FLOTEC
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Toll Free: 1-800-401-1723

Declaration of Conformity EU

Product Identification

Product Name	Part Number	UDI-DI
RW Regulator	RXXXX-XXXXX	+B741RW0
InGage Regulator	DXXXX-XXXXX	+B741DL0
Flowmeter	FXXX-XXXXX	+B741FM0
Mass Casualty Assembly	MCA-XXXXX-XXXXX	+B741MC0

Manufacturer

Name of company	Address	Contact information
Flotec	7625 West New York Street Indianapolis, Indiana 46214-4911 United States of America	+1 317-273-6960 +1 317-273-6979 Orderdesk@floteco2.com

Notified Body

Name of company/CE number	Address	Contact information
Polskie Centrum Badań i Certyfikacji S.A. z siedzibą w Warszawie (PCBC) (Polish Center for Testing and Certification) CE 1434	ul. Pulawska 469 02-844 Warszawa Poland	+48 (22) 46 45 200 +48 (22) 46 45 251 pcbc@pcbc.gov.pl

Authorized representative

Name of company	Address	Contact information
Medical Device Safety Service EC REP	Medical Device Safety Service GmbH Schiffgraben 41 D-30175 Hannover Germany	+49 511-6262-8630 +49 511-6262-8633 info@mdss.com

Conformity assessment

Device classification	Route to conformity	Standards applied
Class IIb Rule 11	Annex II (excluding section 4) of Council Directive 93/42/EEC	Council Directive 93/42/EEC EN ISO 13485:2016

Other standards applied where appropriate

EN ISO 14971:2012	RoHS Directive	CGA E-7	CGA V-1	ASTM G175-03

Flotec declares that the above-mentioned products meet the provisions of Council Directive 93/42/EEC.
Company representative:

Brian R. Davidson
Title: President
Date: 2021-04-20