Ohio® Medical

MANUFACTURER'S DECLARATION OF CONFORMITY

AUSTRALIAN THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATIONS 2002

FULL QUALITY ASSURANCE PROCEDURES

This is a declaration of conformity made under clause 1.8 of Schedule 3 to the Therapeutic Goods (Medical Devices) Regulations 2002.

Manufacturer's name:	Ohio Medical
Business address:	1111 Lakeside Drive Gurnee, Illinois 60031, USA
Medical device(s):	47XX-XXXX-XXX Series, 57XX-XXXX-XXX Series, 67XX-XXXX-XXX Series, 87XX-XXXX-XXX Series, VRXX-XXXX-XXYZ Matrix, VRXX-XXXX-XXY Matrix
Classification:	Class IIa
GMDN code and term:	44809, Suction System Regulator Surgical
Scope of application:	All

Each kind of medical device to which the system has been applied complies with the applicable provisions of the essential principles, the classification rules, and the full quality assurance procedures, at each stage, from the design of the device until its final inspection before being supplied.

Full quality assurance procedures certificate:	European conformity assessment certificate under Annex II.3 of the Directive 93/42/EEC on Medical Devices; OR
Standards applied:	ISO 10079-3:2014 ISO 13485:2016

1111 Lakeside Drive Ohio Medical LLC Gurnee Illinois 60031

Authorised signatory:

Signature

Jessica Barrile, Sr Quality Assurance Manager — February 9, 2021

Name, Position — Date