

EC Declaration of Conformity

Manufacturer: BPR Medical Limited

Address: 22 Hamilton Way, Oakham Business Park,
Mansfield, Nottinghamshire
NG18 5BU, United Kingdom

Name of Device: Medical Gas Hose

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
BS 5682:2015 - Specification for probes (quick connectors) for use with medical gas pipeline systems
EN ISO 18082:2014+A1:2017 - Anaesthetic and respiratory equipment — Dimensions of non-interchangeable screw-threaded (NIST) low-pressure connectors for medical gases
EN ISO 15001:2011 - Anaesthetic and respiratory equipment. Compatibility with oxygen.
EN ISO 5359:2014+A1:2017 - Low-pressure hose assemblies for use with medical gases

GMDN Codes: 42039, 37936, 40484

GMDN Terms: Oxygen low pressure tubing, nitrous oxide low pressure tubing, medical air low pressure tubing.

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:
Place of Issue:

1st October 2020
Mansfield, UK

Appendix 1 – List of Device Models

Device Ref.	Name	UDI DI
832-0002	Manifold Assembly - O2 NIST/ DISS Pole	(01)05060274503633
832-1000	Hose Assembly - O2 - 2m - NIST to BS5682 Probe	(01)05060274501950
832-1001	Hose Assembly - O2 - 3m - NIST to BS5682 Probe	(01)05060274501967
832-1002	Hose Assembly - O2 - 4m - NIST to BS5682 Probe	(01)05060274501974
832-1003	Hose Assembly - O2 - 5m - NIST to BS5682 Probe	(01)05060274501981
832-1004	Hose Assembly - O2 - 6m - NIST to BS5682 Probe	(01)05060274503640
832-1006	Hose Assembly - O2 - 1m - NIST to BS5682 Probe	(01)05060274503664
832-2000	Hose Assembly - MA4 - 2m - NIST to BS5682 Probe	(01)05060274501998
832-2001	Hose Assembly - MA4 - 3m - NIST to BS5682 Probe	(01)05060274502001
832-2002	Hose Assembly - MA4 - 4m - NIST to BS5682 Probe	(01)05060274502018
832-2003	Hose Assembly - MA4 - 5m - NIST to BS5682 Probe	(01)05060274502025
832-2004	Hose Assembly - MA4 - 6m - NIST to BS5682 Probe	(01)05060274503763
832-2006	Hose Assembly - MA4 - 1m - NIST to BS5682 Probe	(01)05060274503770
832-3000	Hose Assembly - N2O - 2m - NIST to BS5682 Probe	(01)05060274502032
832-3001	Hose Assembly - N2O - 3m - NIST to BS5682 Probe	(01)05060274502049
832-3002	Hose Assembly - N2O - 4m - NIST to BS5682 Probe	(01)05060274502056
832-3003	Hose Assembly - N2O - 5m - NIST to BS5682 Probe	(01)05060274502063
832-3004	Hose Assembly - N2O - 6m - NIST to BS5682 Probe	(01)05060274503848
832-3006	Hose Assembly - N2O - 1m - NIST to BS5682 Probe	(01)05060274503855
832-4005	Hose Assembly - Vac - 1m - NIST to BS5682 Probe	(01)05060274503886
832-4000	Hose Assembly - Vac - 2m - NIST to BS5682 Probe	(01)05060274502070
832-4001	Hose Assembly - Vac - 3m - NIST to BS5682 Probe	(01)05060274502087
832-4002	Hose Assembly - Vac - 4m - NIST to BS5682 Probe	(01)05060274502094
832-4003	Hose Assembly - Vac - 5m - NIST to BS5682 Probe	(01)05060274502100
832-4004	Hose Assembly - Vac - 6m - NIST to BS5682 Probe	(01)05060274503879