

SuctionPro72™ **Closed Ventilation Suction System**



Reduce Infection. Reduce Patient Stay. Reduce Costs.

SuctionPro72™



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

[illegible]

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

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www.smiths-medical.com

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

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smiths medical

MHYTCA-1030

Respiratory Care Solutions Improving Quality of Life



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

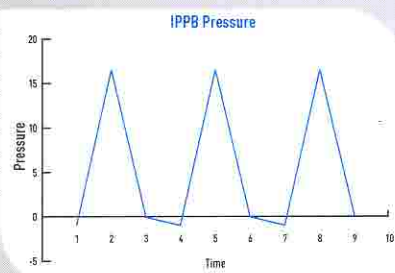
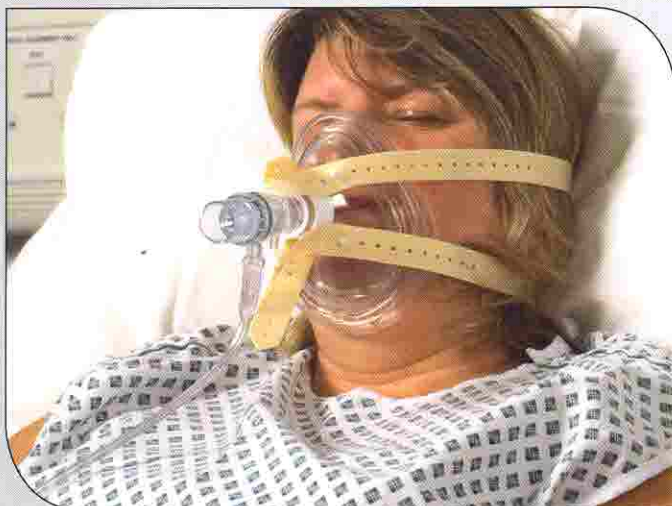


Figure 1

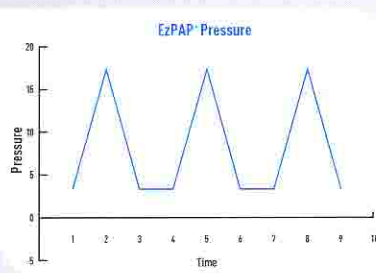
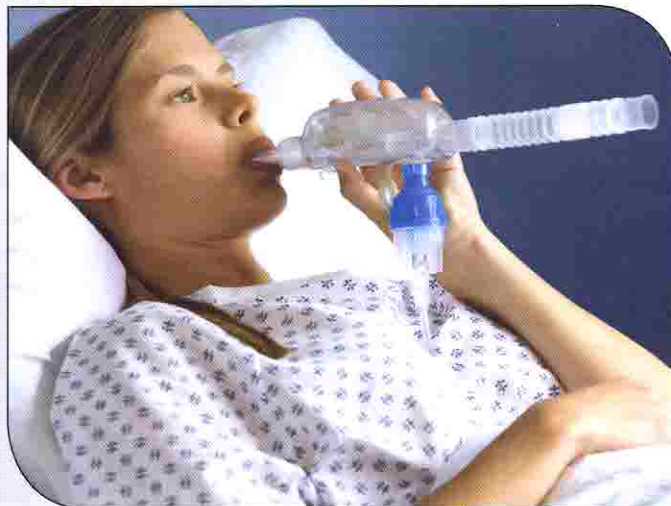


