



DECLARATION OF CONFORMITY

This is to confirm that the

Therapy Equipment Diamond Flowmeter Range & Direct Dial Flowmeters

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.

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

Therapy Equipment declare that the product conforms to ISO 15002:2008, 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.

The GMDN Code of the Product is 37132.

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

Part No.	Description
9501	0-15LPM Diamond Flowmeter – O2
9502	0-15LPM Diamond Flowmeter – Air
9505	0-15LPM Diamond Flowmeter & Probe – O2
9506	0-15LPM Diamond Flowmeter & Probe – Air
9510	0-15LPM Diamond Flowmeter & Probe & Humidifier – O2
9550	Twin 0-15LPM Diamond Flowmeter on Back Bar – O2
9551	Twin 0-15LPM Diamond Flowmeter on Back Bar – Air
9555	Twin 0-15LPM Diamond Flowmeter on Back Bar with Probe – O2
9556	Twin 0-15LPM Diamond Flowmeter on Back Bar with Probe – Air
9557	Twin Diamond Flowmeter (1 x 0-15LPM; 1 x 0-2.5LPM) with Probe – O2
9620	Rail Mounted Single 0-15LPM Diamond Flowmeter (1.5M Hose) – O2
9621	Rail Mounted Single 0-15LPM Diamond Flowmeter (1.5M Hose) – Air
9625	Rail Mounted Twin 0-15LPM Diamond Flowmeter (1.5M Hose) – O2
9626	Rail Mounted Twin 0-15LPM Diamond Flowmeter (1.5M Hose) – Air
9620/2M	Rail Mounted Single 0-15LPM Diamond Flowmeter (2M Hose) – O2
9621/2M	Rail Mounted Single 0-15LPM Diamond Flowmeter (2M Hose) – Air
9625/2M	Rail Mounted Twin 0-15LPM Diamond Flowmeter (2M Hose) – O2
9626/2M	Rail Mounted Twin 0-15LPM Diamond Flowmeter (2M Hose) – Air
9620/3M	Rail Mounted Single 0-15LPM Diamond Flowmeter (3M Hose) – O2
9621/3M	Rail Mounted Single 0-15LPM Diamond Flowmeter (3M Hose) – Air
9625/3M	Rail Mounted Twin 0-15LPM Diamond Flowmeter (3M Hose) – O2
9626/3M	Rail Mounted Twin 0-15LPM Diamond Flowmeter (3M Hose) – Air
9630	V Dovetail Single 0-15LPM Diamond Flowmeter (1.5M Hose) – O2
9631	V Dovetail Single 0-15LPM Diamond Flowmeter (1.5M Hose) – Air
9635	V Dovetail Twin 0-15LPM Diamond Flowmeter (1.5M Hose) – O2
9636	V Dovetail Twin 0-15LPM Diamond Flowmeter (1.5M Hose) – Air
9211	New for Old 0-15LPM Diamond Flowmeter – O2
9211/AIR	New for Old 0-15LPM Diamond Flowmeter – Air
9213	New for Old 0-15LPM Diamond Flowmeter – O2 (10 off)
9213/AIR	New for Old 0-15LPM Diamond Flowmeter – O2 (10 off)
9216	New for Old 0-15LPM Diamond Flowmeter & Probe – O2
9216/AIR	New for Old 0-15LPM Diamond Flowmeter & Probe – Air
9217	New for Old 0-15LPM Diamond Flowmeter & Probe – O2 (10 off)
9217/AIR	New for Old 0-15LPM Diamond Flowmeter & Probe – Air (10 off)
9212	New for Old Twin 0-15LPM Diamond Flowmeter on Back Bar – O2
9212/AIR	New for Old Twin 0-15LPM Diamond Flowmeter on Back Bar – Air
9214	New for Old Twin 0-15LPM Diamond Flowmeter on Back Bar with Probe – O2

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<u>Part No.</u>	<u>Description</u>
9214/AIR	New for Old Twin 0-15LPM Diamond Flowmeter on Back Bar with Probe – Air
9218	New for Old Rail Mounted Single Diamond Flowmeter (1.5M Hose) – O2
9218/AIR	New for Old Rail Mounted Single Diamond Flowmeter (1.5M Hose) – Air
9219	New for Old Rail Mounted Twin Diamond Flowmeter (1.5M Hose) – O2
9219/AIR	New for Old Rail Mounted Twin Diamond Flowmeter (1.5M Hose) – Air
9586	0-2.5LPM Diamond Flowmeter – O2
9587	0-2.5LPM Diamond Flowmeter & Probe – O2
9575	0-5LPM Diamond Flowmeter – O2
9576	0-5LPM Diamond Flowmeter & Probe – O2
9577	Twin 0-5LPM Diamond Flowmeter & Probe – O2
9510/PB	0-15LPM Diamond Flowmeter & Puritan Bennett Probe & Humidifier – O2
9506/AG	0-15LPM Diamond Flowmeter & Probe – Air with Airguard
9582	0-500cc Diamond Low Flowmeter with 3/8" Nut (Green Body)
9583	0-500cc Diamond Flowmeter & Probe – O2
6560	0-15LPM Direct Dial Flowmeter – O2
6568	0-2.5LPM Direct Dial Flowmeter – O2
6561	0-1LPM Direct Dial Flowmeter – O2
6564	0-0.5LPM Direct Dial Flowmeter – O2
6557	0-15LPM Direct Dial Flowmeter with 3/8" BSP – O2
6558	Twin 0-15LPM Direct Dial Flowmeter on Back Bar with Probe – O2
6640	Rail Mounted 0-15LPM Direct Dial Flowmeter – O2
6641	Rail Mounted Twin 0-15LPM Direct Dial Flowmeter – O2
6580	0-15LPM Direct Dial Flowmeter – Air
6645	Rail Mounted 0-15LPM Direct Dial Flowmeter – Air