



## **DECLARATION OF CONFORMITY**

This is to confirm that the

### **Therapy Equipment Injector Suction Unit**

<u>Part No.</u>	<u>Description</u>
4450	Injector Suction Unit Only
4451	Injector Suction Unit – Straight Through Valve
4452	Injector Suction Unit with Direct Oxygen Probe
4425	Rail Mounted Injector Suction/Flowmeter Unit
4426	Rail Mounted Injector Suction/Flowgauge Unit
4427	Complete Injector Suction/Flowmeter Unit
4428	Complete Injector Suction/Flowgauge Unit
4430	Direct Injector Suction/Flowmeter Unit for Regulator
4455	Emergency Injector Suction Unit

Conforms to the EC Declaration of Conformity regarding Medical Devices as outlined in Annex II MDD 93/42 EEC consolidated 2007/47/EC of the Official Journal of the European Communities.

Therapy Equipment ensure and declare that the above products which have been classified as Class IIA (Annex IX Rule 11) are manufactured in conformity with technical documentation (Annex VII, Section 3) and meet the directive which apply to them.

Therapy Equipment declare that the products conform to ISO 10079-3:2014, and that the Quality and Production Standards for the products conform to BS EN ISO 13485:2016.

Notified Body – British Standard Institute (Identification No. 2797)  
CE Marking Certificate Number – CE 01847

The GMDN Code of the Product is 13325.

Steve Munn  
General Manager  
Therapy Equipment Ltd  
18<sup>th</sup> June 2019