Figure 2

WARD

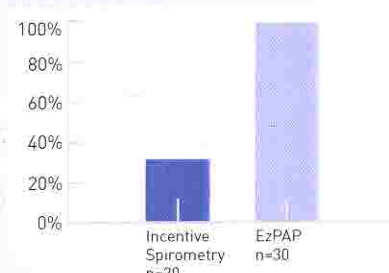


Figure 3
Post-Surgical Atelectasis Improvement
in CABG Patients. $p < .001$

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}

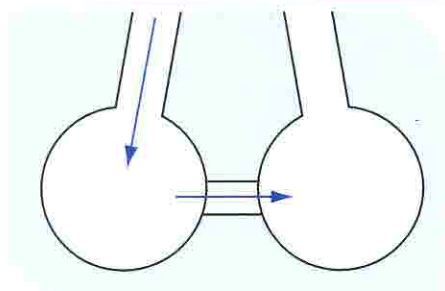
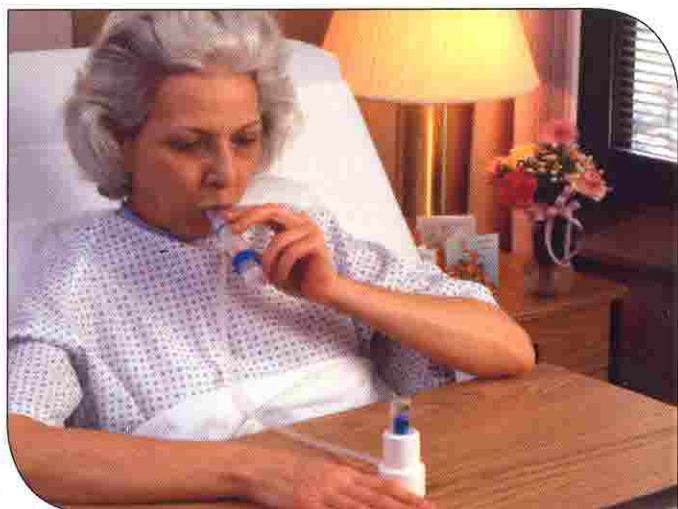


Figure 4
Collateral Ventilation

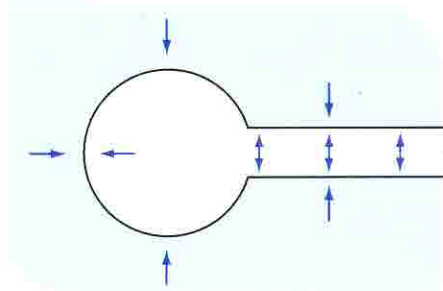


Figure 5 Pursed-lips breathing (or use of a fixed orifice resistor such as a PEP device) creates back pressure that splints the airway open during exhalation.¹⁷

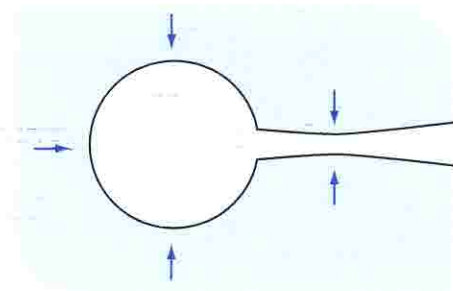


Figure 6 Elevated intrathoracic pressure can compress unstable airways during exhalation.¹⁷

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-flow 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.

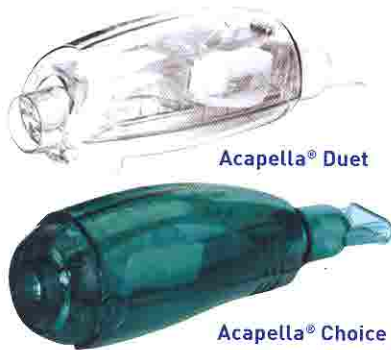
EzPAP®



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



Features and benefits:

- Convenient built-in nebuliser port, standard sized to fit most medication nebulisers (acapella® duet only).
- $\geq 10\text{L/min}$ 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 | Replacement 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® |

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CE Rx
0473 ONLY

smiths medical

MROCCA-0012

EC Certification



EC DESIGN EXAMINATION CERTIFICATE Directive 93/42/EEC for Medical Devices, Annex II (4)

We hereby declare that a design examination has been carried out on the devices(s) listed hereafter following the requirements of the UK national legislation to which the undersigned is subjected, transposing Annex II Section 4 of the Directive 93/42/EEC on medical devices. We certify that the design of the device(s) listed hereafter conforms with the relevant provisions of Annex II Section 4 of the aforementioned legislation, and the result entitles the organization to use the CE 0473 marking on those products*.

