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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By Royal Charter

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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Date:	**2018-05-09**
Issued To:	**Smiths Medical ASD Inc.** **6000 Nathan Lane North** **Minneapolis** **Minnesota** **55442** **USA**

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

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Date:	**2018-05-09**
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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EC Certificate - Full Quality Assurance System

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

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Date:	**2018-05-09**
Issued To:	**Smiths Medical ASD Inc.** **6000 Nathan Lane North** **Minneapolis** **Minnesota** **55442** **USA**

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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By Royal Charter

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
Minneapolis
Minnesota
55442
USA

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

intertek
Total Quality. Assured.

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

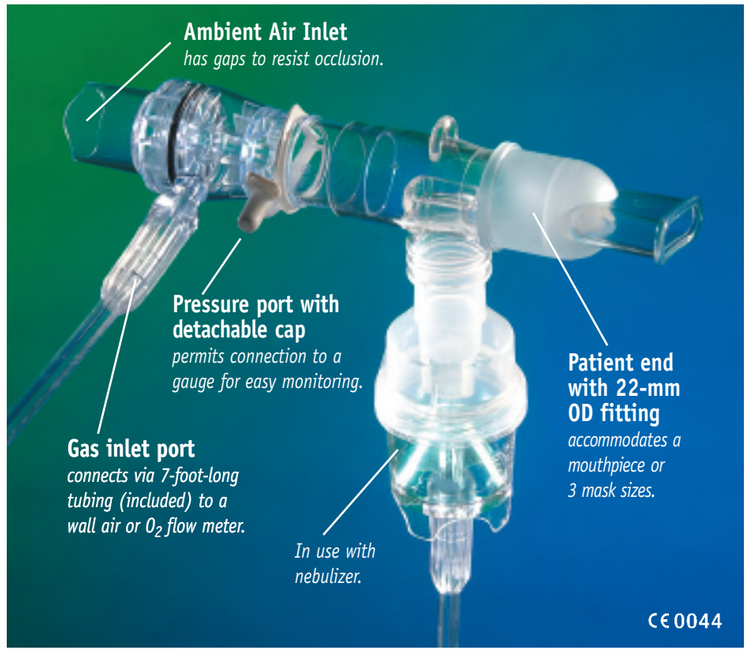
Calin Moldovean
President, Business Assurance

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

"This certificate is the property of AMTAC Certification Services Ltd a wholly owned subsidiary of Intertek Holdings Ltd"

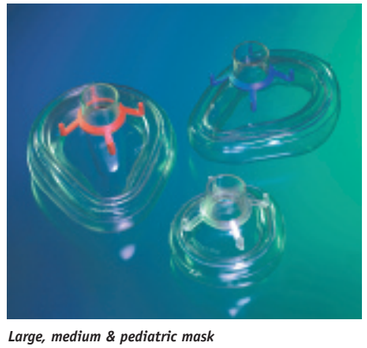
Intertek Certification Limited is a UKAS accredited body under schedule of Accreditation No. 061

Lung Expansion Products.



EzPAP shown with mask

EzPAP with disposable manometer



Large, medium & pediatric mask

EzPAP®

PAP Therapy System

When incentive spirometry alone won't open patients' airways, expand your options with EzPAP. Simply connect to a flow meter (wall air or O_2 for enhanced FiO_2), adjust to 5-15 lpm, and instruct the patient to breathe diaphragmatically through the mouthpiece or mask. Features a pressure port for connection to a gauge (recommended for initial use with each patient), and standard 22-mm OD fitting to accommodate a mouthpiece or mask.

EzPAP with Mouthpiece 23-0747
UPN: 60788942207474 *(10 units per case)*

EzPAP with Pediatric Mask 23-1747
UPN: 00788942217471 *(1 unit per case)*

EzPAP with Medium Mask 23-2747
UPN: 00788942227470 *(1 unit per case)*

EzPAP with Large Mask 23-3747
UPN: 00788942237479 *(1 unit per case)*

EzPAP with disposable manometer . . .23-0757
UPN: 60788942207573 *(1 unit per case)*

EzPAP® Kit

Comes with everything a clinician needs to begin using EzPAP. Kit contains one pressure gauge (with gauge protector), three EzPAP units (with mouthpiece), three gauge guards and ten 22mm ID adaptors in a durable plastic box.

