

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			•		•		•		•	

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

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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

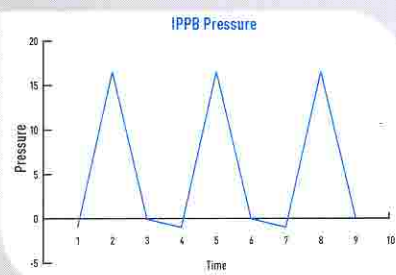
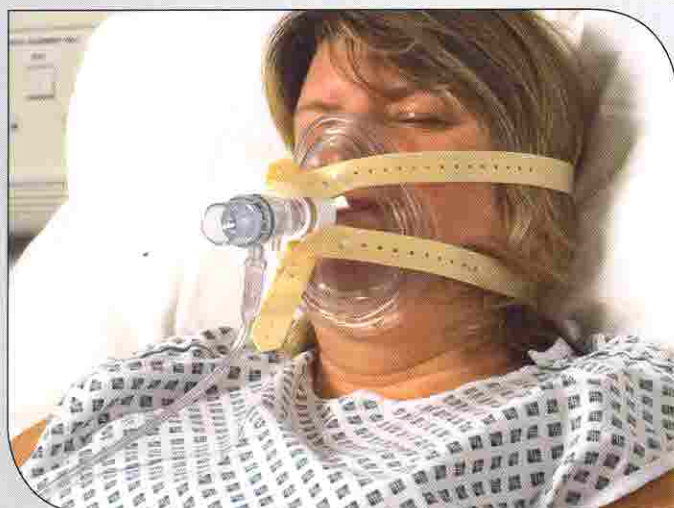


Figure 1

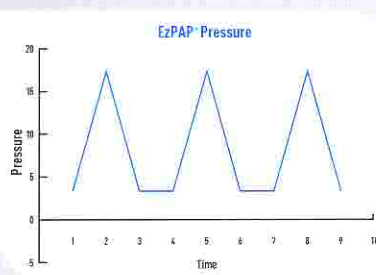
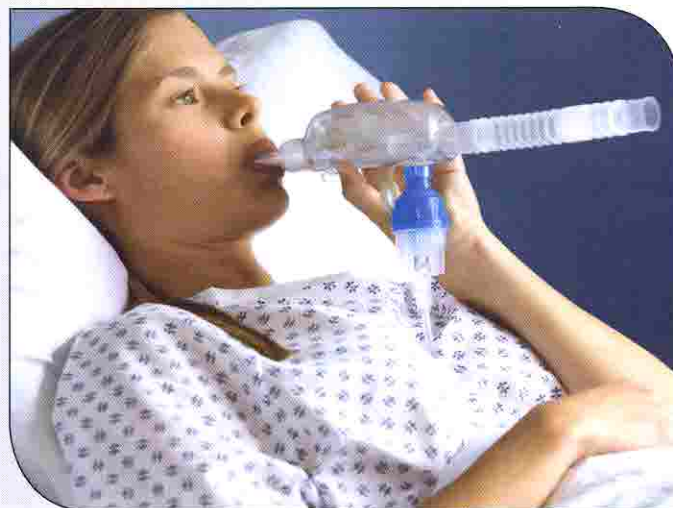


Figure 2

WARD

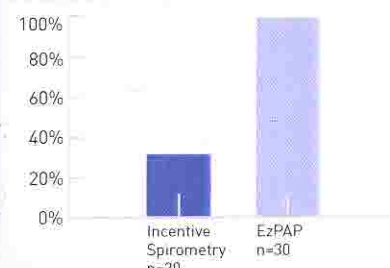


Figure 3
Post-Surgical Atelectasis Improvement
in CABG Patients. $p < .001$

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}

HOME

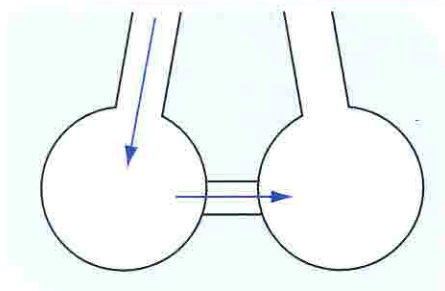
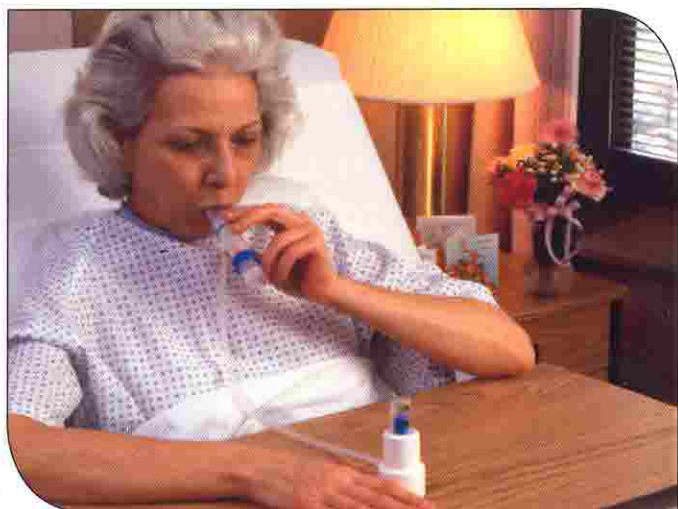


