Date added
Radio Surgical Equipment					
<i>Radiofrequency Surgical Generator</i>					
	IEC3A-S30W Surgitron WOLF	IIb	No	44776	*
	IEC4-SM120 SurgiMax	IIb	No	44776	*
	IEC4-SP SurgiMax Plus	IIb	No	44776	*
	IEC4-JSM120 Surgi-Max Vapor	IIb	No	44776	30 March 2012
	IEC6-SU120 Surgi-Max Ultra	IIb	No	44776	15 April 2016
	IEC6-SU170 Surgi-Max Ultra	IIb	No	44776	15 April 2016
<i>Handpiece</i>					
	IEC-BHP3/D 3-Button Fingerswitch	IIb	Yes	44681	*
	IEC-3FHPD/D 3-Button Fingerswitch	IIb	Yes	44681	*
	IEC-3FHPD/D1 3-Button Fingerswitch	IIb	Yes	44681	*
<i>Handpiece with integral electrode (surgical generator accessory)</i>					
	IEC-I6DBayonette Turbinate Handpiece	IIb	No	42553	*
<i>Electrosurgical forceps</i>					
	ACBF-018 (15.2 cm, Tip Ø 0.4 mm, Bayonet)	IIb	No	44683	*
	ACBF-027 (21.6 cm, Tip Ø 1.0 mm, Bayonet)	IIb	No	44683	*
<i>Hand articulated Instruments</i>					
	Disc FX System, Model Number DFX <i>Including: Disposable Trigger Flex, Guidewires, Cannulas, Trepine, Depth stop, Dilator</i>	IIb	Yes	35703	*

Product category	Type/Model designation	Class	Sterile	GMDN code (not mandatory)	Date added
<i>Disposable Trigger Flex</i>					
	4793.692	IIb	Yes	35703	27 April 2011
	40990.0031	IIb	Yes	35703	27 April 2011
	DTF-13	IIb	Yes	35703	27 April 2011
	DTF-18	IIb	Yes	35703	*
	DTF-24	IIb	Yes	35703	27 April 2011
	DTF-24B	IIb	Yes	35703	*
	DTF-31	IIb	Yes	35703	27 April 2011
	DTF-32	IIb	Yes	35703	27 April 2011
	DTF-35	IIb	Yes	35703	3 Oct 2012
	DTF-38	IIb	Yes	35703	3 Oct 2012
	DTF-39	IIb	Yes	35703	27 April 2011
	DTF-40	IIb	Yes	35703	*
	DTF-45	IIb	Yes	35703	27 April 2011
	JSMDF32	IIb	Yes	35703	27 April 2011
	JSMDF39	IIb	Yes	35703	27 April 2011
	JSMDF45	IIb	Yes	35703	27 April 2011
	TF-S	IIb	Yes	35703	27 April 2011
	Micro Bipolar (Cappabianca) CBS-S, CBS-A	IIb	Yes	35703	27 April 2011
	Disposable Trigger-Flex: Bi-Tip Flextrode (BT-FT)	IIb	Yes	35703	27 April 2011
	Disposable Meddusa Bipolar System: DRY- MAN3 (Tip Dia: 3mm, Electrode Spacing: 1mm, WL: 127 mm)	IIb	Yes	35703	3 Oct 2012
	Disposable Meddusa Bipolar System: DRY- MAN3 (Tip Dia: 5mm, Electrode Spacing: 3mm, WL: 127 mm)	IIb	Yes	35703	3 Oct 3 2012
	Minimally Invasive Discectomy System: MIDS	IIb	Yes	35703	5 June 2014
<i>Hand articulated Instruments</i>					
	DFX-N (DFX-N6, DFX- N8) Sterile needles for use with Disc FX System	IIa	Yes	35150	*
	N6-D4, N6-D4/1 N6-D5, N6-D5-1	IIa	Yes		13 Mar 2017
	Disc-FX Mini System DFXM	IIb	Yes	35703	13 Mar 2017

Product category	Type/Model designation	Class	Sterile	GMDN code (not mandatory)	Date added
	Trigger-Flex Mini Bipolar System DTFM-13 DTFM-18 DTFM-24 DTFM-24B DTFM-31 DTFM-32 DTFM-34 DTFM-35 DTFM-36 DTFM-38 DTFM-39 DTFM-40	IIb	Yes	35703	13 Mar 2017
	<i>Electrosurgical probe</i>				
	Trigger-Flex Dart Bipolar System DFTD-13, DFTD-24	IIb	Yes	35703	13 Mar 2017
	<i>Electrosurgical forceps</i>				
	J1 (9.5 cm, Tip Ø 0.4 mm, Straight)	IIb	No	44683	*
	J2 (9.5 cm, Tip Ø 0.3 mm, Curved, Flat/Angled Tip)	IIb	No	44683	*
	J3 (7.8 cm, Tip Ø 0.4 mm, Angled Tip)	IIb	No	44683	*
	J5 (9.2 cm, Tip Ø 0.3 mm, Bent Tip)	IIb	No	44683	*
	J7 (17.3 cm, Tip Ø 1.0 mm, Bayonet)	IIb	No	44683	*
	J7D (17.3 cm, Tip Ø 1.0 mm, Bayonet, Angled Tip 45° Down)	IIb	No	44683	*
	J7U (17.3 cm, Tip Ø 1.0 mm, Bayonet, Angled Tip 45° Up)	IIb	No	44683	*
	J13 (15.6 cm, Tip Ø 1.0 mm, Bayonet)	IIb	No	44683	*
	J14 (10.8 cm, Tip Ø 0.7 mm, Straight)	IIb	No	44683	*
	J17 (17.9 cm, Tip Ø 1.0 mm, Bayonet)	IIb	No	44683	*
	J18 (16.9 cm, Tip Ø 0.5 mm, Bayonet)	IIb	No	44683	*
	:J19 (13.6 cm, Tip Ø 2.0 mm, Straight)	IIb	No	44683	*

