By Royal Charter

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 669121**

Issued To: **Smiths Medical ASD Inc.**
6000 Nathan Lane North
Minneapolis
Minnesota
55442
USA

In respect of:

See certificate scope page.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):

Stewart Brain, Head of Compliance & Risk - Medical Devices

First Issued: **2017-07-20** Date: **2018-05-09** Expiry Date: **2023-03-18**

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Certificate No: CE 669121

Certificate Scope:

The design, development and manufacture of:

Sterile Disposable infusion kits including cassette, tubes, connectors, needles

Patient warming units

Blood and Fluid Warmers units

Sterile Blood and Fluid Warmers disposables sets

Sterile Central Implantable Access Systems

Sterile Peripheral Implantable Access Systems

Those aspects of Annex II concerned with securing and maintaining sterile conditions of convective warmers blankets.

First Issued: **2017-07-20** Date: **2018-05-09** Expiry Date: **2023-03-18**

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 669121**
Date:	**2018-05-09**
Issued To:	**Smiths Medical ASD Inc.** **6000 Nathan Lane North** **Minneapolis** **Minnesota** **55442** **USA**

Subcontractor:	**Service(s) supplied**
CarTika Medical Inc 6551 Wedgwood Rd N Suite 300 Maple Grove Minnesota 55311 USA	**Manufacture**
Isomedix Operations, Inc. 380 90th Avenue NW Minneapolis MN 55433 USA	**ETO Sterilization**
Isomedix Operations, Inc. 7685 Saint Andrews Avenue San Diego California 92154 USA	**ETO Sterilization**

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Subcontractor:	**Service(s) supplied**
Isomedix Operations, Inc. 43425 Business Park Drive Temecula California 92590 USA	**ETO Sterilization**
Isomedix Operations, Inc. 23 Elizabeth Drive Chester New York 10918 USA	**Gamma Sterilization**
Minnetronix, Inc. 1635 Energy Park Drive St Paul Minnesota 55108 USA	**Design** **Manufacture**

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Subcontractor:	**Service(s) supplied**
Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4 Parque Industrial Internacional Tijuana Baja California 22425 Mexico	**Manufacture**
Smiths Medical ASD Inc. 1265 Grey Fox Road St Paul Minnesota 55112 USA	**Regulatory Compliance**
Smiths Medical ASD, Inc. 3350 Granada Avenue North Oakdale Minnesota 55128 USA	**Manufacture**

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Issued To:	**Smiths Medical ASD Inc.** **6000 Nathan Lane North** **Minneapolis** **Minnesota** **55442** **USA**

Subcontractor:	**Service(s) supplied**
Smiths Medical International Limited 1500 Eureka Park Lower Pemberton Ashford Kent TN25 4BF United Kingdom	**EU Representative**
Sterigenics US, LLC 10811 Withers Cover Park Drive Charlotte North Carolina 28278 USA	**ETO Sterilization**
Sterigenics US, LLC 1700 College Boulevard West Memphis AR 72301 USA	**Gamma Sterilization**

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Subcontractor:	**Service(s) supplied**
Sterigenics US, LLC 344 Bonnie Circle Corona California 92880 USA	**Gamma Sterilization**
Sterigenics US, LLC 7775 South Quincy Willowbrook Illinois 60527 USA	**ETO Sterilization**
Sterigenics US, LLC 84 Park Road Queensbury New York 12804 USA	**ETO Sterilization**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 669121**

Date: **2018-05-09**

Issued To: **Smiths Medical ASD Inc.**
6000 Nathan Lane North
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Date	Reference Number	Action
20 July 2017	8691798	First issue, transferred from another notified body.
Current	8893340	Renewal, scope rewording, scope reduction, subcontractor removal, correction of subcontractor address and activities