Figure 4
Collateral Ventilation

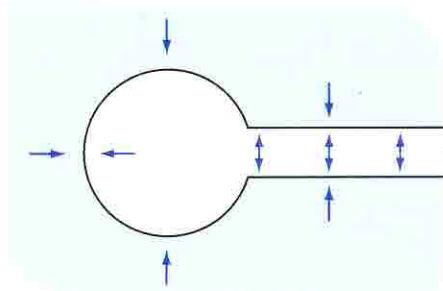


Figure 5 Pursed-lips breathing (or use of a fixed orifice resistor such as a PEP device) creates back pressure that splints the airway open during exhalation.¹⁷

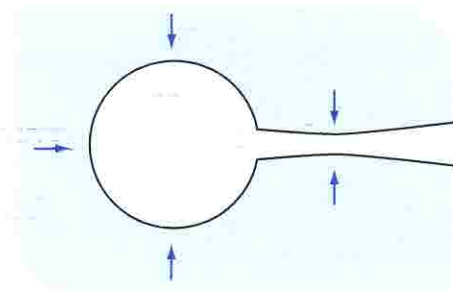


Figure 6 Elevated intrathoracic pressure can compress unstable airways during exhalation.¹⁷

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.

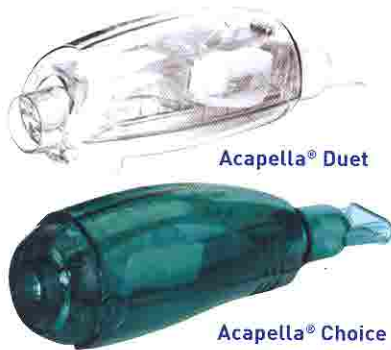
EzPAP®



Features and benefits:

- 22mm OD patient end to accommodate mouthpiece or 3 mask sizes.
- Scalped 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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 Dispozitive și Accesorii de Management al Durerii,
 Dispozitive și Accesorii Invasive de Monitorizare a Tensiunii Pacientului,
 Dispozitive Traheotomie,
 Dispozitive de Unică Folosință pentru Injecții,
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Certificat Număr: 1201-04 B
Data Inițială a Certificării: 10 Ianuarie, 2014
Data Efectivă a Certificatului: 22 Mai 2017
Data Expirării Certificatului: 28 Februarie 2019