Product category	Type/Model designation	Class	Sterile	GMDN code (not mandatory)	Date added
	J20 (16.6 cm, Tip Ø 2.0 mm, Bayonet)	IIb	No	44683	*
	J21 (19.7 cm, Tip Ø 1.0 mm, Bayonet)	IIb	No	44683	*
<i>Disposable electrodes (surgical generator handpiece accessory)</i>					
	A2D Fine Wire -3/8" Needle – 25 pcs	IIb	Yes	44684	*
	A8D VariTip Wire Electrode – 25 pcs	IIb	Yes	44684	*
	B1D Round Loop - 1/4" Diameter - 25 pcs	IIb	Yes	44684	*
	B2D Round Loop - 3/8" Diameter	IIb	Yes	44684	*
	C3D Diamond Loop – 3/16" Diameter	IIb	Yes	44684	*
	CV-B1 Clear-Vu Bayonet 1 mm Ball CV-B1/S	IIb	Yes	44684	*
	CV-B2 Clear-Vu Bayonet 2 mm Ball CV-B2/S	IIb	Yes	44684	*
	CV-B3 Clear-Vu Bayonet 3 mm Ball CV-B3/S	IIb	Yes	44684	*
	CV-L3 Clear-Vu Bayonet 3 mm Loop CV-L3/S	IIb	Yes	44684	*
	CV-L5 Clear-Vu Bayonet 5 mm Loop CV-L5/S	IIb	Yes	44684	*
	CV-L7 Clear-Vu Bayonet 7 mm Loop CV-L7/S	IIb	Yes	44684	*
	CV-N Clear-Vu Bayonet MicroIncision CV-N/S	IIb	Yes	44684	*
	CV-S Clear-Vu Bayonet Spatula CV-S/S	II b	Yes	44684	*
	CV-W Clear-Vu Bayonet Fine Wire CV-W/S	II b	Yes	44684	*
	EE401A Trigger-Flex Bipolar Electrode EE401/S EE412 EE425	IIb	Yes	44684	*

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	XEE401A Trigger-Flex Bipolar Electrode XEE401/S XEE412 XEE425	IIb	Yes	44684	*
	MF-A Micro-Fiber Electrode	IIb	Yes	44684	*
	QCV-B1 Clear-Vu Bayonet 1 mm Ball	IIb	Yes	44684	*
	QCV-B2 Clear-Vu Bayonet 2 mm Ball	IIb	Yes	44684	*
	QCV-B3 Clear-Vu Bayonet 3 mm Ball	IIb	Yes	44684	*
	QCV-L3 Clear-Vu Bayonet 3 mm Loop	IIb	Yes	44684	*
	QCV-L5 Clear-Vu Bayonet 5 mm Loop	IIb	Yes	44684	*
	QCV-L7 Clear-Vu Bayonet 7 mm Loop	IIb	Yes	44684	*
	QCV-N Clear-Vu Bayonet MicroIncision	IIb	Yes	44684	*
	QCV-S Clear-Vu Bayonet Spatula	IIb	Yes	44684	*
	QCV-W Clear-Vu Bayonet Fine Wire	IIb	Yes	44684	*
	QTEE301-QTEE324 Empire MicroIncision Electrodes	IIb	Yes	44684	*
	QTEE325-QTEE328 Empire MicroIncision, <i>diff. variants</i>	IIb	Yes	44684	*
	TEE229A Sub Mucosal UPP Electrode	IIb	Yes	44684	*
	TEE301-TEE316 TEE322-TEE324 TEE326-TEE327 Empire MicroIncision Electrodes	IIb	Yes	44684	*
	TEE325 Empire MicroIncision, 1/16" TEE328	IIb	Yes	44684	*
	W1D LLETZ - 15 mm Loop - 5 pcs	IIb	Yes	44684	*
	W4D LLETZ Electrode Assortment	IIb	Yes	44684	*
	XMF-A Micro-Fiber Electrode	IIb	Yes	44684	*

