EC CERTIFICATE

Respiratory Technology Corporation

11011 Brooklet Drive, Suite 300
Houston, Texas 77099 UNITED STATES

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 of pH monitoring systems, sterile active catheters, active handpiece kits

Device Classifications:
Class IIa
Class IIb

Device Descriptions and Model Type:
Please refer to Attachment: 1

We hereby declare that an examination of the full quality assurance system has been carried out 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 1 attachment listing product references covered by this certificate.

File Number	A17975	Cycle Start Date	December 9, 2017
Certificate Number	641.190729	Effective Date	July 29, 2019
Initial Issue Date	December 9, 2011	Expiry Date	December 8, 2022

Authorised by

Paul Daysh
Medical Notified Body Operations Manager
For and on Behalf of UL International (UK) Ltd

Notified Body
0843

MDD A2 S3 FQ
00-MB-S0043 Issue: 15.0

Check Certificate Status: here

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

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Attachment 1 of 1

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

Product Family	Product Sub-Group	Model/Type	Classification	G/UMDN Code
Active Surgical Device	Secca Handpiece	Accessory Kit 175 5107	Class IIb	38817
		8000	Class IIb	38817
	Stretta Catheter	Accessory Kit 175 5880	Class IIb	45712
		8800	Class IIb	45712
ph Monitoring System	DX-pH Measurement System	DX-1000	Class IIa	36965

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