Brian Johnson

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2000 2001 2002 2003 2004 2005 2006 2007 2008 2009 2010 2011 2012 2013 2014 2015 2016 2017 2018 2019 2020 2021 2022 2023 2024 2025 2026 2027 2028 2029 2030 2031 2032 2033 2034 2035 2036 2037 2038 2039 2040 2041 2042 2043 2044 2045 2046 2047 2048 2049 2050 2051 2052 2053 2054 2055 2056 2057 2058 2059 2060 2061 2062 2063 2064 2065 2066 2067 2068 2069 2070 2071 2072 2073 2074 2075 2076 2077 2078 2079 2080 2081 2082 2083 2084 2085 2086 2087 2088 2089 2090 2091 2092 2093 2094 2095 2096 2097 2098 2099 2100 2101 2102 2103 2104 2105 2106 2107 2108 2109 2110 2111 2112 2113 2114 2115 2116 2117 2118 2119 2120 2121 2122 2123 2124 2125 2126 2127 2128 2129 2130 2131 2132 2133 2134 2135 2136 2137 2138 2139 2140 2141 2142 2143 2144 2145 2146 2147 2148 2149 2150 2151 2152 2153 2154 2155 2156 2157 2158 2159 2160 2161 2162 2163 2164 2165 2166 2167 2168 2169 2170 2171 2172 2173 2174 2175 2176 2177 2178 2179 2180 2181 2182 2183 2184 2185 2186 2187 2188 2189 2190 2191 2192 2193 2194 2195 2196 2197 2198 2199 2200 2201 2202 2203 2204 2205 2206 2207 2208 2209 2210 2211 2212 2213 2214 2215 2216 2217 2218 2219 2220 2221 2222 2223 2224 2225 2226 2227 2228 2229 2230 2231 2232 2233 2234 2235 2236 2237 2238 2239 2240 2241 2242 2243 2244 2245 2246 2247 2248 2249 2250 2251 2252 2253 2254 2255 2256 2257 2258 2259 2260 2261 2262 2263 2264 2265 2266 2267 2268 2269 2270 2271 2272 2273 2274 2275 2276 2277 2278 2279 2280 2281 2282 2283 2284 2285 2286 2287 2288 2289 2290 2291 2292 2293 2294 2295 2296 2297 2298 2299 2300 2301 2302 2303 2304 2305 2306 2307 2308 2309 2310 2311 2312 2313 2314 2315 2316 2317 2318 2319 2320 2321 2322 2323 2324 2325 2326 2327 2328 2329 2330 2331 2332 2333 2334 2335 2336 2337 2338 2339 2340 2341 2342 2343 2344 2345 2346 2347 2348 2349 2350 2351 2352 2353 2354 2355 2356 2357 2358 2359 2360 2361 2362 2363 2364 2365 2366 2367 2368 2369 2370 2371 2372 2373 2374 2375 2376 2377 2378 2379 2380 2381 2382 2383 2384 2385 2386 2387 2388 2389 2390 2391 2392 2393 2394 2395 2396 2397 2398 2399 2400 2401 2402 2403 2404 2405 2406 2407 2408 2409 2410 2411 2412 2413 2414 2415 2416 2417 2418 2419 2420 2421 2422 2423 2424 2425 2426 2427 2428 2429 2430 2431 2432 2433 2434 2435 2436 2437 2438 2439 2440 2441 2442 2443 2444 2445 2446 2447 2448 2449 2450 2451 2452 2453 2454 2455 2456 2457 2458 2459 2460 2461 2462 2463 2464 2465 2466 2467 2468 2469 2470 2471 2472 2473 2474 2475 2476 2477 2478 2479 2480 2481 2482 2483 2484 2485 2486 2487 2488 2489 2490 2491 2492 2493 2494 2495 2496 2497 2498 2499 2500 2501 2502 2503 2504 2505 2506 2507 2508 2509 2510 2511 2512 2513 2514 2515 2516 2517 2518 2519 2520 2521 2522 2523 2524 2525 2526 2527 2528 2529 2530 2531 2532 2533 2534 2535 2536 2537 2538 2539 2540 2541 2542 2543 2544 2545 2546 2547 2548 2549 2550 2551 2552 2553 2554 2555 2556 2557 2558 2559 2560 2561 2562 2563 2564 2565 2566 2567 2568 2569 2570 2571 2572 2573 2574 2575 2576 2577 2578 2579 2580 2581 2582 2583 2584 2585 2586 2587 2588 2589 2590 2591 2592 2593 2594 2595 2596 2597 2598 2599 2600 2601 2602 2603 2604 2605 2606 2607 2608 2609 2610 2611 2612 2613 2614 2615 2616 2617 2618 2619 2620 2621 2622 2623 2624 2625 2626 2627 2628 2629 2630 2631 2632 2633 2634 2635 2636 2637 2638 2639 2640 2641 2642 2643 2644 2645 2646 2647 2648 2649 2650 2651 2652 2653 2654 2655 2656 2657 2658 2659 2660 2661 2662 2663 2664 2665 2666 2667 2668 2669 2670 2671 2672 2673 2674 2675 2676 2677 2678 2679 2680 2681 2682 2683 2684 2685 2686 2687 2688 2689 2690 2691 2692 2693 2694 2695 2696 2697 2698 2699 2700 2701 2702 2703 2704 2705 2706 2707 2708 2709 2710 2711 2712 2713 2714 2715 2716 2717 2718 2719 2720 2721 2722 2723 2724 2725 2726 2727 2728 2729 2730 2731 2732 2733 2734 2735 2736 2737 2738 2739 2740 2741 2742 2743 2744 2745 2746 2747 2748 2749 2750 2751 2752 2753 2754 2755 2756 2757 2758 2759 2760 2761 2762 2763 2764 2765 2766 2767 2768 2769 2770 2771 2772 2773 2774 2775 2776 2777 2778 2779 2780 2781 2782 2783 2784 2785 2786 2787 2788 2789 2790 2791 2792 2793 2794 2795 2796 2797 2798 2799 2800 2801 2802 2803 2804 2805 2806 2807 2808 2809 2810 2811 2812 2813 2814 2815 2816 2817 2

Subsemnata **MUSUROIA MIRELA**, traducator autorizat de Ministerul Justitiei, certific exactitatea acestei traducerii cu textul înscrisului original în limba engleza, ce a fost vizat de mine.

