

EU Declaration of Conformity

Manufacturer:	BPR Medical Limited
Address:	22 Hamilton Way 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:	Exhalation Valve without Mouthpiece
Device Risk Classification:	Class IIa (Rule 2, Annex VIII)
Basic UDI-DI:	5060274500096D
EMDN Code:	R9099
EMDN Term:	Respiratory and Anaesthesia Devices - Other
Applied Common Specifications, harmonised standards and other standards:	BS EN ISO 14971:2019 EN ISO 5356-1:2015 BS EN ISO 15223-1:2021 BS EN ISO 15001:2011 (in part) BS EN ISO 5359:2014 BS 4272-2:1996+A1 (in part) EN ISO 10993-1:2020 BS ISO 18562-1:2024 BS ISO 18190:2016 BS EN ISO 20417:2021 BS EN ISO 5356-1:2015



The intended purpose of the devices covered by this declaration is for the self-administration of N₂O/O₂ 50%/50% v/v (analgesic gas) or oxygen in response to a patient's inspiratory effort.

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

Exhalation Valves

Part Number	Product Name	UDI-DI
828-0039	Exhalation Valve for use with Face Mask (25)	(01)35060274502699
828-0041	Exhalation Valve for use with Face Mask (1)	(01)05060274502698
828-0042	Exhalation Valve for use with Face Mask (100)	(01)25060274502692
828-0044	Exhalation Valve for use with Face Mask (10)	(01)15060274502695
828-0047	AGSS Exhalation Valve for use with Face Mask (1)	(01)05060274500021
828-0048	AGSS Exhalation Valve for use with Face Mask (10)	(01)15060274500028
828-0049	AGSS Exhalation Valve for use with Face Mask (50)	(01)25060274500025