

## EC Declaration of Conformity

Manufacturer:	BPR Medical Limited
Address:	22 Hamilton Way, Oakham Business Park, Mansfield, Nottinghamshire NG18 5BU, United Kingdom
Name of Device:	Pressure Regulator for use with Medical Gases
Model Numbers:	See appendix 1
EC Device Classification:	Class IIb (Rule 11)
Applied Standards:	EN 1041:2008+A1:2013 - Information supplied by the manufacturer of medical devices EN ISO 15223-1:2020 - Symbols to be used with medical device labels, labelling and information to be supplied EN ISO 10524-1:2019 - Pressure regulators and pressure regulators with flow-metering devices EN ISO 15001:2011 - Anaesthetic and respiratory equipment. Compatibility with oxygen EN ISO 14971 :2012 - Medical devices. Application of risk management to medical devices EN ISO 10993-1:2020 - Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process 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 5682:2015 - Dimensions of probes and terminal units for medical gas supply systems – Requirements AS 3840.1-1998 - Pressure regulators for use with medical gases Part 1: Pressure regulators and pressure regulators with flow-metering devices AS 2902-2005 - Medical gas systems - Low pressure flexible hose assemblies BS 341-1:1991 - Specification for industrial valves for working pressures up to and including 300 bar ISO 407:2004 - Small medical gas cylinders - Pin-index yoke-type valve connections BS EN 837-1
GMDN Codes:	43438, 44244, 60944
GMDN Terms:	Non-fixed medical gas cylinder regulator, Medical air cylinder regulator, Nitrous oxide cylinder regulator
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 GB21/968568 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:

3<sup>rd</sup> March 2022  
Mansfield, UK

### Appendix 1 – List of Device Models

Device Ref.	Name	UDI DI
819-0009	Pressure Regulator - O2 - Pin Index/3/8" BSP	(01)05060274501745
819-0010	Pressure Regulator - O2 - Pin Index Inlet- BS5682 Sch Outlet	(01)05060274501752
819-0011	Pressure Regulator - O2 - Pin Index/1/4" Hose Outlet	(01)05060274501769
819-0012	Pressure Regulator - O2 - Pin Index/1/8" BSP Female	(01)05060274504111
819-0015	Pressure Regulator - O2 - UK Bullnose/3/8" BSP	(01)05060274501776
819-0016	Pressure Regulator - O2 - UK Bullnose - BS5682 Sch Outlet	(01)05060274501783
819-0017	Pressure Regulator - O2 - UK Bullnose/1/4" Hose Outlet	(01)05060274501790
819-0033	Pressure Regulator - Air - Pin Index/3/8" BSP	(01)05060274501806
819-0034	Pressure Regulator - Air - Pin Index/Schrader	(01)05060274501813
819-0035	Pressure Regulator - Air - Pin Index/1/4" Hose Outlet	(01)05060274501820
819-0039	Pressure Regulator - Air - Bullnose/3/8" BSP	(01)05060274501837
819-0040	Pressure Regulator - Air - UK Bullnose/Schrader	(01)05060274501844
819-0063	Pressure Regulator - O2/N2O 50%/50% - Pin Index Schrader	(01)05060274501851
819-0071	Pressure Regulator - O2 - Pin Index AS2472.3 - AS2896	(01)05060274500045
819-0073	Pressure Regulator - O2/N2O - Pin Index AS2472.3 - AS2896	(01)05060274500083
819-0077	Pressure Regulator - Air - Pin Index AS2472.3 - AS2896	(01)05060274500076
819-0080	Pressure Regulator - O2 - Pin Index AS2472.3 - BS5682	(01)05060274501868
819-0081	Pressure Reg - O2/N2O - Pin Index AS2472.3 - BS5682	(01)05060274501875
819-0082	Pressure Reg - Air - Pin Index AS2472.3 - BS5682	(01)05060274501882
819-0083	Pressure Regulator (High Flow) - AIR - PI - BS5682	(01)05060274504166