Traducător autorizat
Nr. 2769/2015



EC Certificate - Full Quality Assurance System

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

No.**CE 661325****Issued To:**

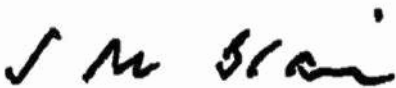
**Smiths Medical International Ltd.
Boundary Road
Hythe
Kent
CT21 6JL
United Kingdom**

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: **2017-06-28**

Date: **2017-06-28**

Expiry Date: **2022-06-27**

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Page 1 of 2

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

Certificate No: CE 661325

Certificate Scope:

The design, development and manufacture of sterile:

Breathing Systems, Drainage Devices, Feeding Devices, Filtration Devices for Breathing Circuits, Infusion Disposables, Intubation Systems, Obstetrics and Gynaecology Sampling Devices, Oxygen and Humidity Management Devices, Pressure Monitoring Accessories, Resuscitation Devices, Suction Catheters, Tracheostomy Tubes, Vascular Access Devices

The design, development and manufacture of non-sterile:

Breathing Systems, Intubation Systems, Resuscitation Devices, Gynecologic Pessaries, Tracheostomy Tubes, Oxygen and Humidity Management Devices



First Issued: **2017-06-28**

Date: **2017-06-28**

Expiry Date: **2022-06-27**

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Page 2 of 2

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

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 661325**
Date: **2017-06-28**
Issued To: **Smiths Medical International Ltd.**
Boundary Road
Hythe
Kent
CT21 6JL
United Kingdom

Subcontractor:	Service(s) supplied
Brightwake Limited Lowmoor Business Park Kirkby-in-Ashfield Nottinghamshire NG17 7JZ United Kingdom	Manufacture
GaleMed Corporation No. 87, Li-Gong 2nd Road Wu-Jia YILAN 268 Taiwan	Manufacture
GE Medical Pollards Wood Nightingales Lane Chalfont Saint Giles HP8 4SP United Kingdom	Manufacture

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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 661325**
 Date: **2017-06-28**
 Issued To: **Smiths Medical International Ltd.**
Boundary Road
Hythe
Kent
CT21 6JL
United Kingdom

Subcontractor:	Service(s) supplied
Koo Medical Equipment (Shanghai) Co., Ltd 100 Zhongde Road Dakun Industrial Park Songjiang, Shanghai 201614 China	Manufacture
Pentair Filtration Solutions 1350 Hammond Road St. Paul Minnesota 55110 USA	Crucial Supplier
Quadrant EPP Belgium N.V. Industriepark Noord Robert Tavernierlaan 2 Tielt 8700 Belgium	Manufacture

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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 661325**
 Date: **2017-06-28**
 Issued To: **Smiths Medical International Ltd.**
Boundary Road
Hythe
Kent
CT21 6JL
United Kingdom

Subcontractor:	Service(s) supplied
Smiths Healthcare Manufacturing SA de CV Avenida Calidad No.4 Parque, Industrial Internacional Tijuana 22425 Mexico	Manufacture
Smiths Healthcare Manufacturing SA de CV Carretera Miguel Alemán Km 21.7 Parque Industrial Monterrey Apodaca Nuevo León 66603 Mexico	Manufacture

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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 661325**
 Date: **2017-06-28**
 Issued To: **Smiths Medical International Ltd.**
Boundary Road
Hythe
Kent
CT21 6JL
United Kingdom

Subcontractor:	Service(s) supplied
Smiths Medical ASD Inc. 10 Bowman Dr. Keene New Hampshire 03431 USA	Manufacture
Smiths Medical ASD Inc. 1265 Grey Fox Road St Paul Minnesota 55112 USA	Manufacture
Smiths Medical ASD Inc. 201 West Queen St., Southington Connecticut 06489 USA	Manufacture

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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 661325**
Date: **2017-06-28**
Issued To: **Smiths Medical International Ltd.**
Boundary Road
Hythe
Kent
CT21 6JL
United Kingdom

Subcontractor:	Service(s) supplied
Smiths Medical ASD Inc. 6250 Shier Rings Road Dublin Ohio 43016 USA	Manufacture
Smiths Medical ASD Inc. 9124 Polk Lane, Suite 101 Olive Branch Mississippi 38654 USA	Distribution
Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice Czech Republic	Manufacture

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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

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Certificate No: **CE 661325**
 Date: **2017-06-28**
 Issued To: **Smiths Medical International Ltd.**
Boundary Road
Hythe
Kent
CT21 6JL
United Kingdom