SMITHS MEDICAL DEUTSCHLAND GmbH

Bretonischer Ring 3, D-85630 Grasbrunn, Germany

Central venous catheters:

- standard sets
- standard kits
- custom sets

*For CE marking the class III devices covered by this certificate, an EC certificate according to Annex II (3) is also required.

Certificate Number: 119-05 B DE
Initial Certification Date: 01 September 2006
Certificate Effective Date: 07 March 2017
Certificate Expiry Date: 06 March 2022

Barry A. Fitch
AMTAC Certification Services Limited, Milton Keynes, UK
This certificate is the property of AMTAC Certification Services Ltd



In the issuance of this certificate, Intertek assumes no liability to any party other than to the Client, and then only in accordance with the agreed upon Certification Agreement. This certificate's validity is subject to the organization maintaining their system in accordance with Intertek's requirements for systems certification. Validity may be confirmed via email at certificate.validation@intertek.com or by scanning the code to the right with a smartphone.

This Certificate is for the exclusive use of AMTAC's client and is provided pursuant to the agreement between AMTAC and its Client. AMTAC's responsibility and liability are limited to the terms and conditions of the agreement. AMTAC assumes no liability to any party, other than to the Client in accordance with the agreement, for any loss, expense or damage occasioned by the use of this Certificate. Only the Client is authorized to permit copying or distribution of this Certificate. Any use of the AMTAC name or one of its marks for the sale or advertisement of the tested material, product or service must first be approved in writing by AMTAC.

The certificate remains the property of Intertek, to whom it must be returned upon request.

The certification is subject to the organization maintaining their system in compliance with the regulations stated in this certificate, allowing regular assessments and following the contracted requirements of the Notified Body.

AMTAC Certification Services Limited is a Notified Body according to Directive 93/42/EEC for medical devices, with identification number 0473.

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Smiths Medical ASD Inc.
6000 Nathan Lane North
Minneapolis
Minnesota
55442
USA

Holds Certificate Number:

MD 669191

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

Please see scope page.

For and on behalf of BSI:



Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2017-08-16

Latest Revision Date: 2019-02-28

Effective Date: 2017-08-16

Expiry Date: 2020-08-15

Page: 1 of 6



003

...making excellence a habit.™

Certificate No: **MD 669191**

Registered Scope:

The design, development and manufacturing of:

- Sterile Disposable infusion kits including cassette, tubes, connectors, needles
- Sterile Blood and Fluid Warmers disposables sets
- Sterile Central Implantable Access Systems
- Sterile Peripheral Implantable Access Systems
- Sterile and non-sterile vital sign monitoring probes
- Sterile Needles and Introducer for Implantable Access
- Sterile Catheters and accessories
- Sterile Blood Sampling Devices
- Sterile Respiratory Therapy Devices and positive airway pressure therapy
- Sterile Catheter Connectors,
- Loss of Resistance Devices Syringes, Epidural Filters
- Epidural Needles,
- Hypodermic Needles and
- Introducer Needles
- Sterile Spinal and combined spinal/epidural needles including correct inject spinal needles Devices
- Sterile Positive expiratory pressure therapy systems
- Sterile and non-sterile Breathing Systems and Circuits including
- Sterile and non-sterile Applications for patient Intubation
- Sterile Tracheostomy Tubes and Kits
- Sterile and non-sterile Oxygen and Humidity Management,
- Non-Sterile Resuscitation,
- Non-Sterile filter,
- And Sterile and Non-Sterile tracheostomy accessories
- Sterile Disposable Pressure Monitoring tubes, connectors and transducers
- Sterile Suction Catheters
- Sterile Drainage Devices
- Sterile Feeding devices
- Sterile Cardiothoracic Catheters
- Patient warming units
- Blood and Fluid Warmers units
- Infusion Pumps for hospital and home use
- Infusion Application Software
- Sterile and non sterile convective warmers blankets and accessories
- Medical Gas Administration Accessories
- Gas Powered Emergency and Transport Ventilators and Resuscitators
- Anesthetic Ventilators
- Monitors and Related Equipment
- Non-Sterile Nebulizers

Original Registration Date: 2017-08-16

Latest Revision Date: 2019-02-28

Effective Date: 2017-08-16

Expiry Date: 2020-08-15

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Certificate No: **MD 669191**

Registered Scope:

Sterile Regional Anesthesia Devices

Sterile Needle safety devices and cough sampling devices and catheters securing devices and kit for applying local anesthesia

Interventional Imaging Devices

Sterile Pain Management Devices

Document Control, Post Market Risk Management, Customer Complaints, Global Sourcing, Regulatory Affairs, Servicing, distribution.



