

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 Cannula Valves and Firesafe Nozzles
Model Numbers: 827-XXXX (refer to Device Specification)
EC Device Classification: Class IIa (Rule 2)
Applied Harmonised: EN ISO 8359:2009+A1:2012 - Oxygen concentrators for
medical use - Safety requirements
EN ISO 80601-2-69:2014 - Medical electrical equipment
Part 2-69: Particular requirements for basic safety and
essential performance of oxygen concentrator equipment
EN 13544-2:2002+A1:2009 - Respiratory therapy equipment -
Part 2: Tubing and connectors
EN 1041:2008 - Information supplied by the manufacturer of
medical devices
GMDN Code: 60391
GMDN Term: Fire Safety Valve

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: 16th December 2019
Place of Issue: Mansfield, UK