



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
4705	Rail Mounted High Old Style Suction Unit
4706	V Dovetail Mounted High Old Style Suction Unit
4715	High Direct Old Style Suction Unit with 1.8L Receiver Jar
4720	Low Direct Old Style Suction Unit with BS Probe
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
4745	Rail Mounted Thoracic Old Style Suction Unit

Conforms to the EC Declaration of Conformity regarding Medical Devices as outlined in Annex V MDD 93/42/EEC – 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 are manufactured in conformity with technical documentation referred to in Section 3 of Annex VII MDD 93/42/EEC – 2007/47/EC and meet the directive which apply to them.

Therapy Equipment declare that the product conforms to ISO 10079-3:2000, and that the Quality and Production Standards for the products conform to ISO 9001:2008 and ISO 13485: 2003.

The GMDN Code of the Product is 13325 (13332 – Thoracic). Under MDD Classification Rule 11 Annex V (Section 3.2).

Steve Munn
General Manager
Therapy Equipment Ltd
26th November 2009