

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: 826-XXXX (refer to Device Specification)
EC Device Classification: Class IIa (Rule 2)
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:



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

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