



# EC CERTIFICATE

## Flotec Inc.

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

Device Classification:  
**IIb**

GMDN Code:  
**61366, 43438, 31273, 14239**

Device Descriptions:

**Pressure Regulators and Flowmeters for Medical Gases**

Model Type:

**See Attachment 1**

We hereby declare that an examination of the full quality assurance system has been carried out per report SR4448102, 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 model numbers covered by this certificate.

File Number	A12714	Initial Certification	28 October 2014
		Cycle Start Date	28 October 2017
Certificate No.	717.171124	Effective Date	24 November 2017
		Expiry Date	27 October 2022
		Authorised by	

**Itoro Udofia**  
Certification Manager

For and on Behalf of UL International (UK) Ltd

**Notified Body**  
**0843**

UL International (UK) Limited  
Wonersh House, The Guildway, Old Portsmouth Road,  
Guildford, Surrey, GU3 1 LR, 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	GMDN Code
Medical Gas Flowmeter	Same	Flowmeter	IIb	61366
Medical Pressure Regulator	Same	Regulator	IIb	43438
Medical Gas Pressure Gauge	Same	Ingage	IIb	31273
Multitatorr & Mass Casualty Assembly	Same	Mass Casualty	IIb	14239

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