Original Registration Date: 2017-08-16

Latest Revision Date: 2019-02-28

Effective Date: 2017-08-16

Expiry Date: 2020-08-15

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A Member of the BSI Group of Companies.

Certificate No: **MD 669191**

Location

Smiths Medical ASD Inc.
3350 Granada Avenue North
Oakdale
Minnesota
55128
USA

Registered Activities

The manufacture of:
Sterile Catheters and Accessories
Sterile and non sterile convective warmers blankets and accessories
Patient warming units
Sterile and non sterile vital sign monitoring probes
Blood and Fluid Warmers units
Sterile Blood and Fluid Warmers disposables sets
Infusion Application Software
Infusion Pumps for hospital and home use
Sterile Disposable infusion kits including cassette, tubes, connectors, needles
Medical Gas Administration Accessories
Servicing, distribution



Original Registration Date: 2017-08-16

Latest Revision Date: 2019-02-28

Effective Date: 2017-08-16

Expiry Date: 2020-08-15

Page: 4 of 6

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Certificate No: **MD 669191**

Location

Smiths Medical ASD Inc.
6000 Nathan Lane North
Minneapolis
Minnesota
55442
USA

Registered Activities

The design, development and manufacturing of:
Sterile Disposable infusion kits including cassette, tubes, connectors, needles
Sterile Blood and Fluid Warmers disposables sets
Sterile Central Implantable Access Systems
Sterile Peripheral Implantable Access Systems
Sterile and non-sterile vital sign monitoring probes
Sterile Needles and Introducer for Implantable Access
Sterile Catheters and accessories
Sterile Blood Sampling Devices
Sterile Respiratory Therapy Devices and positive airway pressure therapy
Sterile Catheter Connectors,
Loss of Resistance Devices Syringes, Epidural Filters
Epidural Needles,
Hypodermic Needles and
Introducer Needles
Sterile Spinal and combined spinal/epidural needles including correct inject spinal needles Devices
Sterile Positive expiratory pressure therapy systems
Sterile and non-sterile Breathing Systems and Circuits including
-Sterile and non-sterile Applications for patient Intubation
-Sterile Tracheostomy Tubes and Kits
-Sterile and non-sterile Oxygen and Humidity Management,
-Non-Sterile Resuscitation,
-Non-Sterile filter,
-And Sterile and Non-Sterile tracheostomy accessories
Sterile Disposable Pressure Monitoring tubes, connectors and transducers
Sterile Suction Catheters
Sterile Drainage Devices
Sterile Feeding devices
Sterile Cardiothoracic Catheters
Patient warming units
Blood and Fluid Warmers units
Infusion Pumps for hospital and home use
Infusion Application Software
Sterile and non sterile convective warmers blankets and accessories
Medical Gas Administration Accessories
Gas Powered Emergency and Transport Ventilators and Resuscitators
Anesthetic Ventilators
Monitors and Related Equipment
Non-Sterile Nebulizers
Sterile Regional Anesthesia Devices

Original Registration Date: 2017-08-16

Effective Date: 2017-08-16

Latest Revision Date: 2019-02-28

Expiry Date: 2020-08-15

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Certificate No: **MD 669191**

Location

Registered Activities

Sterile Needle safety devices and cough sampling devices and catheters securing devices and kit for applying local anesthesia
Interventional Imaging Devices
Sterile Pain Management Devices
Document Control, Post Market Risk Management, Customer Complaints, Global Sourcing, Regulatory Affairs, Servicing, distribution.



Original Registration Date: 2017-08-16

Effective Date: 2017-08-16

Latest Revision Date: 2019-02-28

Expiry Date: 2020-08-15

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