

EC 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
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: 1st October 2020
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	(01)05060274502384
814-0002	Nitric Oxide Pressure Regulator DIN 477-1 Type 14	(01)05060274502391
814-0003	Nitric Oxide Pressure Regulator DIN 477-1 Type 10	(01)05060274502407
814-0004	Nitric Oxide Pressure Regulator CGA 626	(01)05060274502414
814-0005	Nitric Oxide Pressure Regulator CGA 660	(01)05060274502421
814-0007	Nitric Oxide Pressure Regulator UNI 11144	(01)05060274502438
814-0008	Nitric Oxide Pressure Regulator ISO-5145	(01)05060274502445
814-0009	Nitric Oxide Pressure Regulator DIN 477-1 Type 1	(01)05060274502452
814-0010	Nitric Oxide Pressure Regulator BS-341 3	(01)05060274502469
814-0011	Nitric Oxide Pressure Regulator BS-341 4	(01)05060274502476
814-0012	Nitric Oxide Pressure Regulator CGA330	(01)05060274502483
814-0013	Nitric Oxide Pressure Regulator DIN 477-1 Type 6	(01)05060274502490
814-0014	Nitric Oxide Pressure Regulator DIN 477-1 Type 8	(01)05060274502506