

## EC Declaration of Conformity

Manufacturer: BPR Medical Limited  
Address: 22 Hamilton Way, Oakham Business Park,  
Mansfield, Nottinghamshire  
NG18 5BU, United Kingdom  
Name of Device: OASIS Oxygen and Suction Delivery Modules  
Model Numbers: See appendix 1  
EC Device Classification: Class IIa (Rule 11)  
Applied Harmonised Standards: EN 1041:2008+A1:2013 - Information supplied by the manufacturer of medical devices  
EN ISO 15002:2008 - Flow-metering devices for connection to terminal units of medical gas pipeline systems  
EN ISO 15001:2011 - Anaesthetic and respiratory equipment - Compatibility with oxygen  
EN ISO 10079-3:2014 - Medical suction equipment — Part 3: Suction equipment powered from a vacuum or positive pressure gas source  
GMDN Code: 63647  
GMDN Term: Pneumatic suction regulator/regulation set  
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: 1<sup>st</sup> October 2020  
Place of Issue: Mansfield, UK

### Appendix 1 – List of Device Models

Device Ref.	Name	UDI DI
812-0044	OASIS - Medirail - 1.1 m hose - BS 5682	(01)05060274503367
812-0047	OASIS - Medirail - 0.8 m hose - BS 5682	(01)05060274503374
812-0051	OASIS - Medirail - 0.6 m hose - BS 5682	(01)05060274503381
812-0052	OASIS - Medirail - 0.45 m hose - BS 5682	(01)05060274503398
812-0053	OASIS - Medirail - 2.5 m hose - BS 5682	(01)05060274503404
812-0054	OASIS - Medirail - 3 m hose - BS 5682	(01)05060274503411
812-0055	OASIS - Bedrail - 0.45 m hose - BS 5682	(01)05060274503428
812-0056	OASIS - Bedrail - 0.6 m hose - BS 5682	(01)05060274503435
812-0057	OASIS - Bedrail - 0.8 m hose - BS 5682	(01)05060274503442
812-0058	OASIS - Bedrail - 1.1 m hose - BS 5682	(01)05060274503459
812-0059	OASIS - Bedrail - 2.5 m hose - BS 5682	(01)05060274503466
812-0060	OASIS - Bedrail - 3 m hose - BS 5682	(01)05060274503473