

DECLARATION OF CONFORMITY

PRODUCT IDENTIFICATION	
Product Name/Description	Model Number
Medical Gas Flowmeters	67XX-XXXX-XXX Series 77XX-XXXX-XXX Series FM-SS(S)TU(-)VV(WW)-(X)
	FM-CS-XX-YYZZZ

MANUFACTURER		
Name	Address	Company Representative
Ohio Medical	1111 Lakeside Drive	Jessica Barrile
	Gurnee, IL 60031 USA	

AUTHORIZED REPR	RESENTATIVE
Name	Address
Emergo Europe	Prinsessegracht 20
	2514 AP The Hague
	The Netherlands

REGISTRATION INFORMATION				
Notified Body/ID#	CE Certificate Number	Date CE Marking First Applied		
BSI / 2797	502901	12 January 2006		

CONFORMITY ASSESSMENT			
Device Classification	Route to Compliance	Standards Applied	
Class IIa, Rule 11	Annex II of MDD 93/42/EEC	ISO 13485; 2016	
,		ISO 15002	

Ohio Medical LLC declares that the above-mentioned products meet the provisions of the Council Directive 93/42 EEC for Medical Devices. All supporting documentation is retained at the premises of the manufacturer.

COMPANY REPRESENTATIVE: Jessica Barrile

TITLE: Regulatory Affairs Manager

DATE: May 12, 2022

SIGNATURE: