

UK Declaration of Conformity

Manufacturer:	BPR Medical Limited
Address:	22 Hamilton Way, Oakham Business Park, Mansfield, Nottinghamshire NG18 5BU, United Kingdom
Name of Device:	Pressure Regulators
Model Numbers:	See appendix 1
EC Device Classification:	Class IIb (Rule 9)
Applied Standards:	BS EN 1041:2008+A1:2013 - Information supplied by the manufacturer of medical devices BS EN ISO 15223-1:2020 - Symbols to be used with medical device labels, labelling and information to be supplied BS EN ISO 10524-1:2019 - Pressure regulators and pressure regulators with flow-metering devices (model dependent) BS EN ISO 15001:2011 - Anaesthetic and respiratory equipment. Compatibility with oxygen BS EN ISO 14971 :2012 - Medical devices. Application of risk management to medical devices BS EN ISO 10993-1:2020 - Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process BS EN 62366-1:2015 - Medical devices – Part 1: Application of usability engineering to medical devices ISO 18562-1:2017 - Biocompatibility evaluation of breathing gas pathways in healthcare applications Part 1: Evaluation and testing within a risk management process BS EN 13544-2:2002+A1:2009 - Respiratory therapy equipment - Part 2: Tubing and connectors BS 5682:2015 - Dimensions of probes and terminal units for medical gas supply systems – Requirements (model dependent) AS 3840.1-1998 - Pressure regulators for use with medical gases Part 1: Pressure regulators and pressure regulators with flow-metering devices (model dependent) BS 341-1:1991 - Specification for industrial valves for working pressures up to and including 300 bar (model dependent) BS EN ISO 407:2004 - Small medical gas cylinders - Pin-index yoke-type valve connections (model dependent) BS EN 837-1 - Pressure gauges - Part 1. Bourdon tube pressure gauges - Dimensions, metrology, requirements and testing
GMDN Codes:	43438, 60944
GMDN Terms:	Non-fixed medical gas cylinder regulator, Medical air cylinder regulator

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 the UK MDR 2002 (as amended).

UKCA marking is applied the basis of the Annex II route to conformity (full quality assurance). This declaration is supported by UKCA Certificate Number GB22/00000436 issued by SGS United Kingdom Ltd. (Approved Body identification number 0120) and BS EN ISO 13485:2016 Quality Management System Certificate Number GB22/00000436 issued by SGS United Kingdom Ltd.

Signed:



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

Date of Issue:
Place of Issue:

12th October 2022
Mansfield, UK

Appendix 1 – List of Device Models

Device Ref.	Name	UDI DI
818-0001	Dialflow Regulator - O2 - Range A - UK Bullnose/Barb	05060274501530
818-0002	Dialflow Regulator - O2 - Range A - Pin Index/Barb	05060274501592
818-0005	Dialflow Regulator - O2 - Range C - Pin Index/Barb	05060274501608
818-0006	Dialflow Regulator - O2 - Range C - UK Bullnose/Barb	05060274501547
818-0009	Dialflow Regulator - O2 - Range D - Pin Index/Barb	05060274501615
818-0010	Dialflow Regulator - O2 - Range D - UK Bullnose/Barb	05060274501554
818-0017	Dialflow Regulator - O2 - Range D - Pin Index/Barb/Aux Schr	05060274501646
818-0018	Dialflow Regulator - O2 - Range D - UK B-nose/Barb/Aux Schr	05060274501585
818-0019	Dialflow Regulator - O2 - Range C - Pin Index/Barb/Aux Schr	05060274501639
818-0020	Dialflow Regulator - O2 - Range C - UK B-nose/Barb/Aux Schr	05060274501578
818-0024	Dialflow Regulator - Air - Range D - UK Bullnose/Barb	05060274501653
818-0025	Dialflow Regulator - Air - Range D - Pin Index/Barb	05060274501677
818-0028	Dialflow Regulator - Air - Range D - Pin Index/Barb/Aux Sch	05060274501684
818-0030	Dialflow Regulator - O2 - Range E - UK Bullnose/Barb	05060274501561
818-0031	Dialflow Regulator - O2 - Range E - Pin Index/Barb	05060274501622
818-0037	Dialflow Regulator - Air - D - UK B-nose/Barb/Aux Schr	05060274501660
818-0040	Dialflow Regulator - O2 - Range A - Pin Index (Aus) Silver	05060274500052
818-0041	Dialflow Regulator - O2 - Range C - Pin Index - (Aus) Silver	05060274501691
818-0043	Dialflow Regulator - O2 - Range E - Pin Index - (Aus) Silver	05060274501707
818-0051	Dialflow Regulator - O2 - Range D - Pin Index - (Aus) Silver	05060274500069
818-0056	Dialflow Regulator - Air - Range D - Pin Index (Aus) Silver	05060274502896
819-0009	Pressure Regulator - O2 - Pin Index/3/8" BSP	05060274501745
819-0010	Pressure Regulator - O2 - Pin Index Inlet- BS5682 Sch Outlet	05060274501752
819-0011	Pressure Regulator - O2 - Pin Index/1/4" Hose Outlet	05060274501769
819-0012	Pressure Regulator - O2 - Pin Index/1/8" BSP Female	05060274504111
819-0015	Pressure Regulator - O2 - UK Bullnose/3/8" BSP	05060274501776
819-0016	Pressure Regulator - O2 - UK Bullnose - BS5682 Sch Outlet	05060274501783
819-0017	Pressure Regulator - O2 - UK Bullnose/1/4" Hose Outlet	05060274501790
819-0033	Pressure Regulator - Air - Pin Index/3/8" BSP	05060274501806

819-0034	Pressure Regulator - Air - Pin Index/Schrader	05060274501813
819-0035	Pressure Regulator - Air - Pin Index/1/4" Hose Outlet	05060274501820
819-0039	Pressure Regulator - Air - Bullnose/3/8" BSP	05060274501837
819-0040	Pressure Regulator - Air - UK Bullnose/Schrader	05060274501844
819-0063	Pressure Regulator - O2/N2O 50%/50% - Pin Index Schrader	05060274501851
819-0071	Pressure Regulator - O2 - Pin Index AS2472.3 - AS2896	05060274500045
819-0073	Pressure Regulator - O2/N2O - Pin Index AS2472.3 - AS2896	05060274500083
819-0077	Pressure Regulator - Air - Pin Index AS2472.3 - AS2896	05060274500076
819-0080	Pressure Regulator - O2 - Pin Index AS2472.3 - BS5682	05060274501868
819-0081	Pressure Regulator - O2/N2O - Pin Index AS2472.3 - BS5682	05060274501875
819-0082	Pressure Regulator - Air - Pin Index AS2472.3 - BS5682	05060274501882
819-0083	Pressure Regulator (High Flow) - AIR - PI - BS5682	05060274504166