

EC Declaration of Conformity

Manufacturer: BPR Medical Limited

Address: 22 Hamilton Way, Oakham Business Park,
Mansfield, Nottinghamshire
NG18 5BU, United Kingdom

Name of Device: Ultraflow Demand Valves and Exhalation Valves

Model Numbers: See appendix 1

EC Device Classification: Class IIa (Rule 2)

Applied Harmonised Standards: EN 1041:2008+A1:2013 - Information supplied by the manufacturer of medical devices
EN ISO 5359:2008/A1:2011 - Low-pressure hose assemblies for use with medical gases
EN ISO 15001:2011 - Anaesthetic and respiratory equipment - Compatibility with oxygen

Other Applied Standards: BS 4272-2:1992 - Anaesthetic and analgesic machines - Part 2: Specification for intermittent (demand) flow analgesic machines for use with 50/50 % (V/V) nitrous oxide and oxygen

GMDN Code: 17169

GMDN Term: Demand Valve

EC Representative: Qarad EC-REP BV, Pas 257, 2440 Geel, Belgium

I, the undersigned, hereby declare that the medical device specified above, manufactured on or after the date given below, conforms to the Essential Requirements of Annex I of EC Directive 93/42/EEC as amended by Directive 2007/47/EC.

CE marking is applied the basis of the Annex II route to conformity (full quality assurance). This declaration is supported by EC Certificate Number GB19/964430 issued by SGS Belgium NV. (Notified Body identification number 1639) and EN ISO 13485:2016 Quality Management System Certificate Number GB19/963113 issued by SGS United Kingdom Ltd.

Signed:



Richard Radford
Managing Director
For and on behalf of BPR Medical Limited

Date of Issue: 1st October 2020
Place of Issue: Mansfield, UK

Appendix 1 – List of Device Models

Device Ref.	Name	UDI DI
828-0001	Analgesic Demand Valve - 3m Hose - BS5682 connector	(01)05060274500397
828-0001S	Service Exchange Analgesic DV - 3m Hose - BS5682	(01)05060274502933
828-0002	Ultraflow Exhalation Valve with Mouthpiece - Box 100	(01)25060274500018
828-0003	Ultraflow Exhalation Valve with Mouthpiece (1)	(01)05060274500014
828-0004	Ultraflow Exhalation Valve with AGSS for Demand Valve (1)	(01)05060274502681
828-0013	Analgesic Demand Valve - 2m Hose - BS5682 connector	(01)05060274500380
828-0013S	Service Exchange - Analgesic DV - 2m Hose -BS5682	(01)05060274502940
828-0014	Analgesic Demand Valve - 4m Hose - BS5682 connector	(01)05060274500403
828-0014S	Service Exchange - Analgesic DV - 4m Hose -BS5682	(01)05060274502957
828-0015	Analgesic Demand Valve - 5m Hose - BS5682 connector	(01)05060274500410
828-0015S	Service Exchange - Analgesic DV - 5m Hose -BS5682	(01)05060274502964
828-0016	Analgesic Demand Valve - 6m Hose - BS5682 connector	(01)05060274500427
828-0016S	Service Exchange - Analgesic DV - 6m Hose -BS5682	(01)05060274502971
828-0019	Ultraflow AGSS Exhalation Valve with Mouthpiece (50)	(01)25060274502685
828-0022	Analgesic Demand Valve Intro Pack - 3m Hose - BS5682 - 10EV	(01)05060274500700
828-0039	Ultraflow Exhalation Valve for use with Face Mask - Pack 25	(01)35060274502699
828-0040	Ultraflow Exhalation Valve with Mouthpiece - Pack 25	(01)35060274500015
828-0041	Ultraflow Exhalation Valve for use with Face Mask (1)	(01)05060274502698
828-0042	Ultraflow Exhalation Valve for use with Face Mask - Box 100	(01)25060274502692
828-0044	Ultraflow Exhalation Valve for use with Face Mask - Pack 10	(01)15060274502695
828-0045	Ultraflow Exhalation Valve with Mouthpiece - Pack 10	(01)15060274500011
828-0047	Ultraflow Exhalation Valve + AGSS for use with Face Mask 1	(01)05060274500021
828-0048	Ultraflow Exhalation Valve + AGSS for use with Face Mask 10	(01)15060274500028
828-0049	Ultraflow Exhalation Valve + AGSS for use with Face Mask 50	(01)25060274500025
828-0050	Ultraflow AGSS Exhalation Valve with Mouthpiece - Pack 10	(01)15060274502688
828-1002	Analgesic Demand Valve - 2m Hose - AFNOR connector	(01)05060274500007
828-1002S	Service Exchange - Analgesic Demand Valve - 2m Hose - AFNOR	(01)05060274502988
828-1003	Analgesic Demand Valve - 3m Hose - AFNOR connector	(01)05060274500298
828-1003S	Service Exchange - Analgesic Demand Valve - 3m Hose - AFNOR	(01)05060274502995
828-1004	Analgesic Demand Valve - 4m Hose - AFNOR connector	(01)05060274500304



