MEDICAL GAS CONTROL

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:	812-XXXX (refer to Device Specification)
EC Device Classification:	Class IIa (Rule 11)
Applied Harmonised Standards:	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:	37498
GMDN Term:	Oxygen Therapy System

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: 

Date of Issue: 16th December 2019
Place of Issue: Mansfield, UK

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