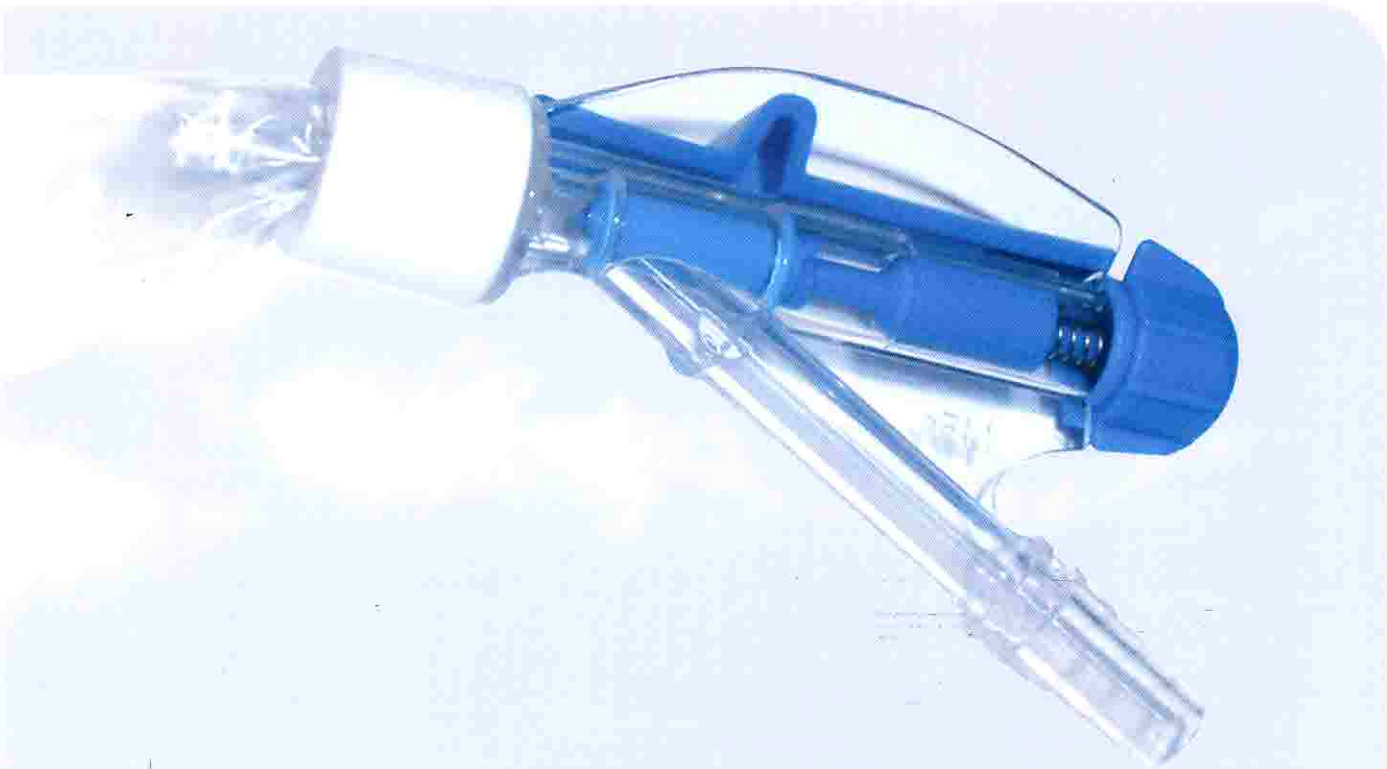
smiths medical
bringing technology to life

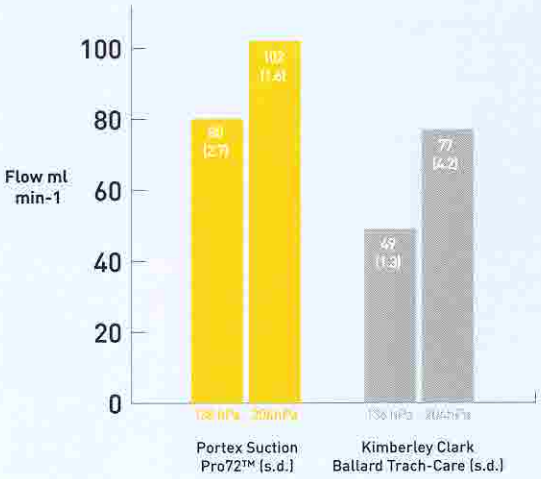
SuctionPro72™
Closed Ventilation Suction System

Reduce Infection. Reduce Patient Stay. Reduce Costs.

PORTEX®

SuctionPro72™





MDI Adaptor

SuctionPro 72™

The Portex® SuctionPro72™ Closed Ventilation Suction System is a single patient use suctioning device for the removal of secretions from the tracheobronchial tree of ventilator dependent adult patients. Intended for 72-hour use.

Key Features

- 3-day recommended duration of use
- Clear pathway evacuation port
- Lockable thumb valve end cap
- Sterile, single patient use
- Clear T piece for visualisation of the pathway
- Soft but strong catheter sleeve
- MDI Adaptor for integrated inhaler capability
- Patient labels now coloured by day for easy identification
- Trac-Wedge™ device to aid in disconnection of the catheter from the patient's endotracheal or tracheostomy tube
- Swivel connector to reduce torque to patient in some packs

Fig. 1

Fig. 2

Fig. 3

Fig. 4

Instructions for Use

To Lavage

Fig: 1 Hold T-piece in one hand and advance catheter approximately 10cm into the airway. Instill saline solution through the irrigation inlet.

To Suction:

Note: Patients may benefit from pre-oxygenation with 100% oxygen.

Fig: 2 Make sure the suction control valve lock is in the 'OPEN' position. Advance the catheter to the desired depth whilst holding the patient end steady. If resistance is met, withdraw the catheter 2-3cm before applying suction .

Fig: 3 Grasp the control valve and apply backwards-sliding pressure on the blue thumb actuator to suction.

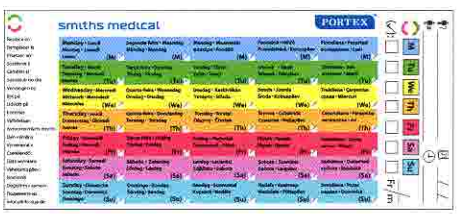
Note: Maximum suction is achieved by sliding the actuator fully back.

Withdraw the catheter slowly with suction activated in a straight motion to avoid kinking until blue mark is just fully visible in catheter sleeve.

Fig: 4 Ensure that the catheter tip is out of the breathing path and in-line with the saline port. Begin to clean catheter tip with saline. The saline should be administered through the irrigation inlet whilst vacuum is applied making sure that the tip and area surrounding it is fully flushed with saline. Release control valve actuator and turn the valve lock to the 'CLOSE' position when finished.

Preparation

- Before attaching the system to the patient turn on the suction, make sure the lock is turned to the 'OPEN' position and check the operation of the control valve by sliding back the actuator. Once in the fully back position release and make sure that the device shuts correctly
- Attach ventilator circuit to dual-swivel or Tpiece adaptor
- Attach the dual-swivel or Tpiece adaptor to the tracheal or tracheostomy tube connector
- Attach male connector of the SuctionPro72™ Closed Ventilation Suction System device to suction tubing
- Attach the suction tubing to the male connector of the SuctionPro72™ closed ventilation suction system



Day Label

SuctionPro72™

Comprehensive product range available in single and dual lumen configurations, with coloured day labels. MDI adaptor in non dual swivel options. Each Portex® SuctionPro72™ suction system offers a wide range of options to enhance patient care outcomes and accommodate clinical practices. Available in a case of 20 units.

IDENTIFICATION MATRIX

	Part No	10 FR	12 FR	14 FR	16 FR	300mm Length	570mm Length	Flex Tube	Coudé Tip	Dual Swivel	MDI adaptor
SINGLE LUMEN	Z110-10	•					•				•
	Z110-12		•				•				•
	Z110-14			•			•				•
	Z110-16				•		•				•
	Z115-10	•				•					•
	Z115-12		•			•					•
	Z115-14			•		•					•
	Z115-16				•	•					•
	Z116-14			•		•		•			•
	Z118-14			•			•	•			•
	Z120-10	•					•		•		•
	Z120-12		•				•		•		•
	Z120-14			•			•		•		•
	Z120-16				•		•		•		•
	Z130- 14*			•			•				•
	Z130- 16*				•		•				•
	Z135- 14*			•		•					•
	Z135- 16*				•	•					•
	Z150-10	•					•			•	
	Z150-12		•				•			•	
	Z150-14			•			•			•	
	Z150-16				•		•			•	
	Z155-10	•				•				•	
	Z155-12		•			•				•	
	Z155-14			•		•				•	
	Z155-16				•	•				•	
	Z156-14			•		•		•		•	
	Z160-14			•			•		•	•	
	Z160-16				•		•		•	•	
DOUBLE LUMEN	Z210-12		•				•				•
	Z210-14			•			•				•
	Z210-16				•		•				•
	Z215-12		•			•					•
	Z215-14			•		•					•
	Z216-14			•		•		•			•
	Z250-12		•				•			•	
	Z250-14			•			•			•	
	Z250-16				•		•			•	
	Z255-12		•			•				•	
	Z255-14			•		•				•	
	Z256-14			•		•		•		•	

*not CE marked

PRODUCT(S) DESCRIBED MAY NOT BE LICENSED OR AVAILABLE FOR SALE IN CANADA AND OTHER COUNTRIES

Smiths Medical International Ltd.
Ashford, UK TN25 4BF
Phone: +44 (0) 845 8500445
www.smiths-medical.com

Find your local contact information at: www.smiths-medical.com/customer-support

CE 0473 Rx ONLY

smiths medical

MHYTCA-1030

smiths medical
bringing technology to life

Respiratory Care Solutions
Improving Quality of Life

PORTEX®

Improving quality of life...

The need to rehabilitate patients effectively after respiratory disorders, is of extreme importance, not only to decrease patient recovery time for improved hospital efficiency, but also for the well-being and quality of life of the patient.

Introducing a Pulmonary Rehabilitation Programme (PRP) can help patients with lung disease achieve the highest possible level of functioning. PRPs have been shown to improve quality of life, mitigate symptoms, improve exercise tolerance, and lower the number of hospital admissions.

Two key elements of a PRP are Bronchial Hygiene Therapy (BHT) and Lung Expansion Therapies.

Smiths Medical has developed a comprehensive range of respiratory care products designed for both hospital and home use.

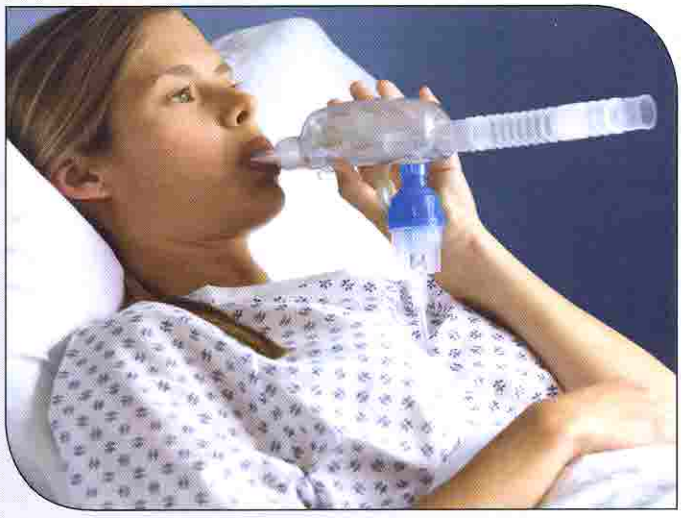
These products help to rehabilitate patients with the aim of improving their physical and social performance. By focusing on the rehabilitation of patients and continued lung training, hospitals can potentially see cost savings due to reduced hospital stays and home rehabilitation.