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828-1004S	Service Exchange - Analgesic Demand Valve - 4m Hose - AFNOR	(01)05060274503008
828-1005	Analgesic Demand Valve - 5m Hose - AFNOR connector	(01)05060274500311
828-1005S	Service Exchange - Analgesic Demand Valve - 5m Hose - AFNOR	(01)05060274503015
828-1006	Analgesic Demand Valve - 6m Hose - AFNOR connector	(01)05060274500328
828-1006S	Service Exchange - Analgesic Demand Valve - 6m Hose - AFNOR	(01)05060274503022
828-3002	Analgesic Demand Valve - 2m Hose - Nordica connector	(01)05060274500335
828-3002S	Service Exchange - Analgesic Demand Valve - 2m Hose -Nordica	(01)05060274503039
828-3003	Analgesic Demand Valve - 3m Hose - Nordica connector	(01)05060274500342
828-3003S	Service Exchange - Analgesic Demand Valve - 3m Hose -Nordica	(01)05060274503046
828-3004	Analgesic Demand Valve - 4m Hose - Nordica connector	(01)05060274500359
828-3004S	Service Exchange - Analgesic Demand Valve - 4m Hose -Nordica	(01)05060274503053
828-3005	Analgesic Demand Valve - 5m Hose - Nordica connector	(01)05060274500366
828-3005S	Service Exchange - Analgesic Demand Valve - 5m Hose -Nordica	(01)05060274503060
828-3006	Analgesic Demand Valve - 6m Hose - Nordica connector	(01)05060274500373
828-3006S	Service Exchange - Analgesic Demand Valve - 6m Hose -Nordica	(01)05060274503077
828-5002	Analgesic Demand Valve - 2m Hose - DISS Connector	(01)05060274500434
828-5002S	Service Exchange - Analgesic Demand Valve - 2m Hose - DISS	(01)05060274503138
828-5003	Analgesic Demand Valve - 3m Hose - DISS Connector	(01)05060274500441
828-5003S	Service Exchange - Analgesic Demand Valve - 3m Hose - DISS	(01)05060274503145
828-5004	Analgesic Demand Valve - 4m Hose - DISS Connector	(01)05060274500458
828-5004S	Service Exchange - Analgesic Demand Valve - 4m Hose - DISS	(01)05060274503152
828-6002	Analgesic Demand Valve - 2m Hose - SANS connector	(01)05060274500519
828-6002S	Service Exchange - Analgesic Demand Valve - 2m Hose - SANS	(01)05060274503169
828-6003	Analgesic Demand Valve - 3m Hose - SANS connector	(01)05060274500526
828-6003S	Service Exchange - Analgesic Demand Valve - 3m Hose - SANS	(01)05060274503176
828-6004	Analgesic Demand Valve - 4m Hose - SANS connector	(01)05060274500533
828-6004S	Service Exchange - Analgesic Demand Valve - 4m Hose - SANS	(01)05060274503183
828-6005	Analgesic Demand Valve - 5m Hose - SANS connector	(01)05060274500540
828-6005S	Service Exchange - Analgesic Demand Valve - 5m Hose - SANS	(01)05060274503190
828-6006	Analgesic Demand Valve - 6m Hose - SANS connector	(01)05060274500557
828-6006S	Service Exchange - Analgesic Demand Valve - 6m Hose - SANS	(01)05060274503206
828-7002	Analgesic Demand Valve - 2m Hose - SIS connector	(01)05060274500137
828-7002S	Service Exchange - Analgesic Demand Valve - 2m Hose - SIS	(01)05060274503213
828-7003	Analgesic Demand Valve - 3m Hose - SIS connector	(01)05060274500564
828-7003S	Service Exchange - Analgesic Demand Valve - 3m Hose - SIS	(01)05060274503220



