



DECLARATION OF CONFORMITY

This is to confirm that the

Therapy Equipment Diamond Range & Injector Suction units.

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, BS EN ISO 14971:2012, BS EN 62366-1:2015+A1:2020, BS EN ISO 15223-1:2016, BS EN 1041:2008+A1:2013.

EU Authorised Representative MedNet EC-REP GmbH, Borkstrasse 10, 48163 Muenster, Germany

Therapy Equipment Ltd is exclusively responsible for this declaration of conformity and its contents.

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

The GMDN Code of the Product is 13325 (13332 – Thoracic).

Paul Robinson
Quality & Regulatory Manager
Therapy Equipment Ltd
1st Jan 2021



Therapy Equipment Ltd

UNIT 1, CRANBOURNE AVENUE, CRANBOURNE INDUSTRIAL ESTATE
POTTERS BAR, HERTS, EN6 3JN TEL: 01707 652270 FAX: 01707 652622



Certificate Number MD 595894

<u>Part No.</u>	<u>Description</u>
7701	Diamond High Suction Controller with Direct Fitting Probe
7702	Diamond High Suction Controller with 9/16 LH Fitting
7703	Diamond High Suction Controller with 1/8 Female Fitting
7705	Rail Mounted Diamond High Suction Controller
7706	V Dovetail Mounted Diamond High Suction Controller
7715	Complete Diamond High Suction Assembly
7707	Complete Rail Mounted Diamond High Suction Assembly
7708	Complete V Dovetail Mounted Diamond High Suction Assembly
7720	Diamond Low Suction Controller with Direct Fitting Probe
7721	Diamond Low Suction Controller with 9/16 LH Fitting
7725	Rail Mounted Diamond Low Suction Controller
7726	V Dovetail Mounted Diamond Low Suction Controller
7736	Complete Diamond Low Suction Assembly
7727	Complete Rail Mounted Diamond Low Suction Assembly
7728	Complete V Dovetail Mounted Diamond Low Suction Assembly
7740	Diamond Thoracic Suction Controller with Direct Fitting Probe
7742	Diamond Thoracic Suction Controller with 9/16 LH Fitting
7745	Rail Mounted Thoracic Diamond Low Suction Controller
7880	Diamond High Suction/Single Flowmeter Package
7890	Diamond High Suction/Twin Flowmeter Package
7765	Diamond Twin Suction Controllers (High/High) with Probe
7770	Diamond Twin Suction Controllers (High/Low) with Probe
7777	Diamond Twin Suction Controllers (High/Thoracic) with Probe
7775	Rail Mounted Diamond Twin Suction Controllers (High/Low)
7780	Rail Mounted Diamond Twin Suction Controllers (High/High)
7830	Diamond Medline 4 Cannister Trolley Conversion (FKD0034D)
7840	Diamond Medline 8 Cannister Trolley Conversion (FKD0035D)
7850	New for Old Diamond High Suction Controller with Direct Fitting Probe
7852	New for Old Rail Mounted Diamond High Suction Controller
7885	New for Old Diamond Package (Single Flowmeter)
7895	New for Old Diamond Package (Twin Flowmeter)
7860	New for Old Diamond Low Suction Controller with Direct Fitting Probe
7862	New for Old Rail Mounted Diamond Low Suction Controller
7870	New for Old Diamond Thoracic Suction Controller with Direct Fitting Probe
7872	New for Old Rail Mounted Diamond Thoracic Suction Controller
7760	Diamond Theatre Suction Unit complete
7761	Diamond Theatre Suction Unit with twin Controller
7763	Diamond Theatre Suction Unit with fitted V Brackets
7763/ABB	Diamond Theatre Suction Unit with fitted Abbots Brackets

**Therapy Equipment Diamond Range, Injector & Emergency Suction Unit
Declaration of Conformity
Page 3 of 2**

<u>Part No.</u>	<u>Description</u>
7763/SERRES	Diamond Theatre Suction Unit with fitted Serres Brackets
7766	Diamond Theatre Suction Unit with 4 Receiver Jars
7767	Diamond Theatre Suction Unit with 4 V Brackets
7768	Diamond Theatre Suction Unit with fitted Diamond Flowmeter
7715/PB	Complete Diamond High Suction (with Puritan Bennett Probe) Assembly
7760/PB	Diamond Theatre Suction Unit (with Puritan Bennett Probe) complete
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