

EU Declaration of Conformity

Manufacturer:	BPR Medical Limited
Address:	22 Hamilton Way Mansfield, Nottinghamshire NG18 5BU, United Kingdom
SRN:	GB-MF-000003347
Authorised Representative:	QbD RepS BV
Address:	Groenenborgerlaan 16 2610 Wilrijk, Belgium
SRN:	BE-AR-000000040
Name of Device:	Demand Valve
Device Risk Classification:	Class IIa (Rule 2, Annex VIII)
Basic UDI-DI:	5060274500096D
EMDN Code:	Z120499
EMDN Term:	General medicine instruments - other
Applied Common Specifications, harmonised standards and other standards:	EN ISO 15001:2011 EN ISO 15223-1:2021 EN ISO 20417:2021 EN ISO 18562-1:2017 EN ISO 10993-1:2020 EN ISO 14971:2012 EN ISO 5359:2014 BS ISO 18190:2016 BS 4272-2:1996+A1 (in part)



The intended purpose of the devices covered by this declaration is for the self-administration of N2O/O2 50%/50% v/v (analgesic gas) or oxygen in response to a patient's inspiratory effort.

This declaration of conformity is issued under the sole responsibility of the manufacturer. I, the undersigned, hereby declare that the medical device specified above, manufactured on or after the date given below, conforms to the requirements of European Union Regulation 2017/745 and any other relevant union legislation that provides for the issuing of a declaration of conformity.

CE marking is applied the basis of Annex IX conformity assessment. This declaration is supported by EC Certificate Number GB26/00000017 issued by SGS Belgium. (Notified Body identification number 1639) and EN ISO 13485:2016 Quality Management System Certificate Number GB19/963113.

Signed:



Date of Issue: 16th February 2026

Place of Issue: Mansfield, UK

Kavnit Kaur
Regulatory Affairs Manager
For and on behalf of BPR Medical Limited

Part Numbers, Product Names and UDI-DI Covered by this Declaration

Analgesic Demand Valves

Part Number	Product Name	UDI-DI
828-0001	Analgesic Demand Valve, BS 5682, 3m	(01)05060274500397
828-0013	Analgesic Demand Valve, BS 5682, 2m	(01)05060274500380
828-0014	Analgesic Demand Valve, BS 5682, 4m	(01)05060274500403
828-0015	Analgesic Demand Valve, BS 5682, 5m	(01)05060274500410
828-0016	Analgesic Demand Valve, BS 5682, 6m	(01)05060274500427
828-0022	Analgesic Demand Valve, BS 5682, 3m	(01)05060274500700
828-1002	Analgesic Demand Valve, NF S 90 116, 2m	(01)05060274500007
828-1003	Analgesic Demand Valve, NF S 90 116, 3m	(01)05060274500298
828-1004	Analgesic Demand Valve, NF S 90 116, 4m	(01)05060274500304
828-1005	Analgesic Demand Valve, NF S 90 116, 5m	(01)05060274500311
828-1006	Analgesic Demand Valve, NF S 90 116, 6m	(01)05060274500328
828-3002	Analgesic Demand Valve, SS 875 24 30, 2m	(01)05060274500335
828-3003	Analgesic Demand Valve, SS 875 24 30, 3m	(01)05060274500342
828-3004	Analgesic Demand Valve, SS 875 24 30, 4m	(01)05060274500359
828-3005	Analgesic Demand Valve, SS 875 24 30, 5m	(01)05060274500366
828-3006	Analgesic Demand Valve, SS 875 24 30, 6m	(01)05060274500373
828-5002	Analgesic Demand Valve, CGA V-5 2020, 2m	(01)05060274500434
828-5003	Analgesic Demand Valve, CGA V-5 2020, 3m	(01)05060274500441
828-5004	Analgesic Demand Valve, CGA V-5 2020, 4m	(01)05060274500458
828-6002	Analgesic Demand Valve, SANS 1409, 2m	(01)05060274500519
828-6003	Analgesic Demand Valve, SANS 1409, 3m	(01)05060274500526
828-6004	Analgesic Demand Valve, SANS 1409, 4m	(01)05060274500533
828-6005	Analgesic Demand Valve, SANS 1409, 5m	(01)05060274500540
828-6006	Analgesic Demand Valve, SANS 1409, 6m	(01)05060274500557
828-7002	Analgesic Demand Valve, AS 2896, 2m	(01)05060274500137
828-7003	Analgesic Demand Valve, AS 2896, 3m	(01)05060274500564
828-7004	Analgesic Demand Valve, AS 2896, 4m	(01)05060274500571
828-7005	Analgesic Demand Valve, AS 2896, 5m	(01)05060274500588
828-7006	Analgesic Demand Valve, AS 2896, 6m	(01)05060274500595
828-8002	Analgesic Demand Valve, BS 5682, 2m	(01)05060274500465
828-8003	Analgesic Demand Valve, BS 5682, 3m	(01)05060274500472
828-8004	Analgesic Demand Valve, BS 5682, 4m	(01)05060274500489
828-8005	Analgesic Demand Valve, BS 5682, 5m	(01)05060274500496
828-8006	Analgesic Demand Valve, BS 5682, 6m	(01)05060274500502
828-9002	Analgesic Demand Valve, ¼ BSP, 2m	(01)05060274500601
828-9003	Analgesic Demand Valve, ¼ BSP, 3m	(01)05060274500618
828-9004	Analgesic Demand Valve, ¼ BSP, 4m	(01)05060274500625

Part Number	Product Name	UDI-DI
828-9005	Analgesic Demand Valve, ¼ BSP, 5m	(01)05060274500632
828-9006	Analgesic Demand Valve, ¼ BSP, 6m	(01)05060274500649

Oxygen Demand Valves

Part Number	Product Name	UDI-DI
831-1003	Oxygen Demand Valve, NF S 90 116, 3m	(01)05060274500656
831-2003	Oxygen Demand Valve, DIN 13260-2, 3m	(01)05060274500038
831-3003	Oxygen Demand Valve, SS 875 24 30, 3m	(01)05060274500663
831-4003	Oxygen Demand Valve, BS 5682, 3m	(01)05060274500670
831-5003	Oxygen Demand Valve - 3m Hose - DISS Connector	(01)05060274500687
831-4010	Oxygen Demand Valve - 3m Hose - BS5682 Connector + 5 EVs	(01)05060274500694