



# EC CERTIFICATE

## Cogentix Medical, Inc.

40 Ramland Road South,  
Orangeburg NY 10962 USA

## Full Quality Assurance System Approval Certificate

Annex II, excluding section 4 of Council Directive 93/42/EEC concerning  
medical devices

Scope of Certificate:

**Design and Manufacture Endoscopes for Gastroenterology,  
Otolaryngology, Pulmonology and Urology**

Device Classification:

**Class IIa**

Device Descriptions:

**Please refer to Attachment 1**

Model Type:

**Please refer to Attachment 1**

Manufacturing/Off Sites located at:

135 Flanders Road  
Westborough, MA 01581,  
USA

File Number	A14523	Cycle Start Date	29 August 2016
Certificate No.	439.160822	Effective Date	29 August 2016
		Expiry Date	28 August 2019

Authorised by

**Deborah Stubbs  
Certification Reviewer**

For and on Behalf of UL International (UK) Ltd

We hereby declare that an examination of the full quality assurance system has been carried out per report 11369668, following the requirements of the national legislation to which the undersigned is subject, transposing Annex II (with the exemption of section 4) of Council 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 is subject to periodic surveillance as required by 93/42/EEC, Annex II, Section 5. For Class III devices where they are covered by this certificate, an EC Design Examination certificate according to 93/42/EEC, Annex II, Section 4 is required. This certificate is issued with (3) attachments listing model numbers.

## Notified Body

# 0843

00-NB-F0413 1.0

UL International (UK) Limited  
Wonersh House, The Guildway, Old Portsmouth Road,  
Guildford, Surrey, GU3 1LR, United Kingdom



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### Attachment 1

The products detailed below are covered under the scope of this certificate

Product Family	Product Sub-Group	Model/Type	Classification
ENT	ENT-4000 Series Flexible Nasopharyngo-Laryngoscope (ENT) Fiberscope	02-4XXX	Class IIa
	ENT-5000 Flexible Video Rhinolaryngoscope	02-520X	Class IIa
	ENT-7000 FLEXIBLE NASOPHARYNGO – LARYNGOSCOPE	02-720X	Class IIa
TNE	TNE-5000 Flexible Video Trans nasal Esophagoscope	03-520X	Class IIa
B/BRS	BRS-4000 Flexible Bronchoscope	04-420X	Class IIa
	BRS-5100 Video Bronchoscope, NTSC	04-520X	Class IIa
	BRS-5100 Video Bronchoscope, PAL	04-520X	Class IIa
CST	CST-4000 Flexible Cystoscope/Hysteroscope	08-420X	Class IIa
	CST-5000 Flexible Videoscope Cystoscope	08-520X	Class IIa
DPU	DPU-5000 Series Digital Video Processors	07-50XX	Class IIa
	DPU-5050 / DPU 5050A Video Processor with LCD Display	04-50xx	Class IIa
	DPU-7000 / DPU-7000A Video Processor with LCD Display	07-70XX	Class IIa

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