MEDICAL GAS CONTROL

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: 

Date of Issue: 1st October 2020
Place of Issue: Mansfield, UK

Richard Radford
Managing Director
For and on behalf of BPR Medical Limited

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

BPR Medical Ltd.
Hamilton Way, 22
Mansfield, NG18 5BU
UK

02/05/2023

Confirmation Letter Reference: CLNB1639 GBPC228381

To whom it may concern,

Confirmation of receipt of a formal application and conclusion of written agreement in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, SGS Belgium NV, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 1639 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

BPR Medical Ltd.
Hamilton Way, 22
Mansfield, NG18 5BU
UK
SRN: GB-MF-000003347

Authorised Represantative
Qarad EC-REP BV
Pas 257, 2440 Geel,
Belgium
SRN: BE-AR-000000040

The devices covered by the formal application and the written agreement mentioned above are shown at the end of this letter.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired prior to the publication of the Regulation EU 2023/607 on 15 March 2023, this letter also confirms that:

- the manufacturer submitted the MDR application and signed the written agreement by the date of MDD/AIMDD certificate expiry;
- the certificates expired after 26 May 2021 by course of time and were valid at the date of their expiry neither having been suspended nor withdrawn.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3 of MDR (as amended by EU 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body SGS Belgium NV 1639,

Virginie SILORET
Global Medical Device Certification Manager
Email: Virginie.siloret@sgs.com
Phone : +41 22 739 98 58

Devices covered by this letter:

Device name / Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
-Firesafe Cannula Valves and Nozzles for Oxygen therapy circuits for patient protection from fire hazards, 50602745000667 **-Demand Valves for oxygen and analgesic gases,** 5060274500096D	Class IIa	N/A	GB19/964430; NB1639

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2023/05/02	Version 1	Initial issue

EC Certificate Full Quality Assurance System: Certificate GB19/964430

The management system of

BPR Medical Ltd

22 Hamilton Way, Mansfield, Nottinghamshire, NG18 5BU, UK

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

Microdial Flowmeters for medical gases,
Dial Flowmeters for medical gases,
Dialflow Regulators for medical gases,
Domiciliary Oxygen Switches for controlling the delivery of oxygen within the home care environment,
Medical Gas Hoses,
Firesafe Cannula Valves and Nozzles for Oxygen therapy circuits for patient protection from fire hazards,
Oasis Oxygen and Suction Delivery Modules,
Firesafe Flowmeters for medical gases,
Demand Valves for oxygen and analgesic gases,
Pressure Regulators for medical gases,
Nitric Oxide Pressure Regulators.

This certificate is valid from 16 December 2019 until 07 February 2023
and remains valid subject to satisfactory surveillance audits.
Issue 1. Certified since 08 February 2009
and first certified by SGS Belgium NV since 16 December 2019

Certification is based on reports numbered GB/PC 228381

Authorised by

Pieter Weterings
Certification Manager

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