ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 17 04 97063 001

Manufacturer:

Smiths Medical ASD, INC.
6000 Nathan Lane North
Minneapolis MN 55442
USA

EC-Representative:

Smiths Medical International Ltd.
1500 Eureka Park
Lower Pemberton
Ashford
Kent TN25 4BF
UNITED KINGDOM

Product Category(ies):

Vibratory positive expiratory devices, Incentive Spirometers, Silicone Laryngeal Mask, Oxygen Line accessory, Nasal Cannula, Oxygen Masks, Drainage bags, Oxygen tubing, Adult Face Tent, Disposable Anesthesia Face Masks

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 72126765

Valid from: 2017-04-24
Valid until: 2021-09-21

Date, 2017-04-24

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV®

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Facility(ies):

Smiths Medical ASD, INC.
6000 Nathan Lane North, Minneapolis MN 55442, USA

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

TÜV®

Traducere din limba engleză

Certificat CE
Sistem de Asigurare a Calității
Directiva 93/42/CEE cu privire la Dispozitivele Medicale (MDD), Anexa II fără (4)
(Dispozitive din Clasa IIa, IIb sau III)

Nr. G1 17 04 97063 001

Producător:	**Smiths Medical ASD, INC.** 6000 Nathan Lane North Minneapolis MN 55442 SUA
Reprezentant CE:	**Smiths Medical International Ltd.** 1500 Eureka Park Lower Pemberton, Ashford Kent TN25 4BF REGATUL UNIT
Categorie(i) Produs	**Dispozitive monitorizare gaz medical, Spirometru de Stimulare, Mască Laringiană din Silicon, Accesoriu Linie Oxigen, Canulă Nazală, Măști de Oxigen, Pungi Drenaj, Tubulatură Oxigen, Mască Adulți, Măști Faciale Anestezie de Unică Folosință**

Organul de Certificare al TÜV SÜD Product Service GmbH declară că producătorul mai sus menţionat a implementat un sistem de asigurare a calităţii pentru proiectarea, producerea şi inspecţia finală a produselor respective / categorii de produs, în conformitate cu Anexa II MDD. Numitul sistem de asigurare a calităţii se conformează prevederilor Directivei şi se supune unei supravegheri periodice. Pentru comercializarea produselor clasa III un Certificat Anexa II (4) este obligatoriu. Vedeţi notele de pe pagina următoare.

Raport Nr.: **72126765**
Valabil de la: **24-04-2017**
Valabil până la: **21-09-2021**

Data, **24-04-2017**

Stefan Preiß
Semnătura – indescifrabil

TÜV SÜD Product Service GmbH este Organism de Notificare cu nr. de identificare 0123.

MINISTERUL JUSTIȚIEI
MUȘUROIA MIRELA
Aut. Nr. 2769
Engleză/Franceză
TRADUCĂTOR AUTORIZAT

Certificat CE
Sistem de Asigurare a Calității
Directiva 93/42/CEE cu privire la Dispozitivele Medicale (MDD), Anexa II fără (4)
(Dispozitive din Clasa IIa, IIb sau III)

Nr. G1 17 04 97063 001

Unități Producție: Smiths Medical ASD, INC.
6000 Nathan Lane North, Minneapolis MN 55442, SUA

****

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

MINISTERUL JUSTIȚIEI
MUȘUROIA
MIRELA
Aut. Nr. 2769
Engleză/Franceză
TRADUCĂTOR AUTORIZAT

Certificate of Registration

This is to certify that the quality management system of

SMITHS MEDICAL CZECH REPUBLIC a.s.

Olomoucká 306, 753 01 Hranice, Czech Republic

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:

The design, assembly, manufacture, packaging and supply of:

Obstetrics and Gynaecology Devices and Accessories,
Interventional Imaging Devices and Accessories,
Oxygen & Humidity Management Devices,
Pain Management Devices and Accessories,
Invasive Patient Pressure Monitoring Devices and Accessories,
Tracheostomy Devices,
Disposable Infusion Devices,
Suction Catheters Devices,
Intubation Systems Devices.

Certificate Number:	**1201-04 B**
Initial Certification Date:	**10 January 2014**
Certificate Effective Date:	**22 May 2017**
Certificate Expiry Date:	**28 February 2019**

UKAS MANAGEMENT SYSTEMS
061

Brian Johnson
AMTAC Certification Services Limited, Milton Keynes, UK
This certificate is the property of AMTAC Certification Services Ltd

Certificate of Registration

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

Certificat de Înregistrare

Intertek

Prin prezenta se certifică faptul că sistemul de management al calității al

SMITHS MEDICAL INTERNATIONAL LIMITED

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

a fost evaluat și înregistrat de AMTAC Certification Services Limited ca fiind conform cerințelor:

EN ISO 13485:2012

Sistemul de management al calității este aplicabil pentru:

