

## 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 9)

Applied Harmonised Standards: EN 1041:2008+A1:2013 - Information supplied by the manufacturer of medical devices  
EN ISO 10524-1:2006 - Pressure regulators for use with medical gases -- Part 1: Pressure regulators and pressure regulators with flow-metering devices for use with medical gases  
EN ISO 15001:2011 - Anaesthetic and respiratory equipment - Compatibility with oxygen

GMDN Codes: 43438, 60944

GMDN Terms: Non-fixed medical gas cylinder regulator, Medical air 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 GB19/963113 issued by SGS United Kingdom Ltd.

Signed:



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

Date of Issue: 1<sup>st</sup> October 2020  
Place of Issue: 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