References

1. Wiersgalla Susan, RRT, RCP, North Memorial Medical Center, Robbinsdale, MN. Abstract presented at the 48th International Respiratory Congress for the AARC Annual Convention and Exhibition on October 5th, 2002 in Tampa, Florida.
2. Steen HJ, Redmond AOB, O'Neill D, Beattie F. Acta Paediatr Scand. Evaluation of the PEP mask in cystic fibrosis. 1991; 80:51-56.
3. Tyrell JC, Hiller EJ, Martin J. Face mask physiotherapy in cystic fibrosis. Archives of Dis in Child 1986; 61: 598-611.
4. Mahlmeister MJ, Fink JB, Hoffman GL, Fifer LF. "Positive-expiratory-pressure mask therapy: Theoretical and Practical Considerations and a Review of the Literature", Respiratory Care, 1991;36:1218-1230.
5. Guell R. Breath, Home- Based Rehabilitation 2008,5 pg:37

CRITICAL CARE

WARD



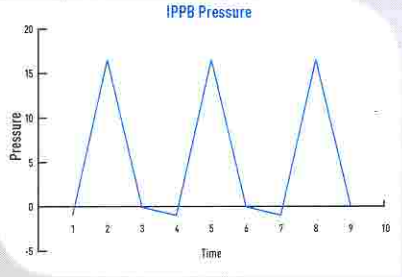


Figure 1

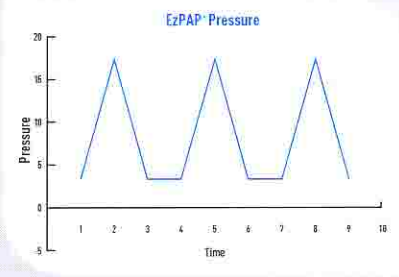


Figure 2

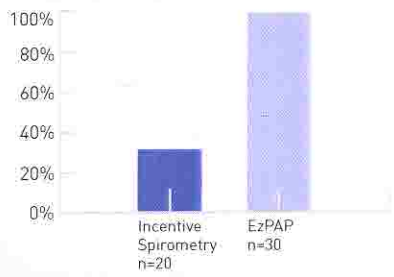


Figure 3
Post-Surgical Atelectasis Improvement in CABG Patients. p=<.001

Rehabilitation

For hospitalised patients, the correct rehabilitation can save the hospital both time and money, as well as making the experience more tolerable for the patient.

Many hospitals today, use Intermittent Positive Pressure Breathing (IPPB) to treat and reverse atelectasis as well as being used in re-expanding lung parenchyma. IPPB is a form of assisted ventilation that triggers a positive pressure breath to the patient when the machine senses either effort by the patient, or a negative pressure of an inspiratory breath. Once a certain pressure is reached it then returns to zero. However, IPPB starts with a negative pressure and does not deliver positive expiratory pressure during exhalation. (See figure 1)

EzPAP® is a simple and effective "In-Hospital' method for delivering positive airway pressure throughout the breathing cycle. Pressure does decrease during inhalation, but it always remains positive, helping to open airways and re-inflate collapsed alveoli. (See figure 2). EzPAP® also provides the additional benefit of Positive Expiratory Pressure therapy during exhalation offering further rehabilitation to the patient. (See figures 4,5 &6)

The combination of therapies offers a safe and effective alternative to IPPB for hospitalised patients. EzPAP® is easy to use and inexpensive in comparison to IPPB. Wiersgella has also demonstrated that EzPAP®, when used post operatively on coronary artery bypass graft patients, shows measurable improvements in atelectasis levels. [1] (figure 3)

Positive Expiratory Pressure therapy can also be achieved using the acapella® duet from Smiths Medical. The acapella® duet is a vibratory PEP device that

from Hospital...

has a built-in port for aerosolised medication via a small volume nebuliser. Medication such as bronchodilator or mucolytic treatments can be delivered simultaneously with PEP therapy, cutting treatment time to one session, saving time and effort for both clinicians and patients.

