



Medical Device Safety Service 



MDSS · Schiffgraben 41 · 30175 Hannover, Germany

Flotec, Inc.
Mr. John Pichon
7625 West New York Street
Indianapolis, IN 46214
UNITED STATES OF AMERICA

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30175 Hannover, Germany

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2017.12.20

Confirmation of CE Registration

Dear John

It is our pleasure to enclose the new Certificate of CE-Registration for your product.

Please note that registration was performed under § 25 MPG (Medizinproduktegesetz). This is the *Federal Republic of Germany's national interpretation of Medical Device Directive 93/42/EEC*. Registration is therefore in accordance with EU legislation. We remind you that all products must meet the applicable provision of the European and national regulation before they may be placed on the market.

We are looking forward to continuing our good business relationship and wish you a successful product launch in Europe.

Best regards,

Mahvish Wali
Administrative Assistant
Medical Device Safety Service GmbH

Encl.

1 Certificate of CE-Registration
1 Annex A

MDSS · Medical Device Safety Service GmbH

Handelsregister Hannover HRB 57318 · USt-IdNr. DE 177346163 · Geschäftsführer: Ludger Möller

Bankverbindungen
Sparkasse Hannover
S.W.I.F.T.: SPKHDE2H

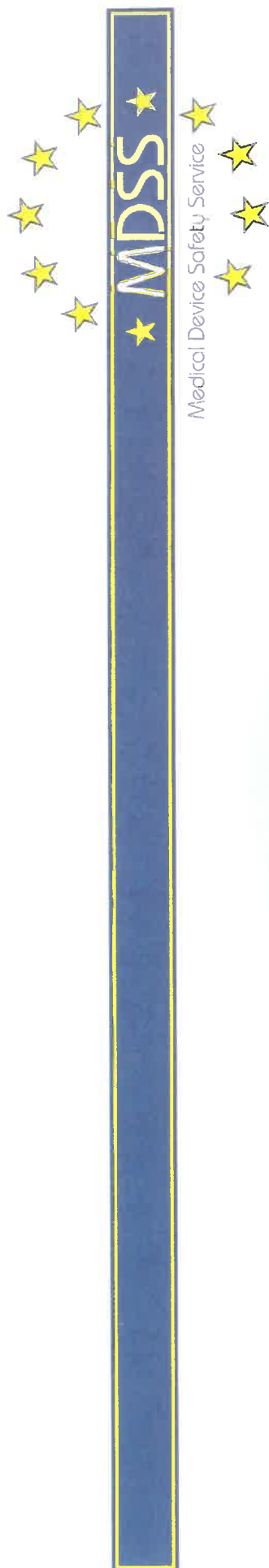
IBAN: DE24 2505 0180 0910 0792 77

Commerzbank AG, Hannover
S.W.I.F.T.: COBADEFF 250

IBAN: DE67 2504 0066 0338 8816 00



Certificate of CE-Registration



This is to certify that, in accordance with the Medical Device Directive 93/42/EEC, Medical Device Safety Service GmbH (MDSS) agrees to perform all duties and responsibilities as the Authorized Representative for:

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as stipulated and demanded by the aforementioned Directive. The German Competent Authority has allocated the medical devices of the Manufacturer registration numbers as foreseen in:

Annex A dated December 20, 2017

The Manufacturer has provided MDSS with the appropriate Declaration(s) of Conformity confirming that the medical devices fulfill the applicable requirements of Directive 93/42/EEC. In compliance with German law, a safety officer has been appointed for Germany.

2017-12-20

A handwritten signature in blue ink, appearing to read 'Joy Grimm', is written over the date.

**Joy Grimm
Senior Consultant
MDSS GmbH**

**Annex A dated December 20, 2017
Manufacturer: Flotec, Inc.**

UMDNS Code Description Notified Medical Device Product Name & Catalogue Number	UMDNS Code	Risk Class	Cat. Code	Registration Number	NB No. / NB Certificate No.	NB Cert. Valid Until YYYY-MM-DD
Flowmeters, Gas	11-748	IIb	02	DE/CA09/0170/F07/002	0843/717.171028	2022-10-27
Flowmeters						
FXXX-XXXXX Flowmeters						
Regulators, High-Pressure Gas	13-323	IIb	02	DE/CA09/0170/F07/001	0843/717.171028	2022-10-27
Regulators; Ingage Regulators; Mini Regulators						
RXXXX-XXXXX Regulators						
DXXXX-XXXXX Ingage Regulators						
MXXXX-XXXXX Mini Regulators						