Product category	Type/Model designation	Class	Sterile	GMDN code (not mandatory)	Date added
	Disposable Cobbra Monopolar Elevator: RF-COBB/MS, Tip Dia.: .5 in WL: 127mm, Standard Plug	IIb	Yes		24 Feb 2014
	Disposable Cobbra Monopolar Elevator: RF-COBB/LS, Tip Dia.: 1 in WL: 127mm, Standard Plug	IIb	Yes		24 Feb 2014
	Disposable Cobbra Monopolar Elevator: RF-COBB/M, Tip Dia.: .5 in WL: 127mm.	IIb	Yes		24 Feb 2014
	Disposable Cobbra Monopolar Elevator: RF-COBB/L, Tip Dia.: 1 in WL: 127mm.	IIb	Yes		24 Feb 2014
	Disposable Cobbra Monopolar Elevator: RF-COBB/MS, Tip Dia.: .5 in WL: 127mm, Standard Plug	IIb	Yes		24 Feb 2014
	Disposable Cobbra Monopolar Elevator: RF-COBB/LS, Tip Dia.: 1 in WL: 127mm, Standard Plug	IIb	Yes		24 Feb 2014
	Disposable Cobbra Monopolar Elevator: RF-COBB/M, Tip Dia.: .5 in WL: 127mm.	IIb	Yes		24 Feb 2014
	Disposable Cobbra Monopolar Elevator: RF-COBB/L, Tip Dia.: 1 in WL: 127mm.	IIb	Yes		24 Feb 2014
<i>Disposable Suction Coagulator</i>					
	SC8, Foot Control	IIb	Yes		17 Nov 17 2011
	SC8B, Hand Control	IIb	Yes		17 Nov 17 2011
	SC10, Foot Control	IIb	Yes		17 Nov 17 2011
	SC10B, Hand Control	IIb	Yes		17 Nov 17 2011
	SC12, Foot Control	IIb	Yes		17 Nov 17 2011
	SC12B, Hand Control	IIb	Yes		17 Nov 17 2011
<i>Disposable electrodes, FT-Series</i>					
	FT-B1, FT-B2, FT-B3	IIb	Yes	44684	*
	FT-D	IIb	Yes	44684	*
	FT-L3, FT-L5, FT-L7	IIb	Yes	44684	*
	FT-N, FT-S, FT-W	IIb	Yes	44684	*

Product category	Type/Model designation	Class	Sterile	GMDN code (not mandatory)	Date added
	FT-B1/S, FT-B2/S, FT-B3/S	IIb	Yes	44684	*
	FT-D/S	IIb	Yes	44684	*
	FT-L3/S, FT-L5/S, FT-L7/S	IIb	Yes	44684	*
	FT-N/S, FT-S/S, FT-W/S	IIb	Yes	44684	*
<i>Disposable electrodes</i>					
	IEC-BC/I, IEC-DJX, IEC-BC	IIb	Yes	44684	*
	ST-B2	IIb	Yes	44684	*
	ST-L5	IIb	Yes	44684	*
	ST-L7	IIb	Yes	44684	*
	ST-L10	IIb	Yes	44684	*
	ST-S	IIb	Yes	44684	*
	ST-W	IIb	Yes	44684	*
<i>Reusable electrodes (surgical generator handpiece accessory)</i>					
	S10B, Standard Electrode Set	IIb	No	44683	*
	S13B, ENT Electrode Set	IIb	No	44683	*
	TB5B 3/8" Round Loop Electrode	IIb	No	44683	*
	TB6B 1/2" Round Loop Electrode	IIb	No	44683	*
	TEE227A, Micro Tip Needle 1/16"	IIb	No	44683	*
	TEE284 HLTZ Tonsillotomy Loop	IIb	No	44683	*
	W4, SetLLETZ Electrode Assortment	IIb	No	44683	*
	W18, Genital Lesion Electrode	IIb	No	44683	*
Endoscope					
	Endoscope 10-2016	IIa	No	-	25 June 2018
	Endoscope 10-2017	IIa	No	-	25 June 2018
	Endoscope 10-2018	IIa	No	-	25 June 2018
	Endoscope 10-2019	IIa	No	-	25 June 2018
	Endoscope 10-2020	IIa	No	-	25 June 2018
	Endoscope 10-2021	IIa	No	-	25 June 2018

Product category	Type/Model designation	Class	Sterile	GMDN code (not mandatory)	Date added
	Endoscope 10-2022	Ila	No	-	25 June 2018
	Endoscope 10-2023	Ila	No	-	25 June 2018
	Endoscope 10-2024	Ila	No	-	25 June 2018
	Endoscope 10-2025	Ila	No	-	25 June 2018
	Endoscope 10-2026	Ila	No	-	25 June 2018
	Endoscope 10-2027	Ila	No	-	25 June 2018
	Endoscope 10-2028	Ila	No	-	25 June 2018
	Endoscope 10-2029	Ila	No	-	25 June 2018

Date of Issue: 15 March 2019

Intertek Semko AB
Notified Body MDD



Peter Nermander
Certification Authority MDD

This product list is only valid together with the referenced, valid EC certificate.

The GMDN codes are assigned by the manufacturer and are only provided for convenience.

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