Products that encourage PEP therapy are usually well tolerated by most patients and due to the option of self-administering, are an ideal choice for patients who are out of ICU. In contrast to traditional chest physiotherapy (CPT) options, PEP therapy offers effective secretion removal at a low cost. By being independent of daily assistance from clinicians, the compliance level is enhanced and this in turn can also reduce related health-care costs. [2, 3]

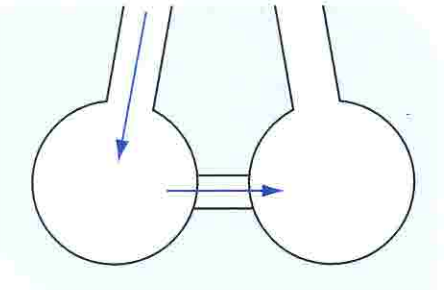


Figure 4
Collateral Ventilation

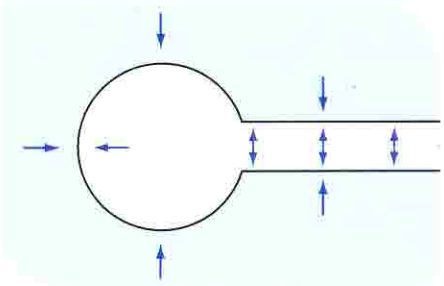


Figure 5 Pursed-lips breathing (or use of a fixed orifice resistor such as a PEP device) creates back pressure that splints the airway open during exhalation.[17]

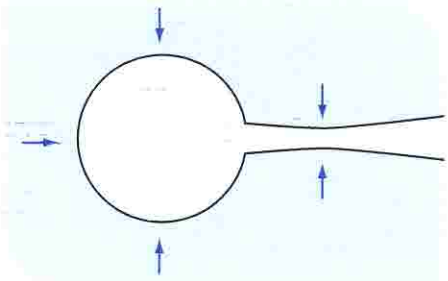


Figure 6 Elevated intrathoractic pressure can compress unstable airways during exhalation.[17]

to Home

acapella® duet and acapella® choice, are inexpensive, easy to use standalone options, providing vibratory PEP therapy to remove secretions. They can be used in any position and offer high and low flow rates for the patient. These devices, with the option of a mouthpiece or mask, are a fully versatile product for both patient and hospital.

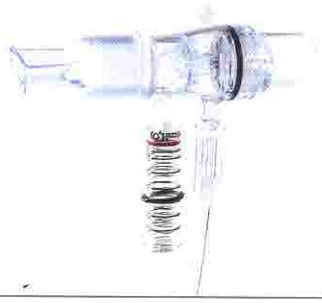
TheraPEP® is an alternative product offering PEP therapy. This therapy can also be self-administered in half the time of CPT.[4] TheraPEP® can accommodate virtually any lung capacity and allows inhalation and exhalation without removal from the mouth. With a 22mm ID connector to allow small volume nebulisers or MDI spacers and the option of mouthpiece or mask, this is another great choice for secretion clearance and atelectasis reversal in the hospital setting or at home.

For post-surgical patients, medical devices that help improve their lungs are an important function. Incentive spirometers encourage patients to take slow and deep breaths to expand the lungs. Smiths Medical offers both the Coach® 2 incentive spirometer and the CliniFLO® low-flo incentive spirometer. Coach® 2 combines a one-way valve, highly visible piston and easy to understand graphics indicating correct inspiratory flow rate to help patients perform and monitor their own post-surgical breathing exercises without the need for direct supervision. CliniFLO® is ideal for generic, paediatric or weakened patients due to flow settings as low as 100ml/sec.

Once a patient has been trained to self-administer their chosen therapy in a clinical setting, they are able to continue this therapy at home. acapella® duet, acapella® choice, TheraPEP®, Coach® 2 and CliniFLO® all offer the versatility to be used in a clinical and/or home setting to provide continued therapy. Each is lightweight, easy to use and transportable. Studies have indicated that home-based rehabilitation programmes not only provide similar benefits to hospital rehabilitation programmes but also can reduce the use of medication and the number of hospitalisations.[5]

Continued lung exercises for patients, whether it is post-surgical in the hospital or at home are key to facilitating patient recovery and therefore an improved quality of life. The respiratory care range from Smiths Medical tailors to each patient's need whilst enabling the clinician to save time and money.

