

EC Declaration of Conformity

Manufacturer: BPR Medical Limited
Address: 22 Hamilton Way, Oakham Business Park,
Mansfield, Nottinghamshire
NG18 5BU, United Kingdom
Name of Device: Regulators with Integral Flowmeters for Medical Gases
Model Numbers: 818-XXXX (refer to Device Specification)
EC Device Classification: Class IIb (Rule 9)
Applied Harmonised Standards: EN ISO 10524-1:2006 - Pressure regulators for use with
medical gases -- Part 1: Pressure regulators and pressure
regulators with flow-metering devices for use with medical
gases
EN ISO 15001:2011 - Anaesthetic and respiratory equipment -
Compatibility with oxygen
GMDN Code: 43438
GMDN Term: Oxygen cylinder regulator

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