

EC Declaration of Conformity

Manufacturer: BPR Medical Limited
Address: 22 Hamilton Way, Oakham Business Park,
Mansfield, Nottinghamshire
NG18 5BU, United Kingdom
Name of Device: Firesafe Flowmeter
Model Numbers: See appendix 1
EC Device Classification: Class IIa (Rule 2)
Applied Harmonised Standards: EN ISO 5359:2014 - Low-pressure hose assemblies
for use with medical gases
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
EN 1041:2008 - Information supplied by the manufacturer of
medical devices
GMDN Code: 61365
GMDN Term: Medical gas flowmeter, Thorpe tube
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 2020
Place of Issue: Mansfield, UK

Appendix 1 – List of Device Models

Device Ref.	Name	UDI DI
829-0301	Firesafe Flowmeter - O2 - BS5682 - Single Direct - 0-15l/min	(01)05060274504234
829-0302	Firesafe Flowmeter - O2 - BS5682 - Dual Direct - 0-15 l/min	(01)15060274504231
829-0303	Firesafe FM - O2 BS5682 - Single Indirect (1.5m) - 0-15 lpm	(01)25060274504238
829-0304	Firesafe FM - O2 - BS5682 - Dual Indirect (1.5m) - 0-15 lpm	(01)35060274504235
829-0306	Firesafe FM - O2 BS5682 - Single Indirect (custom length) - 0-15 lpm	(01)05060274502834
829-0307	Firesafe FM - O2 - BS5682 - Dual Indirect (custom length) - 0-15 lpm	(01)15060274502831
829-0351	Firesafe Flowmeter - Air - BS5682 - Single Direct - 0-15 lpm	(01)15060274502794
829-0352	Firesafe Flowmeter - Air - BS5682 - Dual Direct - 0-15 lpm	(01)05060274502841
829-0353	Firesafe Flowmeter O2 BS5682 Dual Indirect 3m 0-15 lpm	(01)15060274502848
829-0901	Firesafe Flowmeter - O2 - AS2896 - Single Direct - 0-15 lpm	(01)15060274502800
829-0902	Firesafe Flowmeter - O2 - AS2896 - Dual Direct - 0-15 lpm	(01)05060274502858
829-0951	Firesafe Flowmeter - AIR - AS2896 - Single Direct - 0-15 lpm	(01)15060274502855
829-0952	Firesafe Flowmeter - AIR - AS2896 - Dual Direct - 0-15 lpm	(01)25060274502852
829-1001	Firesafe Flowmeter - O2 - BS5682 Single Direct - 0-15lpm NZ	(01)15060274502817
829-1002	Firesafe Flowmeter - O2 - BS5682 Dual Direct - 0-15lpm NZ	(01)15060274502862
829-1051	Firesafe Flowmeter - Air - BS5682 Single Direct - 0-15lpm NZ	(01)25060274502869
829-1052	Firesafe Flowmeter - Air - BS5682 Dual Direct - 0-15lpm NZ	(01)05060274500243