

## EC Declaration of Conformity

Manufacturer: BPR Medical Limited  
Address: 22 Hamilton Way, Oakham Business Park,  
Mansfield, Nottinghamshire  
NG18 5BU, United Kingdom  
Name of Device: Microdial Flowmeter for use with Medical Gases  
Model Numbers: 816-XXXX (refer to Device Specification)  
EC Device Classification: Class IIa (Rule 2)  
Applied Harmonised Standards: 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: 37132  
GMDN Term: Oxygen Therapy Flowmeter

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 01639) 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: 16<sup>th</sup> December 2019  
Place of Issue: Mansfield, UK