EzPAP®



Features and benefits:
- 22mm OD patient end to accommodate mouthpiece or 3 mask sizes.
- Scalloped ambient air inlet with gaps to resist occlusion.
- Pressure port with detachable cap, allows connection to a gauge for easy monitoring.
- Complete procedural kit.
- Disposable manometer.
- Easy to use, no extensive training.
- Can be used in conjunction with aerosol medication (e.g. nebuliser) via 22mm connection.

acapella® Vibratory PEP Therapy System

Acapella® Duet

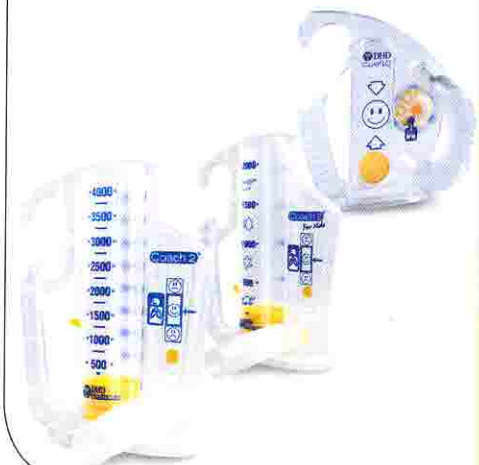
Acapella® Choice

Features and benefits:
- Convenient built-in nebuliser port, standard sized to fit most medication nebulisers (acapella® duet only).
- ≥ 10L/min expiratory flow requirement.
- Streamlined body design offers easy grip (acapella® duet only).
- Adjustable frequency and flow resistance settings.
- Clear colouring aids in visual recognition of cleanliness (acapella® duet only).
- Tethered cap to reduce risk of contamination when in resting position (acapella® duet only).
- Easily disassembled for heat disinfection by boiling, autoclaving and dishwasher (top shelf only)
- Functional in any position – Trendelenburg, standing or sitting.
- Distal 22mm OD fitting allows nebuliser connection via tee adaptor (acapella® choice only).
- One-way inspiratory valve allows inhalation without removal from the mouth.
- Proximal 22mm OD connection allows use with mouthpiece or mask.

TheraPEP®

Features and benefits:
- Six Fixed Orifice Options.
- Built-in durable pressure indicator.
- 22mm OD patient end.
- Inspiratory valve.
- Can accommodate virtually any patient's lung capacity.
- Resists breakage, unlike fragile, costly manometers.
- Provides immediate, visual 360° feedback of prescribed pressure.
- May be used with a mask or mouthpiece, or Nebulizer.
- Allows inhalation and exhalation without removing from mouth

Coach® 2 and CliniFLO®



Features and benefits:

Coach® 2
- Ensures patients inhale, rather than exhale into the unit.
- Easily adjustable for each patient's use.
- Can be seen by patients emerging from the effects of anesthesia.
- Easy to train.
- Stays with the patient for maximum compliance.
- Accommodates patients requiring supplemental oxygen.
- Saves space.
- Colourful deep-sea characters, games, puzzles and stickers.

CliniFLO®
- Can accommodate virtually any patient.
- Reduces the possibility of contamination.
- Provides immediate patient feedback.
- Easy to train.
- Reduces the chance that the setting will be changed inadvertently.

EzPAP®

ORDERING INFORMATION

Product Code	PRODUCT DESCRIPTION	UNITS / CASE
23-0747	EzPAP® System with Mouthpiece	10
23-0757	EzPAP® System with Disposable Manometer and Mouthpiece	10
23-1747	EzPAP® System with Paediatric Mask	1
23-2747	EzPAP® System with Medium Mask	1
23-3747	EzPAP® System with Large Mask	1
23-6000*	EzPAP® Kit: One Pressure Gauge (With Gauge Protector), Three EzPAP® Units (with Mouthpiece), Three Gauge Guards and Ten 22 mm ID Adaptors in a Durable Plastic Box.	1

Each system includes EzPAP® one 7 ft oxygen tube, one pressure port cap, and one of the above

