

EU Declaration of Conformity

Manufacturer:	BPR Medical Limited
Address:	22 Hamilton Way, Oakham Business Park, Mansfield, Nottinghamshire NG18 5BU, United Kingdom
SRN:	GB-MF-000003347
Authorised Representative:	QbD RepS BV
Address:	Groenenborgerlaan 16 2610 Wilrijk, Belgium
SRN:	BE-AR-000000040
Name of Device:	Firesafe Cannula Valve and Nozzles
Device Risk Classification:	Class IIa (Rule 2, Annex VIII)
Basic UDI:	50602745000667
EMDN Code:	R03010280
EMDN Term:	Oxygen therapy masks and nasal cannulas - accessories
Applied Common Specifications, harmonised standards and other standards:	EN ISO 13485:2016 EN ISO 15001:2011 (in part) EN ISO 15223-1:2021 EN ISO 20417:2021 EN 62366-1:2015 EN ISO 80601-2-67:2020 (in part) EN ISO 80601-2-69:2020 (in part) EN ISO 18562-1:2020 EN 13544-2:2002+A1:2009 (in part) EN ISO 10993-1:2020 EN ISO 14971:2019+A11:2021 ISO 19211:2024 (in part)



The intended purpose of the devices covered by this declaration is to connect to oxygen tubing and oxygen delivery accessories for use during normobaric oxygen therapy in the home healthcare environment and for ambulatory use. A further non-medical purpose is to extinguish a fire in oxygen tubing and stop the flow of oxygen.

This declaration of conformity is issued under the sole responsibility of the manufacturer. I, the undersigned, hereby declare that the medical device specified above, manufactured on or after the date given below, conforms to the requirements of European Union Regulation 2017/745 and any other relevant union legislation that provides for the issuing of a declaration of conformity.

CE marking is applied the basis of Annex IX conformity assessment. This declaration is supported by EC Certificate Number GB26/00000017 issued by SGS Belgium (Notified Body identification number 1639) and EN ISO 13485:2016 Quality Management System Certificate Number GB19/963113.

Signed:

Date of Issue: 16th February 2026
Place of Issue: Mansfield, UK

Kavnit Kaur
Regulatory Affairs Manager
For and on behalf of BPR Medical Limited

Part Numbers, Product Names and UDI-DI Covered by this Declaration

Firesafe Cannula Valves

Part Number	Product Name	UDI-DI
827-2001	Firesafe Cannula Valve	05060274504234
827-2001x10	Firesafe Cannula Valve, pack of 10	15060274504231
827-2001x20	Firesafe Cannula Valve, pack of 20	25060274504238
827-2001x100	Firesafe Cannula Valve, box of 100	35060274504235

Firesafe Nozzles

Part Number	Product Name	UDI-DI
827-0030	Firesafe Nozzle – 9/16 UNF	05060274502858
827-0031	Firesafe Nozzle – 9/16 UNF (10)	15060274502855
827-0031X20	Firesafe Nozzle – 9/16 UNF (20)	25060274502852
827-0020	Firesafe Nozzle – Universal	05060274502841
827-0021	Firesafe Nozzle – Universal (10)	15060274502848
827-0027	Firesafe Nozzle – Universal (1) – Blue ID Band	05060274502803
827-0028	Firesafe Nozzle – Universal (250) – Blue ID Band	15060274502800
827-0037	Firesafe Nozzle – 9/16 UNF (1) - Blue ID Band	05060274502810
827-0038	Firesafe Nozzle – 9/16 UNF (500) - Blue ID Band	15060274502817