



# 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.**

Device Classifications:

**Class IIa**

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	641.190623	Effective Date	June 23, 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
ph Monitoring System	DX-pH Measurement System	DX-1000	Class IIa	36965

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