



# EC CERTIFICATE

## Respiratory Technology Corporation

114 Holmes Road, Suite 201  
Houston, TX 77045  
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, manufacture and refurbishment of pH monitoring systems**

Device Classification:

**Ila**

G/UMDN Code:

**36965**

Device Descriptions:

**The Dx-pH Measurement System measures pH in the airway to assist in diagnosing gastric reflux. The Dx-System assists physicians in determining the existence of laryngopharyngeal reflux and its relationship to various patient symptoms**

Model Type:

**Dx-1000 Dx-pH Measurement System (includes DataView Software Recorder, Transmitter, Sleep Adapter, Dx-pH Probe, Dx-pH Long Probe, and Primus pH Probe)**

Manufacturing Site Located at:

7905 Silverton Avenue, Suite 101  
San Diego, CA 92126  
USA

**We hereby declare that an examination of the full quality assurance system has been carried out per report 11982565, 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.**

File Number A17975  
Certificate No. 641.171209

Cycle Start Date 09 December 2017  
Effective Date 09 December 2017  
Expiry Date 08 December 2022

Authorised by

**Deborah Stubbs**  
Certification Manager

For and on Behalf of UL International (UK) Ltd

**Notified Body**

**0843**