

UK Declaration of Conformity

Manufacturer: BPR Medical Limited

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

Name of Device: Nitric Oxide Pressure Regulator

Model Numbers: See appendix 1

EC Device Classification: Class IIb (Rule 9)

Applied Harmonised Standards: EN ISO 10524-1:2006 - Pressure regulators for use with medical gases -- Part 1: Pressure regulators and pressure regulators with flow-metering devices for use with medical gases
EN ISO 15001:2011 - Anaesthetic and respiratory equipment - Compatibility with oxygen

Other Applied Standards: DD CEN TS 14507-1 2003 - Inhalational nitric oxide systems - Part 1: Delivery systems
DD CEN TS 14507-2 2003 - Inhalational nitric oxide systems - Part 2: Supply systems
PD CR 13903 - 2001 General guidance on the equipment used for inhaled nitric oxide therapy

GMDN Code: 43438

GMDN Term: Gas Pressure Regulator

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 the UK MDR 2002 (as amended).

UKCA marking is applied the basis of the Annex II route to conformity (full quality assurance). This declaration is supported by UKCA Certificate Number GB22/00000436 issued by SGS United Kingdom Ltd. (Approved Body identification number 0120) and BS EN ISO 13485:2016 Quality Management System Certificate Number GB22/00000436 issued by SGS United Kingdom Ltd.

Signed:



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

Date of Issue: 12th October 2022
Place of Issue: Mansfield, UK

Appendix 1 – List of Device Models

Device Ref.	Name	UDI DI
814-0001	Nitric Oxide Pressure Regulator BS-341 14	05060274502384
814-0002	Nitric Oxide Pressure Regulator DIN 477-1 Type 14	05060274502391
814-0003	Nitric Oxide Pressure Regulator DIN 477-1 Type 10	05060274502407
814-0004	Nitric Oxide Pressure Regulator CGA 626	05060274502414
814-0005	Nitric Oxide Pressure Regulator CGA 660	05060274502421
814-0007	Nitric Oxide Pressure Regulator UNI 11144	05060274502438
814-0008	Nitric Oxide Pressure Regulator ISO-5145	05060274502445
814-0009	Nitric Oxide Pressure Regulator DIN 477-1 Type 1	05060274502452
814-0010	Nitric Oxide Pressure Regulator BS-341 3	05060274502469
814-0011	Nitric Oxide Pressure Regulator BS-341 4	05060274502476
814-0012	Nitric Oxide Pressure Regulator CGA330	05060274502483
814-0013	Nitric Oxide Pressure Regulator DIN 477-1 Type 6	05060274502490
814-0014	Nitric Oxide Pressure Regulator DIN 477-1 Type 8	05060274502506