

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: 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 15223-1:2016 - Symbols to be used with medical device labels, labelling and information to be supplied
EN ISO 15001:2011 - Anaesthetic and respiratory equipment. Compatibility with oxygen.
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
GMDN Codes: 60391
GMDN Terms: Fire Safety Valve
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
827-2001	FSCV, BiDi MK 2.0	(01)05060274504234
827-2001x10	FSCV, BiDi MK 2.0	(01)15060274504231
827-2001x20	FSCV, BiDi MK 2.0	(01)25060274504238
827-2001x100	FSCV, BiDi MK 2.0	(01)35060274504235
827-0010	Firesafe Nozzle – Bayonet	(01)05060274502834
827-0011	Firesafe Nozzle – Bayonet (10)	(01)15060274502831
827-0018	Firesafe Nozzle – Bayonet (250) - Blue ID Band	(01)15060274502794
827-0020	Firesafe Nozzle – Universal	(01)05060274502841
827-0021	Firesafe Nozzle – Universal (10)	(01)15060274502848
827-0028	Firesafe Nozzle – Universal (250) – Blue ID Band	(01)15060274502800
827-0030	Firesafe Nozzle – 9/16 UNF	(01)05060274502858
827-0031	Firesafe Nozzle – 9/16 UNF (10)	(01)15060274502855
827-0031X20	Firesafe Nozzle – 9/16 UNF (20)	(01)25060274502852
827-0038	Firesafe Nozzle – 9/16 UNF (500) - Blue ID Band	(01)15060274502817
827-1001x20	Firesafe Cannula Valve (20) - BPR	(01)15060274502862
827-1001x100	Firesafe Cannula Valve (100) - BPR	(01)25060274502869