Subcontractor:	Service(s) supplied
Smiths Medical Gary 5700 W 23rd Ave Gary Indiana 46406 USA	Manufacture
Smiths Medical International Ltd 52 Grayhill Rd Cumbernauld Glasgow G68 9HQ United Kingdom	Manufacture
Smiths Medical International Nijmegen Bijsterhuizen 22-08 6604 LD Wijchen The Netherlands	Distribution

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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

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Certificate No: **CE 661325**
 Date: **2017-06-28**
 Issued To: **Smiths Medical International Ltd.**
Boundary Road
Hythe
Kent
CT21 6JL
United Kingdom

Subcontractor:	Service(s) supplied
Smiths Medical Italia Srl Via della Stazione, 2 Latina Scalo 04100 Italy	Packaging
Sterigenics Belgium (Petit-Rechain) SA Zoning Industriel de Petit-Rechain Avenue Andre Ernst 21 B-4800 Verviers Belgium	ETO Sterilization
Sterigenics UK Limited Cotes Park Estate Somercoates Alfreton DE55 4NJ United Kingdom	ETO Sterilization

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EC Certificate - Full Quality Assurance System

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

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Certificate No: **CE 661325**
 Date: **2017-06-28**
 Issued To: **Smiths Medical International Ltd.**
Boundary Road
Hythe
Kent
CT21 6JL
United Kingdom

Subcontractor:	Service(s) supplied
Sterigenics US, LLC 344 Bonnie Circle Corona California 92880 USA	Gamma Sterilization
Sterigenics, LLC 1700 College Blvd. West Memphis Arkansas 72301 USA	Gamma Sterilization
Sterilization Services of Tennessee, Inc 2396 Florida Street Memphis Tennessee 38109 USA	ETO Sterilization

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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

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 Date: **2017-06-28**
 Issued To: **Smiths Medical International Ltd.**
Boundary Road
Hythe
Kent
CT21 6JL
United Kingdom

Subcontractor:	Service(s) supplied
STERIS ISOMEDIX Services, Inc 7685 Saint Andrews Avenue San Diego California 92154 USA	ETO Sterilization
UPG Avenida La Cuspide #1 Parque Industrial Tecnomex Del. Playas de Tijuana Tijuana Baja California 22700 Mexico	Manufacture
Velcro USA Inc. 95 Sundial Avenue Manchester New Hampshire 03103-7206 USA	Crucial Supplier

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EC Certificate - Full Quality Assurance System

Certificate History

Certificate No: **CE 661325**
Date: **2017-06-28**
Issued To: **Smiths Medical International Ltd.**
Boundary Road
Hythe
Kent
CT21 6JL
United Kingdom

Date	Reference Number	Action
Current	8603100 8603169	First issue. Transferred from another Notified Body. Certificate renewal.

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Page 1 of 1

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

Certificat CE - Sistem Integral de Asigurare a Calitatii

Directiva 93/42/CEE privind dispozitivele medicale, Anexa II excluzand Sectiunea 4

Nr. **CE 661325**
Titular: **Smiths Medical International Ltd.**
Boundary Road
Hythe
Kent
CT21 6JL
Marea Britanie

Obiect:

Consultati pagina cu obiectul certificatului.

pe baza examinarii noastre a sistemului de asigurare a calitatii conform cerintelor Directivei Consiliului 93/42/CEE, Anexa II excluzand Sectiunea 4. Sistemul de asigurare a calitatii indeplineste cerintele Directivei. Pentru lansarea pe piata a produselor din clasa III este necesar certificatul mentionat in Anexa II, Sectiunea 4.

Pentru si in numele BSI, organ de certificare in acceptiunea sus-mentionatei Directive (Organ de certificare cu numarul 0086):



Stewart Brain, Sef compartiment conformitate si risc

Dispozitive medicale

Prima editie: **2017-06-28**

Data: **2017-06-28**

Data expirarii: **2022-06-27**

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Pagina 1 din 2

Valabilitatea prezentului certificat este conditionata de mentinerea sistemului nde calitate la cerintele Directivei dovedita de organul de certificare care supravegheaza compania. Prezenta aprobare exclude toate produsele proiectate si/sau fabricate de o terta parte on in numele companiei care detine prezentul certificat, cu exceptia unui acord contrar, incheiat cu BSI. Prezentul certificat a fost redactat electronic si este conditionat de respectarea caietului de sarcini.

Informatii si contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000 BSI Assurance UK Limited, inregistrata in Anglia sub numarul 7805321 in 389 Chiswick High Road, Londra W4 4AL, UK. A membra a grupului BSI.



