EC CERTIFICATE

Flotec, Inc.

7625 W. New York St.
Indianapolis, IN 46214
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 and manufacture of regulators, flowmeters, pressure regulators with flowmeters and pressure regulators integrated with cylinder for medical gases

Device Classification:
Class IIb

Device Descriptions:
Pressure Regulators and Flowmeters for Medical Gases

We hereby declare that an examination of the full quality assurance system has been carried out per report 4786427324, 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	A12714	Cycle Start Date	20 August 2014
Certificate No.	717.140820	Effective Date	20 August 2014
		Expiry Date	27 October 2014

Authorised by

Anwen Evans
Certification Manager
For and on Behalf of UL International (UK) Ltd

Notified Body
0843

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