

## 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  
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 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 01639) 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:

16<sup>th</sup> December 2019  
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