

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: 829-XXXX (refer to Device Specification)
EC Device Classification: Class IIa (Rule 2)
Applied Harmonised Standards: EN ISO 5359:2008/A1:2011 - 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: 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:
Place of Issue:

16th December 2019
Mansfield, UK