

# Declaration of Conformity

## Procedure Pack

This is a declaration made in accordance with the requirements in Article 12 of the Medical Device Directive 93/42/EEC as amended by Directive 2007/47/EC.

Procedure Pack: 827-0100, Firesafe Oxygen Therapy Kits, 5m, 20 NC + 2 masks  
827-0101, Oxygen Mask Kit, adult, medium concentration  
827-0102, Firesafe Oxygen Therapy Kit, 5 m, adult, NC  
827-0103, Firesafe Oxygen Therapy Kits, 2m, 20 NC + 2 masks  
827-0104, Firesafe Oxygen Therapy Kit, 2m, adult, NC  
827-0105, Firesafe Oxygen Therapy Kits, 10m, 20 NC, 2 FSCV + 2 masks  
827-0106, Firesafe Oxygen Therapy Kit, 10m, adult, NC, 2 FSCV  
827-0107, Firesafe Oxygen Therapy Kits, 5m, 20 NC, 1 FSCV + 2 masks  
827-0108, Firesafe Oxygen Therapy Kit, 5m, adult, NC, 1 FSCV  
827-0109, Firesafe Oxygen Therapy Kits, 2m, 20 NC, 1 FSCV + 2 masks  
827-0110, Firesafe Oxygen Therapy Kit, 2m, adult, NC, 1 FSCV  
827-0111, Firesafe Oxygen Therapy Kits, 10m, 20 NC, 1 FSCV + 2 masks  
827-0112, Firesafe Oxygen Therapy Kit, 10m, adult, NC, 1 FSCV  
827-0113, Oxygen Mask Kit, adult, medium concentration, 20 masks

Assembler: BPR Medical Ltd.  
22 Hamilton Way  
Oakham Business Park  
Mansfield  
Nottinghamshire  
NG18 5BU, UK


The assembler of the procedure pack has evidence that the conformity assessment procedures have been applied to each medical device in the package; and that each medical device in the package conforms to the Essential Requirements of Annex I of EC Directive 93/42/EEC as amended by Directive 2007/47/EC.

Each medical device in the system or procedure pack is intended to be used for its original intended purpose. The mutual compatibility of each medical device within the procedure pack has been assessed and compatibility has been confirmed.

The original packaging and the instructions for use have been replaced. The suitability of the replacement packaging and instructions for use supplied have been evaluated and confirmed to be adequate and appropriate. In particular, all requirements for packaging provided by the component manufacturers have been followed.



The processes of manufacturing and packaging of the procedure pack have been subjected to documented methods of internal control and inspection that ensures the safety, quality, performance and effectiveness of each item in the package are maintained.

Signed:		Date of Issue:	16 <sup>th</sup> December 2019
	Ben Johnson	Place of Issue:	Mansfield, UK
	Technical Director		
	For and on behalf of BPR Medical Limited		

**Ref. 827-0100, Firesafe Oxygen Therapy Kits, 5m, 20 NC + 2 masks**

Product	Class	Notified Body
Firesafe™ Cannula Valve - BPR Medical Ltd. ref. 827-1001	Ila	CE 1639
Nasal cannula - Salter Labs ref. 1600-1	Ila	CE 2797
Oxygen tube, 5 m long - Salter Labs ref. 2015-15	Ila	CE 2797
Oxygen tube, 0.3 m long - Salter Labs ref. 2001-1	Ila	CE 2797
Oxygen mask, medium concentration – Salter Labs ref. 8115	Ila	CE 2797

**Ref. 827-0101, Oxygen Mask Kit, adult, medium concentration**

Product	Class	Notified Body
Oxygen tube, 0.3 m long - Salter Labs ref. 2001-1	Ila	CE 2797
Oxygen mask, medium concentration – Salter Labs ref. 8115	Ila	CE 2797

**Ref. 827-0102, Firesafe Oxygen Therapy Kit, 5 m, adult, NC**

Product	Class	Notified Body
Firesafe™ Cannula Valve - BPR Medical Ltd. ref. 827-1001	Ila	CE 1639
Nasal cannula - Salter Labs ref. 1600-1	Ila	CE 2797
Oxygen tube, 5 m long - Salter Labs ref. 2015-15	Ila	CE 2797
Oxygen tube, 0.3 m long - Salter Labs ref. 2001-1	Ila	CE 2797

**Ref. 827-0103, Firesafe Oxygen Therapy Kits, 2m, 20 NC + 2 masks**

Product	Class	Notified Body
Firesafe™ Cannula Valve - BPR Medical Ltd. ref. 827-1001	Ila	CE 1639
Nasal cannula - Salter Labs ref. 1600-1	Ila	CE 2797
Oxygen tube, 2 m long - Salter Labs ref. 2015-7	Ila	CE 2797
Oxygen tube, 0.3 m long - Salter Labs ref. 2001-1	Ila	CE 2797
Oxygen mask, medium concentration – Salter Labs ref. 8115	Ila	CE 2797

**Ref. 827-0104, Firesafe Oxygen Therapy Kit, 2m, adult, NC**

Product	Class	Notified Body
Firesafe™ Cannula Valve - BPR Medical Ltd. ref. 827-1001	Ila	CE 1639
Nasal cannula - Salter Labs ref. 1600-1	Ila	CE 2797
Oxygen tube, 2 m long - Salter Labs ref. 2015-7	Ila	CE 2797
Oxygen tube, 0.3 m long - Salter Labs ref. 2001-1	Ila	CE 2797

