

## EC Declaration of Conformity

Manufacturer: BPR Medical Limited  
Address: 22 Hamilton Way, Oakham Business Park,  
Mansfield, Nottinghamshire  
NG18 5BU, United Kingdom  
Name of Device: Dialflow Regulators  
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 Code: 43438  
GMDN Term: Non-fixed medical gas 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
818-0001	Dialflow Regulator - O2 - Range A - UK Bullnose/Barb	(01)05060274501530
818-0002	Dialflow Regulator - O2 - Range A - Pin Index/Barb	(01)05060274501592
818-0005	Dialflow Regulator - O2 - Range C - Pin Index/Barb	(01)05060274501608
818-0006	Dialflow Regulator - O2 - Range C - UK Bullnose/Barb	(01)05060274501547
818-0009	Dialflow Regulator - O2 - Range D - Pin Index/Barb	(01)05060274501615
818-0010	Dialflow Regulator - O2 - Range D - UK Bullnose/Barb	(01)05060274501554
818-0017	Dialflow Regulator - O2 - Range D - Pin Index/Barb/Aux Schr	(01)05060274501646
818-0018	Dialflow Regulator - O2 - Range D - UK B-nose/Barb/Aux Schr	(01)05060274501585
818-0019	Dialflow Regulator - O2 - Range C - Pin Index/Barb/Aux Schr	(01)05060274501639
818-0020	Dialflow Regulator - O2 - Range C - UK B-nose/Barb/Aux Schr	(01)05060274501578
818-0024	Dialflow Regulator - Air - Range D - UK Bullnose/Barb	(01)05060274501653
818-0025	Dialflow Regulator - Air - Range D - Pin Index/Barb	(01)05060274501677
818-0028	Dialflow Regulator - Air - Range D - Pin Index/Barb/Aux Sch	(01)05060274501684
818-0030	Dialflow Regulator - O2 - Range E - UK Bullnose/Barb	(01)05060274501561
818-0031	Dialflow Regulator - O2 - Range E - Pin Index/Barb	(01)05060274501622
818-0037	Dialflow Regulator - Air - D - UK B-nose/Barb/Aux Schr	(01)05060274501660
818-0040	Dialflow Regulator - O2 - Range A - Pin Index (Aus) Silver	(01)05060274500052
818-0041	Dialflow Regulator - O2 - Range C - Pin Index - (Aus) Silver	(01)05060274501691
818-0043	Dialflow Regulator - O2 - Range E - Pin Index - (Aus) Silver	(01)05060274501707
818-0051	Dialflow Regulator - O2 - Range D - Pin Index - (Aus) Silver	(01)05060274500069
818-0056	Dialflow Regulator - Air - Range D - Pin Index (Aus) Silver	(01)05060274502896