* not CE marked

acapella® Vibratory PEP Therapy System

ORDERING INFORMATION

PART No.	PRODUCT DESCRIPTION	UNITS/CASE
27-9000	acapella® duet kit, includes acapella® duet, mouthpiece, Portex® SVN, oxygen tubing, collapsible flex tubing	10
27-9001	acapella® duet and mouthpiece only	10
007760	Portex® updraft medication nebulizer	50
27-7000	acapella® choice with mouthpiece	10
21-1530	acapella® DH with mouthpiece	10
21-3530	acapella® DH with Paediatric mask	1
21-5530	acapella® DH with medium mask	1
21-7530	acapella® DH with large mask	1
21-1015	acapella® DM with mouthpiece	10
21-3015	acapella® DM with Paediatric mask	1
21-5015	acapella® DM with medium mask	1
21-7015	acapella® DM with large mask	1

ACCESSORIES

Product Code	PRODUCT DESCRIPTION	UNITS/CASE
27-0050	Replacem01ent mouthpiece; fits all acapella® family designs	50

Note: Product is for single patient use only.

For further information please visit: www.smiths-medical.com/respiratorycare

TheraPEP®

ORDERING INFORMATION

Part No.	PRODUCT DESCRIPTION	UNITS/CASE
20-1112	TheraPEP® System with Mouthpiece	10
20-3112	TheraPEP® System with Paediatric Mask	1
20-5112	TheraPEP® System with Small Mask	1
20-7112	TheraPEP® System with Large Mask	1

ACCESSORIES

Part No.	PRODUCT DESCRIPTION	UNITS/CASE
20-3115	Paediatric Mask	1
20-5115	Small Adult Mask	1
20-7115	Large Adult Mask	1
20-0005	Connector, Straight, 22 mm I. D.	10
20-0010	TheraPEP® Pressure Port	10
20-0022	TheraPEP® Pressure Port, Tubing, Indicator	10
20-0050	TheraPEP® Mouthpiece 22 mm I. D.	50
20-0120	TheraPEP® Pressure Port and Resistor	10
20-1110	TheraPEP® Pressure Port, Resistor and Mouthpiece	10

All TheraPEP® Systems Include: Pressure Port, Resistor, 22 mm ID Straight Connector, Tubing and Pressure Indicator.

Coach® 2 Incentive Spirometers

ORDERING INFORMATION

PART No.	PRODUCT DESCRIPTION	Volume
22-4000	Coach®2 One way valve	4000ml
22-4001	Coach®2	4000ml
22-2500	Coach®2 One way valve	2500ml
22-2501	Coach®2	2500ml
22-2000	Coach®2 Kids One way valve	2000ml

CliniFLO® Low-Flow Incentive Spirometers

ORDERING INFORMATION

PART No.	PRODUCT DESCRIPTION
22-1200	CliniFlo®

PRODUCT(S) DESCRIBED MAY NOT BE LICENSED OR AVAILABLE FOR SALE IN CANADA AND OTHER COUNTRIES

Smiths Medical International Ltd.
Ashford, UK TN25 4BF
Phone: +44 (0) 845 8500445
www.smiths-medical.com

Find your local contact information at: www.smiths-medical.com/customer-support

MROCCA-0012

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CERTIFICATE OF REGISTRATION

Certificate Number:
119-04 C

Initial Certification Date:
08 June 2004

Date of Certification Decision:
25 June 2018

Issuing Date:
25 June 2018

Valid Until:
24 June 2021

This is to certify that the management system of:

SMITHS MEDICAL DEUTSCHLAND GmbH

Bretonischer Ring 3, D-85630 Grasbrunn, Germany

See appendix for additional sites and additional site scopes

has been registered by Intertek as conforming to the requirements of:

EN ISO 13485:2016

The management system is applicable to:

Design, manufacture, inspection, storage and distribution of Pressure Monitoring, Infusion Disposables, Interventional Imaging, Neurosurgery, Vascular Access.

The Servicing of active medical devices.

UKAS MANAGEMENT SYSTEMS
061

Calin Moldovean
President, Business Assurance

AMTAC Certification Services Limited, T/A Intertek;
Milton Keynes, UK

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