

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: See appendix 1
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: 1st October 2019
Place of Issue: Mansfield, UK

Appendix 1 – List of Device Models

| Device Ref. | Name | UDI DI |
|-------------|--|--------------------|
| 816-0001 | Microdial Flowmeter - Range A 0.02 - 3 l/min - BS 5682/Barb | (01)05060274501042 |
| 816-0003 | Microdial Flowmeter - Range E 0.01 - 1 l/min - BS 5682/Barb | (01)05060274501059 |
| 816-0005 | Microdial Flowmeter - Range A 0.02 - 3 l/min - DIN/Barb | (01)05060274501080 |
| 816-0006 | Microdial Flowmeter - Range A 0.02 - 3 l/min - BS 5682/DISS | (01)05060274501066 |
| 816-0008 | Microdial Flowmeter - Range A 0.02 - 3 l/min - DIN/DISS | (01)05060274501103 |
| 816-0010 | Microdial Flowmeter - Range A 0.02 - 3 l/min - 3/8BSP/Barb | (01)05060274504005 |
| 816-0011 | Microdial Flowmeter - Range E 0.01 - 1 l/min - BS 5682/DISS | (01)05060274501073 |
| 816-0016 | Microdial Flowmeter - A - 0.02 - 3 l/min - BOC 19314031 | (01)05060274501226 |
| 816-0017 | Microdial Flowmeter - E - 0.01 - 1 l/min - BOC 19314032 | (01)05060274501233 |
| 816-0019 | Microdial Flowmeter - E - 0.01 - 1 l/min - Air Prod 130378 | (01)05060274501240 |
| 816-0022 | Microdial Flowmeter - Rng A 0.02 - 3 l/min - Mini AGA/Barb | (01)05060274501141 |
| 816-0023 | Microdial Flowmeter - Rng A 0.02 - 3 l/min - Mini AGA/DISS | (01)05060274504043 |
| 816-0024 | Microdial Flowmeter - Rng E 0.01 - 1 l/min - Mini AGA/Barb | (01)05060274501158 |
| 816-0025 | Microdial Flowmeter - Rng E 0.01 - 1 l/min - Mini AGA/DISS | (01)05060274504050 |
| 816-0026 | Microdial Flowmeter - Rng A 0.02 - 3 l/min - SIS AS2896/barb | (01)05060274500106 |
| 816-0027 | Microdial Flowmeter - Rng E 0.01 - 1 l/min - SIS AS2896/barb | (01)05060274500090 |
| 816-0032 | Microdial Flowmeter - Range A 0.02 - 3 l/min - DISS/Barb | (01)05060274501257 |
| 816-0033 | Microdial Flowmeter - Range A 0.02 - 3 l/min - DISS/DISS | (01)05060274501264 |
| 816-0034 | Microdial Flowmeter - Range E 0.01 - 1 l/min - DISS/Barb | (01)05060274501271 |
| 816-0035 | Microdial Flowmeter - Range E 0.01 - 1 l/min - DISS/DISS | (01)05060274501288 |
| 816-0037 | Microdial Flowmeter - Range E - 0.01 - 1 lpm - Ohmeda/Barb | (01)05060274504067 |
| 816-0038 | Microdial Flowmeter - Range A - 0.02 - 3 lpm - Ohmeda/Barb | (01)05060274504074 |
| 816-0039 | Microdial Flowmeter - Rng A 0.02 - 3 lpm - BS 5682/Barb Sil | (01)05060274501295 |
| 816-0040 | Microdial Flowmeter - Rng E 0.01 - 1 lpm - BS 5682/Barb Sil | (01)05060274504081 |
| 816-0041 | Microdial Flowmeter - Rng A 0.02 - 3 l/min - DISS/Barb 4.5b | (01)05060274504098 |
| 816-0042 | Microdial Flowmeter - Rng E 0.01 - 1 l/min - DISS/Barb 4.5b | (01)05060274504104 |
| 816-0043 | Microdial Flowmeter - Rng A 0.02 - 3 l/min - DIN/DISS 4.5b | (01)05060274501165 |
| 816-0044 | Microdial Flowmeter - Rng E 0.01 - 1 l/min - DISS/DISS 4.5b | (01)05060274501172 |
| 816-0045 | Microdial Flowmeter - Rng A 0.02 - 3 l/min - DIN/Barb 4.5b | (01)05060274501189 |
| 816-0046 | Microdial Flowmeter - Rng E 0.01 - 1 l/min - DIN/Barb 4.5b | (01)05060274501196 |
| 816-0047 | Microdial Flowmeter - Rng E 0.01 - 1 l/min - DIN/DISS 4.5b | (01)05060274501202 |