

## EC Declaration of Conformity

Manufacturer: BPR Medical Limited  
Address: 22 Hamilton Way, Oakham Business Park,  
Mansfield, Nottinghamshire  
NG18 5BU, United Kingdom  
Name of Device: Flowmeters for use with Medical Gases  
Model Numbers: 817-XXXX (refer to Device Specification)  
EC Device Classification: Class IIa (Rule 2)  
Applied Harmonised standards EN 1041:2008+A1:2013 - Information supplied by the manufacturer of medical devices  
EN ISO 15002:2008 - Flow-metering devices for connection to terminal units of medical gas pipeline systems  
EN ISO 15001:2011 - Anaesthetic and respiratory equipment - Compatibility with oxygen  
GMDN Code: 61366  
GMDN Term: Medical gas flowmeter, dial-type  
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
817-0001	Dialflow Meter - Range C 0.1 - 1.5 l/min - BS 5682/Barb	(01)05060274501318
817-0002	Dialflow Meter - Range C 0.1 - 1.5 l/min - BS 5682/Barb	(01)05060274501325
817-0005	Dialflow Meter - Range C 0.1 - 1.5 l/min - BS 5682/DISS	(01)05060274501332
817-0009	Dialflow Meter - Range D 0.5 - 15 l/min - BS 5682/DISS	(01)05060274501349
817-0015	Dialflow Meter - Air - Range D 0.5 - 15 l/min - MA/Barb	(01)05060274504203
817-0017	Dialflow Meter - Multi Block - Dual Range D - Indirect	(01)05060274501363
817-0018	Dialflow Meter - Multi Block - Range C & D - Indirect	(01)05060274501370
817-0027	Dialflow Meter - Range C 0.1 - 1.5 l/min - Baywater 130377	(01)05060274501431
817-0031	Dialflow Meter - Range C - 0.1 - 1.5 l/min - BOC 19316099	(01)05060274501462