Certificat nr.: CE 661325

Obiectul certificatului:

Proiectarea, dezvoltarea si fabricatia produselor sterile:

Sisteme de respiratie, Dispozitive de drenaj, Dispozitive de nutritie, Dispozitive de filtrare pentru Circuite respiratorii, Consumabile pentru perfuzii, Sisteme de intubatie, Dispozitive de prelevare a probelor pentru obstetrica si ginecologie, Dispozitive de gestionare a oxigenului si umiditatii, Accesorii de control al presiunii, Dispozitive de resuscitare, Catetere de absorbtie, Tuburi de traheostomie, Dispozitive de acces vascular

Proiectarea, dezvoltarea si fabricatia de produse nesterile:

Sisteme de respiratie, Sisteme de intubatie, Dispozitive de resuscitare, Supozitoare vaginale, Tuburi de traheostomie, Dispozitive de gestionare a oxigenului si umiditatii



Prima editie: **2017-06-28**

Data: **2017-06-28**

Data expirarii: **2022-06-27**

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Pagina 2 of 2

Valabilitatea prezentului certificat este conditionata de mentinerea sistemului nde calitate la cerintele Directivei dovedita de organul de certificare care supravegheaza compania. Prezenta aprobare exclude toate produsele proiectate si/sau fabricate de o terta parte on in numele companiei care detine prezentul certificat, cu exceptia unui acord contrar, incheiat cu BSI.
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Assurance UK Limited, inregistrata in Anglia sub numarul 7805321 in 389 Chiswick High Road, Londra W4 4AL, UK. A
membra a grupului BSI.



Certificat CE - Sistem Integral de Asigurare a Calitatii

Directiva 93/42/CEE privind dispozitivele medicale, Anexa II excluzand Sectiunea 4

Lista subcontractantilor majori

Recunoscuti ca participanti la prestatii aferente produsului certificat prin:

Certificat nr.: **CE 661325**
Data: **2017-06-28**
Titular: **Smiths Medical International Ltd.**
Boundary Road
Hythe
Kent
CT21 6JL
Marea Britanie

Subcontractant:**Servicii prestate**

Brightwake Limited
Lowmoor Business Park
Kirkby-in-Ashfield
Nottinghamshire
NG17 7JZ
Marea Britanie

Fabricatie

GaleMed Corporation
Nr. 87, Li-Gong 2nd Road
Wu-Jia
YILAN 268
Taiwan

Fabricatie

GE Medical
Pollards Wood
Nightingales Lane
Chalfont Saint Giles
HP8 4SP
Marea Britanie

Fabricatie

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Certificat CE - Sistem Integral de Asigurare a Calitatii

Directiva 93/42/CEE privind dispozitivele medicale, Anexa II excluzand Sectiunea 4

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Data: **2017-06-28**
Titular: **Smiths Medical International Ltd.**
Boundary Road
Hythe
Kent
CT21 6JL
Marea Britanie

Subcontractant:**Servicii prestate**

Koo Medical Equipment (Shanghai)
Co., Ltd
100 Zhongde Road
Dakun Industrial Park
Songjiang, Shanghai 201614
China

Fabricatie

Pentair Filtration Solutions
1350 Hammond Road
St. Paul
Minnesota
55110
USA

Furnizor crucial

Quadrant EPP Belgium N.V.
Industriepark Noord
Robert Tavernierlaan 2
Tielt
8700
Belgia

Fabricatie

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Certificat CE - Sistem Integral de Asigurare a Calitatii

Directiva 93/42/CEE privind dispozitivele medicale, Anexa II excluzand Sectiunea 4

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 Titular: **Smiths Medical International Ltd.**
Boundary Road
Hythe
Kent
CT21 6JL
Marea Britanie

Subcontractant:

Servicii prestate

Smiths Healthcare Manufacturing
 SA de CV
 Avenida Calidad Nr.4
 Parque, Industrial Internacional
 Tijuana
 22425
 Mexic

Fabricatie

Smiths Healthcare Manufacturing
 SA de CV
 Carretera Miguel Alemán Km 21.7
 Parque Industrial Monterrey
 Apodaca
 Nuevo León
 66603
 Mexic

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Certificat CE - Sistem Integral de Asigurare a Calitatii

Directiva 93/42/CEE privind dispozitivele medicale, Anexa II excluzand Sectiunea 4

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Data: **2017-06-28**
Titular: **Smiths Medical International Ltd.**
Boundary Road
Hythe
Kent
CT21 6JL
Marea Britanie

Subcontractant:

Servicii prestate

Smiths Medical ASD Inc.
10 Bowman Dr.
Keene
New Hampshire
03431
USA

Fabricatie

Smiths Medical ASD Inc.
1265 Grey Fox Road
St Paul
Minnesota
55112
USA

Fabricatie

Smiths Medical ASD Inc.
201 West Queen St.,
Southington
Connecticut
06489
USA

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Certificat CE - Sistem Integral de Asigurare a Calitatii

Directiva 93/42/CEE privind dispozitivele medicale, Anexa II excluzand Sectiunea 4

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Certificat nr.: **CE 661325**
Data: **2017-06-28**
Titular: **Smiths Medical International Ltd.**
Boundary Road
Hythe
Kent
CT21 6JL
Marea Britanie

Subcontractant:**Servicii prestate**

Smiths Medical ASD Inc.
6250 Shier Rings Road
Dublin
Ohio
43016
USA

Fabricatie

Smiths Medical ASD Inc.
9124 Polk Lane, Suite 101
Olive Branch
Mississippi
38654
USA

Distributie

Smiths Medical Republica Ceha a.s.
Olomoucká 306
753 01 Hranice
Republica Ceha

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Certificat CE - Sistem Integral de Asigurare a Calitatii

Directiva 93/42/CEE privind dispozitivele medicale, Anexa II excluzand Sectiunea 4

Lista subcontractantilor majori

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Data: **2017-06-28**
Titular: **Smiths Medical International Ltd.**
Boundary Road
Hythe
Kent
CT21 6JL
Marea Britanie

Subcontractant:**Servicii prestate**

Smiths Medical Gary
5700 W 23rd Ave
Gary
Indiana
46406
USA

Fabricatie

Smiths Medical International Ltd
52 Grayhill Rd
Cumbernauld
Glasgow
G68 9HQ
Marea Britanie

Fabricatie

Smiths Medical International
Nijmegen
Bijsterhuizen 22-08
6604 LD Wijchen
Olanda

Distributie

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Certificat CE - Sistem Integral de Asigurare a Calitatii

Directiva 93/42/CEE privind dispozitivele medicale, Anexa II excluzand Sectiunea 4

Lista subcontractantilor majori

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Data: **2017-06-28**
Titular: **Smiths Medical International Ltd.**
Boundary Road
Hythe
Kent
CT21 6JL
Marea Britanie

Subcontractant:**Servicii prestate**

Smiths Medical Italia Srl
Via della Stazione, 2
Latina Scalo
04100
Italia

Ambalare

Sterigenics Belgium
(Petit-Rechain) SA
Zoning Industriel de Petit-Rechain
Avenue Andre Ernst 21
B-4800 Verviers
Belgium

Sterilizare ETO

Sterigenics UK Limited
Cotes Park Estate
Somercotes
Alfreton
DE55 4NJ
Marea Britanie

Sterilizare ETO

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Certificat CE - Sistem Integral de Asigurare a Calitatii

Directiva 93/42/CEE privind dispozitivele medicale, Anexa II excluzand Sectiunea 4

Lista subcontractantilor majori

Recunoscuti ca participanti la prestatii aferente produsului certificat prin:

Certificat nr.: **CE 661325**
 Data: **2017-06-28**
 Titular: **Smiths Medical International Ltd.**
Boundary Road
Hythe
Kent
CT21 6JL
Marea Britanie

Subcontractant:

Servicii prestate

Sterigenics US, LLC
 344 Bonnie Circle
 Corona
 California
 92880
 USA

Sterilizare cu raze gamma

Sterigenics, LLC
 1700 College Blvd.
 West Memphis
 Arkansas
 72301
 USA

Sterilizare cu raze gamma

Sterilization Services of
 Tennessee, Inc
 2396 Florida Street
 Memphis
 Tennessee 38109
 USA

Sterilizare ETO

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Certificat CE - Sistem Integral de Asigurare a Calitatii

Directiva 93/42/CEE privind dispozitivele medicale, Anexa II excluzand Sectiunea 4

Lista subcontractantilor majori

Recunoscuti ca participanti la prestatii aferente produsului certificat prin:

Certificat nr.: **CE 661325**
Data: **2017-06-28**
Titular: **Smiths Medical International Ltd.**
Boundary Road
Hythe
Kent
CT21 6JL
Marea Britanie

Subcontractant:

STERIS ISOMEDIX Services, Inc
7685 Saint Andrews Avenue
San Diego
California 92154
USA

Servicii prestate

Sterilizare ETO

UPG
Avenida La Cuspide #1
Parque Industrial Tecnomex
Del. Playas de Tijuana
Tijuana
Baja California
22700
Mexic