Proiectarea:
Sistemelor de Respirat, Dispozitivelor de Drenaj, Dispozitivelor de Alimentare, Dispozitivelor de Filtrare, Infuzoare de Unică Folosință, Sisteme de Intubare, Dispozitive de Obstetrică și Ginecologie, Dispozitive de Management al Oxigenului și Umidității, Dispozitive de Monitorizare a Presiunii, Dispozitive Mecanice de Respirație, Dispozitive de Resuscitare, Catetere Sucțiune, Tuburi Traheotomie, Dispozitive Acces Vascular, Catetere Cardio Toracice și Comprese Chirurgicale

Poziții Suplimentare:
Resurse Umane și Pregătire Profesională, Transport, Cerere Planificare, Supraveghere Post Piață, Cunoașterea Pieței, E-Business, Servicii Client Internațional, Dezvolatre Afacere, Înregistrări, Finanțe, Wallace Women's Healthcare

Certificat Număr: Inițial Data **053-01 B**
Certificării: Dată Efectivă **20 Octombrie 2005**
Certificat: **23 Iulie 2016**
Data Expirării Certificatului: **22 Iulie 2019**

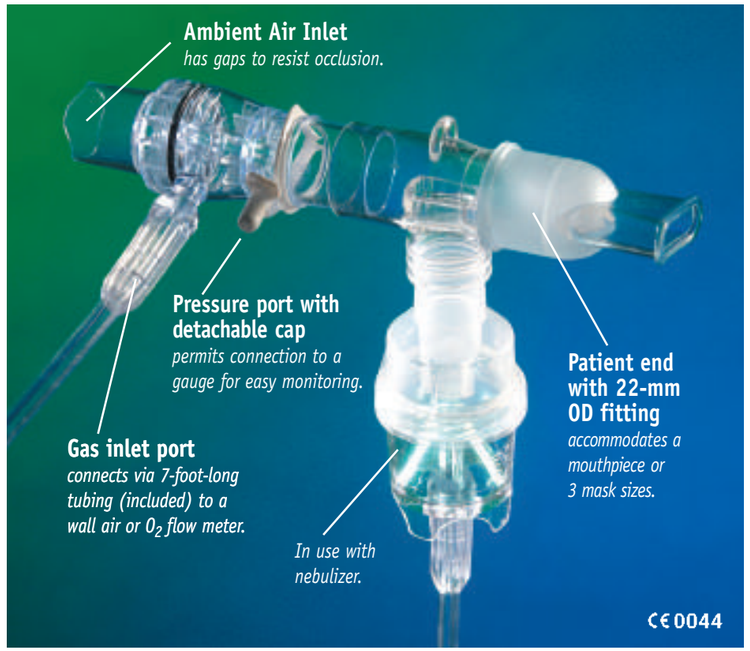
UKAS MANAGEMENT SYSTEMS
061

Brian Johnson

AMTAC Certification Services Limited, Milton Keynes, UK
Acest certificat este proprietatea AMTAC Certification Services Ltd

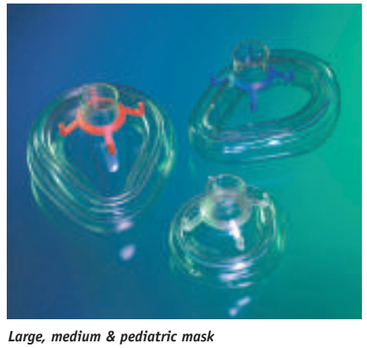
MINISTERUL JUSTIȚIEI
MUȘUROIA MIRELA
Atestat nr. 2769
TRADUCĂTOR AUTORIZAT

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.

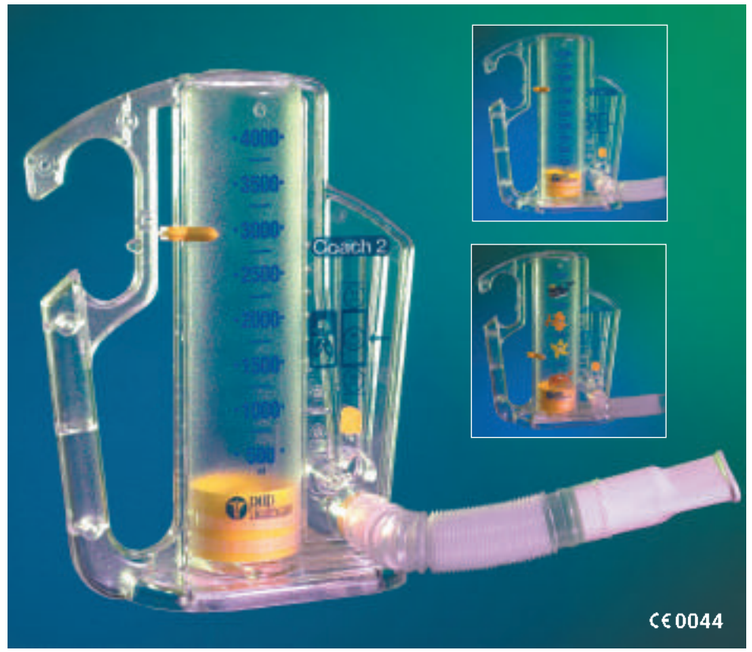
DHD Coach 2 4001 22-4001
UPN: 60788942240013
4,000 ml capacity, no one-way valve.

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

Certificate of Registration

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Additional Site:
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