EzPAP Kit 23-6000
UPN: 00788942260002 *(1 kit per case)*

CEU 1 hour unit

DHD Coach® 2

Incentive Spirometers

Coach 2 makes incentive spirometry easier for patients and staff alike. One-way valve ensures patients inhale, rather than exhale into the unit. Highly-visible pistons, universal graphics (indicating correct inspiratory flowrate), and instructions in the base, help patients perform and monitor their own post-surgical breathing exercises without direct supervision. Other features include an O_2 connection for supplemental oxygen, convenient handle, flexible popple tubing and bedrail holder.

All Coach 2 products are shipped 12 units per case.

DHD Coach 2 4000. 22-4000
UPN: 60788942240006
4,000 ml capacity and one-way valve.

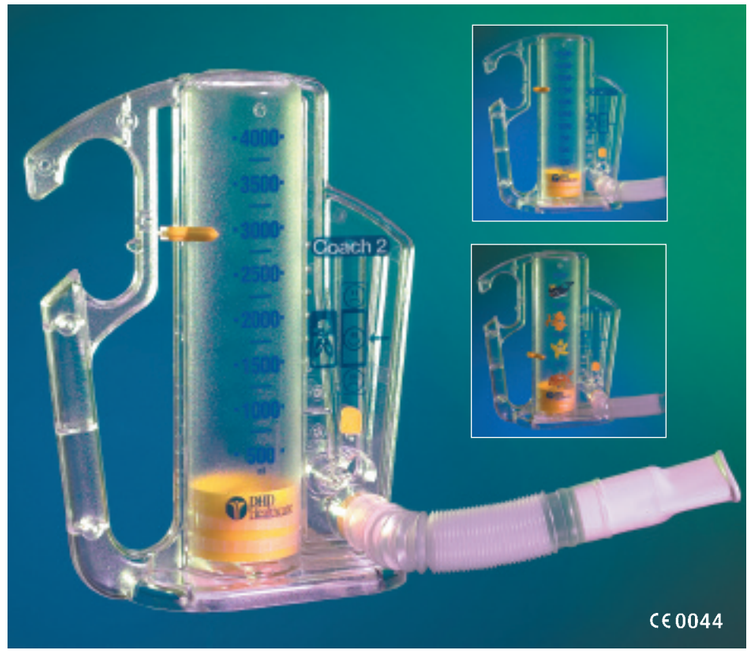
DHD Coach 2 4001 22-4001
UPN: 60788942240013
4,000 ml capacity, no one-way valve.

DHD Coach 2 2500. 22-2500
UPN: 60788942225003
2,500 ml capacity and one-way valve.

DHD Coach 2 2501. 22-2501
UPN: 60788942225010
2,500 ml capacity, no one-way valve.

DHD Coach 2 for Kids. 22-2000
UPN: 60788942220008

Volumetric incentive spirometer with 2,000 ml capacity and one-way valve for the pediatric patient. Features colorful, eye-catching graphics and booklet.



DHD CliniFLO®

Low-Flow Breathing Exerciser

DHD CliniFLO is ideal for SMI therapy in geriatric, pediatric or weakened patients. With flow settings as low as 100 ml/sec, virtually any patient can sustain the minimum inspiratory effort required for effective therapy. Slow inspirations enhance collateral ventilation, and minimize patient discomfort when performing post-surgical breathing exercises. To adjust the flow rate on DHD CliniFLO, simply rotate the dial on the back of the unit until the arrow points to the desired flow rate. The dial is located on the back of DHD CliniFLO so a patient is not tempted to change it to a higher flow rate. O_2 port makes it easy to provide oxygen during therapy. DHD CliniFLO unit comes with preassembled popple tubing, mouthpiece, and instructions.

All DHD CliniFLO products are shipped 12 units per case.

DHD CliniFLO. 22-1200
UPN: 60788942212003