

EC Declaration of Conformity

Manufacturer: BPR Medical Limited
Address: 22 Hamilton Way, Oakham Business Park,
Mansfield, Nottinghamshire
NG18 5BU, United Kingdom
Name of Device: Domiciliary Oxygen Switch
Model Numbers: See appendix 1
EC Device Classification: Class IIa (Rule 2)
Applied Harmonised Standards: EN 1041:2008+A1:2013 - Information supplied by the
manufacturer of medical devices
EN ISO 15001:2011 - Anaesthetic and respiratory equipment -
Compatibility with oxygen
GMDN Code: 37498
GMDN Term: Oxygen Therapy System
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
826-0001	Domiciliary Oxygen Switch (1)	(01)05060274501530
826-0002	Domiciliary Oxygen Switch - Box of 10 Blank Switches	(01)05060274501592
826-0004	Domiciliary Oxygen - Membrane Panel (ON/OFF - Box 20)	(01)05060274501608
826-0005	Domiciliary Oxygen - Membrane Panel (2 Way + OFF - Box 20)	(01)05060274501547
826-0006	Domiciliary Oxygen - Membrane Panel (3 Way + OFF - Box 20)	(01)05060274501615
826-0007	Domiciliary Oxygen - Membrane Panel (4 Way + OFF - Box 20)	(01)05060274501554
826-0024	Domiciliary Oxygen - Membrane Panel (ON/OFF Box 20 FR)	(01)05060274501646
826-0025	Domiciliary Oxygen - Membrane Panel (2 Way + OFF Box 20 FR)	(01)05060274501585
826-0026	Domiciliary Oxygen - Membrane Panel (3 Way + OFF Box 20 FR)	(01)05060274501639
826-0027	Domiciliary Oxygen - Membrane Panel (4 Way + OFF Box 20 FR)	(01)05060274501578
826-0029	Commutateur d'oxygène à domicile (x10) Blank Switches France	(01)05060274501653