Fabricatie

Velcro USA Inc.
95 Sundial Avenue
Manchester
New Hampshire
03103-7206
USA

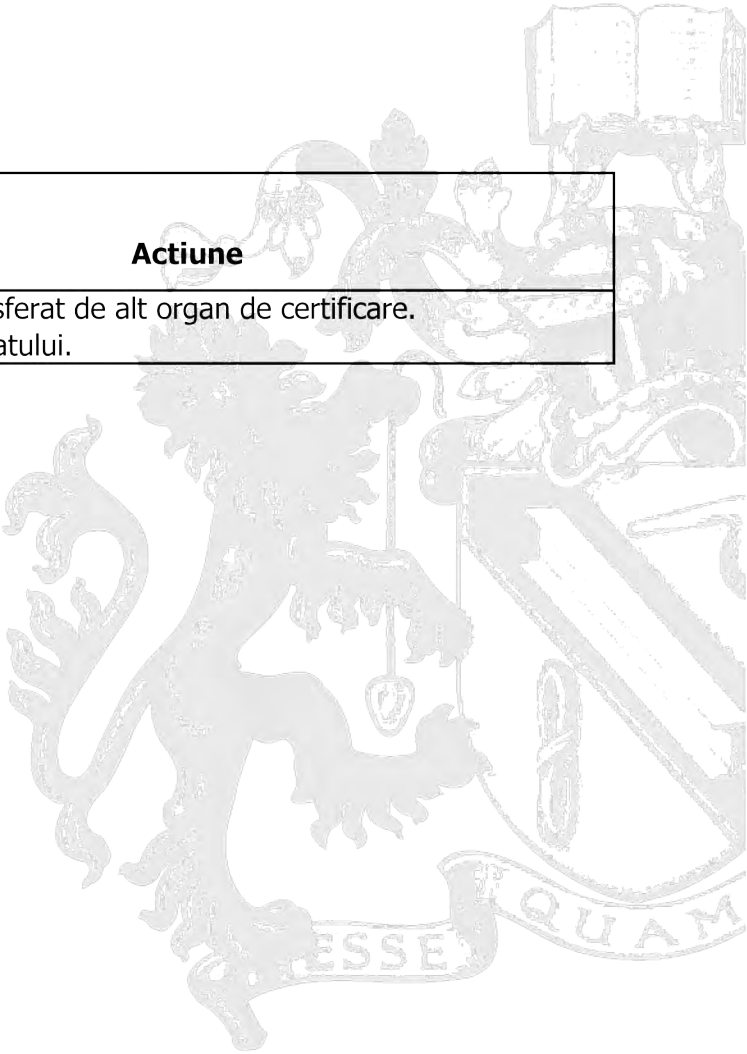
Furnizor crucial

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Certificat CE - Sistem Integral de Asigurare a Calitatii – Istoricul certificatului

Certificat nr.: **CE 661325**
Data: **2017-06-28**
Titular: **Smiths Medical International Ltd.**
Boundary Road
Hythe
Kent
CT21 6JL
Marea Britanie

Data	Numar de referinta	Actiune
Curenta	8603100 8603169	Prima editie. Transferat de alt organ de certificare. Reinnoirea certificatului.



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Prezentul certificat a fost redactat electronic si este conditionat de respectarea caietului de sarcini.

Informatii si contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000 BSI Assurance UK Limited, inregistrata in Anglia sub numarul 7805321 in 389 Chiswick High Road, Londra W4 4AL, UK. A membra a grupului BSI.



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Traducător autorizat
Nr. 2769/2015

Certificate of Registration



Intertek

This is to certify that the quality management system of

SMITHS MEDICAL INTERNATIONAL LIMITED

Boundary Road, Hythe, Kent, CT21 6JL, UK

has been assessed and registered by AMTAC Certification Services Limited as conforming to the requirements of:

EN ISO 13485:2012

The quality management system is applicable to:

Design of:

Breathing Systems, Drainage Devices, Feeding Devices,
Filtration Devices, Infusion Disposables, Intubation Systems, Obstetrics and Gynaecology
Devices, Oxygen and Humidity Management Devices, Pressure Monitoring Devices,
Respiratory Mechanics Devices, Resuscitation Devices,
Suction Catheters, Tracheostomy Tubes, Vascular Access Devices, Cardio Thoracic
Catheters and Drapes

Additional Site:

Human Resources and Training, Shipping, Demand Planning, Post Market Surveillance,
Market Intelligence, E-Business, International Customer Services, Business Development,
Registrations, Finance, Wallace Women's Healthcare

Certificate Number:	053-01 B
Initial Certification Date:	20 October 2005
Certificate Effective Date:	23 July 2016
Certificate Expiry Date:	22 July 2019



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Brian Johnson

AMTAC Certification Services Limited, Milton Keynes, UK

This certificate is the property of AMTAC Certification Services Ltd

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