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828-7004	Analgesic Demand Valve - 4m Hose - SIS connector	(01)05060274500571
828-7004S	Service Exchange - Analgesic Demand Valve - 4m Hose - SIS	(01)05060274503237
828-7005	Analgesic Demand Valve - 5m Hose - SIS connector	(01)05060274500588
828-7005S	Service Exchange - Analgesic Demand Valve - 5m Hose - SIS	(01)05060274503244
828-7006	Analgesic Demand Valve - 6m Hose - SIS connector	(01)05060274500595
828-7006S	Service Exchange - Analgesic Demand Valve - 6m Hose - SIS	(01)05060274503251
828-8002	Analgesic Demand Valve - 2m Hose - BS5682 connector NZ	(01)05060274500465
828-8002S	Service Exchange - Analgesic Demand Valve -2m Hose-BS5682 NZ	(01)05060274503268
828-8003	Analgesic Demand Valve - 3m Hose - BS5682 connector NZ	(01)05060274500472
828-8003S	Service Exchange - Analgesic Demand Valve -3m Hose-BS5682 NZ	(01)05060274503275
828-8004	Analgesic Demand Valve - 4m Hose - BS5682 connector NZ	(01)05060274500489
828-8004S	Service Exchange - Analgesic Demand Valve -4m Hose-BS5682 NZ	(01)05060274503282
828-8005	Analgesic Demand Valve - 5m Hose - BS5682 connector NZ	(01)05060274500496
828-8005S	Service Exchange - Analgesic Demand Valve -5m Hose-BS5682 NZ	(01)05060274503299
828-8006	Analgesic Demand Valve - 6m Hose - BS5682 connector NZ	(01)05060274500502
828-8006S	Service Exchange - Analgesic Demand Valve -6m Hose-BS5682 NZ	(01)05060274503305
828-9002	Analgesic Demand Valve - 2m Hose - 1/4 BSP	(01)05060274500601
828-9002S	Service Exchange - Analgesic Demand Valve - 2m Hose - 1/4BSP	(01)05060274503312
828-9003	Analgesic Demand Valve - 3m Hose - 1/4 BSP	(01)05060274500618
828-9003S	Service Exchange - Analgesic Demand Valve - 3m Hose - 1/4BSP	(01)05060274503329
828-9004	Analgesic Demand Valve - 4m Hose - 1/4 BSP	(01)05060274500625
828-9004S	Service Exchange - Analgesic Demand Valve - 4m Hose - 1/4BSP	(01)05060274503336
828-9005	Analgesic Demand Valve - 5m Hose - 1/4 BSP	(01)05060274500632
828-9005S	Service Exchange - Analgesic Demand Valve - 5m Hose - 1/4BSP	(01)05060274503343
828-9006	Analgesic Demand Valve - 6m Hose - 1/4 BSP	(01)05060274500649
828-9006S	Service Exchange - Analgesic Demand Valve - 6m Hose - 1/4BSP	(01)05060274503350
831-1003	Oxygen Demand Valve - 3m Hose - AFNOR Connector	(01)05060274500656
831-2003	Oxygen Demand Valve - 3m Hose - DIN Connector	(01)05060274500038
831-3003	Oxygen Demand Valve - 3m Hose - Nordica Connector AGA mini	(01)05060274500663
831-4003	Oxygen Demand Valve - 3m Hose - BS5682 Connector	(01)05060274500670
831-4010	Oxygen Demand Valve - 3m - BS5682 Total of 5 EVs & Facemasks	(01)05060274500694