



EC CERTIFICATE

RESPIRATORY TECHNOLOGY CORP

10804 Willow Ct., Suite B
San Diego, CA 92127 United States

Full Quality Assurance System Approval Certificate

Annex II, section 3 of Council Directive 93/42/EEC concerning medical devices

Scope of Certificate:

Design, manufacture and refurbishment of pH monitoring systems

Device Classification:

Class IIa

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 Recorder, Transmitter, Sleep Adapter and Dx-pH Probe)

File Number A17975
Certificate No. 641.111123

Cycle Start Date 9 Dec 2011
Effective Date 9 Dec 2011
Expiry Date 8 December 2014

Authorised by

Barry A. Fitch

Certification Manager

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 11SC03283, 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.

Notified Body

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