**Ref. 827-0105, Firesafe Oxygen Therapy Kits, 10m, 20 NC, 2 FSCV + 2 masks**

Product	Class	Notified Body
Firesafe™ Cannula Valve - BPR Medical Ltd. ref. 827-1001	Ila	CE 1639
Nasal cannula - Salter Labs ref. 1600-1	Ila	CE 2797
Oxygen tube, 5 m long - Salter Labs ref. 2015-15	Ila	CE 2797
Oxygen tube, 0.3 m long - Salter Labs ref. 2001-1	Ila	CE 2797
Oxygen mask, medium concentration – Salter Labs ref. 8115	Ila	CE 2797
Oxygen tube connector – Salter Labs ref. 1215-0	Ila	CE 2797

**Ref. 827-0106, Firesafe Oxygen Therapy Kit, 10m, adult, NC, 2 FSCV**

Product	Class	Notified Body
Firesafe™ Cannula Valve - BPR Medical Ltd. ref. 827-1001	Ila	CE 1639
Nasal cannula - Salter Labs ref. 1600-1	Ila	CE 2797
Oxygen tube, 5 m long - Salter Labs ref. 2015-15	Ila	CE 2797
Oxygen tube, 0.3 m long - Salter Labs ref. 2001-1	Ila	CE 2797
Oxygen tube connector – Salter Labs ref. 1215-0	Ila	CE 2797

**Ref. 827-0107, Firesafe Oxygen Therapy Kits, 5m, 20 NC, 1 FSCV + 2 masks**

Product	Class	Notified Body
Firesafe™ Cannula Valve - BPR Medical Ltd. ref. 827-1001	Ila	CE 1639
Nasal cannula - Salter Labs ref. 1600-1	Ila	CE 2797
Oxygen tube, 5 m long - Salter Labs ref. 2015-15	Ila	CE 2797
Oxygen tube, 0.3 m long - Salter Labs ref. 2001-1	Ila	CE 2797
Oxygen mask, medium concentration – Salter Labs ref. 8115	Ila	CE 2797

**Ref. 827-0108, Firesafe Oxygen Therapy Kit, 5m, adult, NC, 1 FSCV**

Product	Class	Notified Body
Firesafe™ Cannula Valve - BPR Medical Ltd. ref. 827-1001	Ila	CE 1639
Nasal cannula - Salter Labs ref. 1600-1	Ila	CE 2797
Oxygen tube, 5 m long - Salter Labs ref. 2015-15	Ila	CE 2797

**Ref. 827-0109, Firesafe Oxygen Therapy Kits, 2m, 20 NC, 1 FSCV + 2 masks**

Product	Class	Notified Body
Firesafe™ Cannula Valve - BPR Medical Ltd. ref. 827-1001	Ila	CE 1639
Nasal cannula - Salter Labs ref. 1600-1	Ila	CE 2797
Oxygen tube, 2 m long - Salter Labs ref. 2015-7	Ila	CE 2797
Oxygen tube, 0.3 m long - Salter Labs ref. 2001-1	Ila	CE 2797
Oxygen mask, medium concentration – Salter Labs ref. 8115	Ila	CE 2797

**Ref. 827-0110, Firesafe Oxygen Therapy Kit, 2m, adult, NC, 1 FSCV**

Product	Class	Notified Body
Firesafe™ Cannula Valve - BPR Medical Ltd. ref. 827-1001	Ila	CE 1639
Nasal cannula - Salter Labs ref. 1600-1	Ila	CE 2797
Oxygen tube, 2 m long - Salter Labs ref. 2015-7	Ila	CE 2797

**Ref. 827-0111, Firesafe Oxygen Therapy Kits, 10m, 20 NC, 1 FSCV + 2 masks**

Product	Class	Notified Body
Firesafe™ Cannula Valve - BPR Medical Ltd. ref. 827-1001	Ila	CE 1639
Nasal cannula - Salter Labs ref. 1600-1	Ila	CE 2797
Oxygen tube, 5 m long - Salter Labs ref. 2015-15	Ila	CE 2797
Oxygen tube, 0.3 m long - Salter Labs ref. 2001-1	Ila	CE 2797
Oxygen mask, medium concentration – Salter Labs ref. 8115	Ila	CE 2797
Oxygen tube connector – Salter Labs ref. 1215-0	Ila	CE 2797

**Ref. 827-0112, Firesafe Oxygen Therapy Kit, 10m, adult, NC, 1 FSCV**

Product	Class	Notified Body
Firesafe™ Cannula Valve - BPR Medical Ltd. ref. 827-1001	Ila	CE 1639
Nasal cannula - Salter Labs ref. 1600-1	Ila	CE 2797
Oxygen tube, 5 m long - Salter Labs ref. 2015-15	Ila	CE 2797
Oxygen tube connector – Salter Labs ref. 1215-0	Ila	CE 2797

**Ref. 827-0113, Oxygen Mask Kit, adult, medium concentration, 20 masks**

Product	Class	Notified Body
Oxygen tube, 0.3 m long - Salter Labs ref. 2001-1	Ila	CE 2797
Oxygen mask, medium concentration – Salter Labs ref. 8115	Ila	CE 2797