



DECLARATION OF CONFORMITY

This is to confirm that the

Therapy Equipment Pipeline Suction Unit

<u>Part No.</u>	<u>Description</u>
4701	High Direct Old Style Suction Unit with BS Probe
4703	High Old Style Suction Unit with 1/8 Female Fitting
4705	Rail Mounted High Old Style Suction Unit
4706	V Dovetail Mounted High Old Style Suction Unit
4707	Complete Rail Mounted Old Style High Suction Assembly
4708	Complete V Dovetail Old Style High Suction Assembly
4715	High Direct Old Style Suction Unit with 1.8L Receiver Jar
4720	Low Direct Old Style Suction Unit with BS Probe
4721	Low Direct Old Style Suction Unit with 9/16LH Fitting
4725	Rail Mounted Low Old Style Suction Unit
4726	V Dovetail Mounted Low Old Style Suction Unit
4735	Low Direct Old Style Suction Unit with 1.8L Receiver Jar
4740	Thoracic Direct Old Style Suction Unit with BS Probe
4742	Thoracic Direct Old Style Suction Unit with 9/16LH Fitting
4745	Rail Mounted Thoracic Old Style Suction Unit
4760	Theatre Suction Unit with Twin Jars
4763	Theatre Suction Unit without Jars

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 product conforms 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 (13332 – Thoracic).

Steve Munn
General Manager
Therapy Equipment Ltd
18th June 2019