

DECLARATION OF CONFORMITY

PRODUCT IDENTIFICATION	
Product Name/Description	Model Number
Vacuum Regulators	47XX-XXXX-XXX Series 57XX-XXXX-XXX Series 67XX-XXXX-XXX Series 87XX-XXXX-XXX Series VRXX-XXXX-XYZ Matrix VRXX-XXXX-XY Matrix

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

AUTHORIZED REPRESENTATIVE	
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 10079-3

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

SIGNATURE:



DATE: May 12, 2022

