

**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):** HS-UUYZ-XXYYXX(U), HS-CS-XX-YYZZ  
**Classification:** Class IIa  
**GMDN code and term:** 63209, General Gas Low Pressure Tubing, Reusable  
**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:** BS EN ISO 5359:2014  
ISO 13485:2016

**Authorised signatory:**



Signature



Jessica Barrile, Sr Quality Assurance Manager  
Name, Position

February 9, 2021  
Date