

EC Certificate - Full Quality Assurance System

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

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

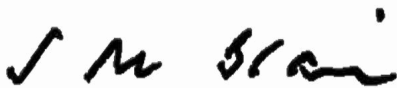
Smiths Medical International Ltd.
Boundary Road
Hythe
Kent
CT21 6JL
United Kingdom

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

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 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

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 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

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
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

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
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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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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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 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

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

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**

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

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

Lista subcontractantilor majori

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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

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

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**

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

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**

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

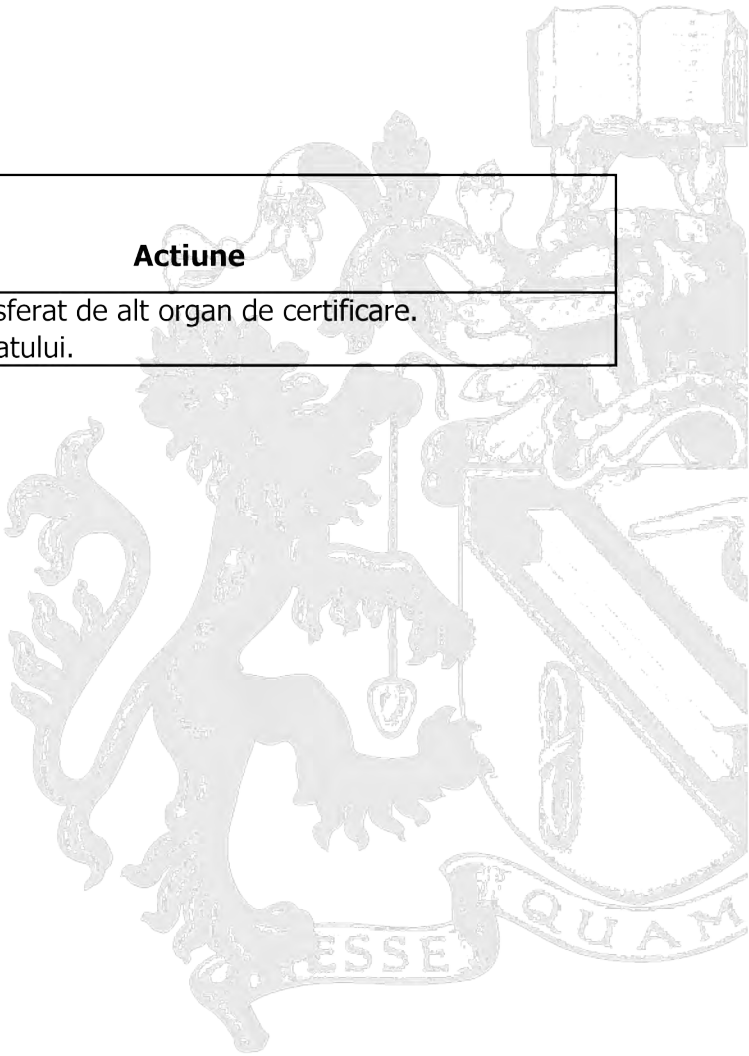
Furnizor crucial

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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.



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.



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 Design-Examination Certificate

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

No.

CE 661326

Issued To:

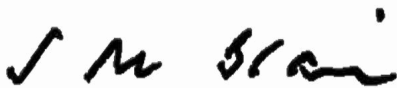
**Smiths Medical International Ltd.
Boundary Road
Hythe
Kent
CT21 6JL
United Kingdom**

In respect of:

Cardiothoracic Catheters.

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4. The design conforms to the requirements of this directive. For marketing of these products an additional Annex II excluding 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 3

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

EC Design-Examination Certificate

Supplementary Information to CE 661326

Issued To:

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

Product Description	Product Code
Thoracic Catheter, Straight, Soft, Radio-Opaque – 10F	200/810/100
Thoracic Catheter, Straight, Soft, Radio-Opaque – 12F	200/810/120
Thoracic Catheter, Straight, Soft, Radio-Opaque – 16F	200/810/160
Thoracic Catheter, Straight, Soft, Radio-Opaque – 20F	200/810/200
Thoracic Catheter, Straight, Soft, Radio-Opaque – 24F	200/810/240
Thoracic Catheter, Straight, Soft, Radio-Opaque – 28F	200/810/280
Thoracic Catheter, Straight, Soft, Radio-Opaque – 32F	200/810/320
Thoracic Catheter, Straight, Soft, Radio-Opaque – 36F	200/810/360
Thoracic Catheter, Angled, Soft, Radio-Opaque – 10F	200/812/100
Thoracic Catheter, Angled, Soft, Radio-Opaque – 12F	200/812/120
Thoracic Catheter, Angled, Soft, Radio-Opaque – 16F	200/812/160
Thoracic Catheter, Angled, Soft, Radio-Opaque – 20F	200/812/200
Thoracic Catheter, Angled, Soft, Radio-Opaque – 24F	200/812/240
Thoracic Catheter, Angled, Soft, Radio-Opaque – 28F	200/812/280
Thoracic Catheter, Angled, Soft, Radio-Opaque – 32F	200/812/320
Thoracic Catheter, Angled, Soft, Radio-Opaque – 36F	200/812/360
Thoracic Catheter, Straight, Radio-Opaque – 16F	200/815/160
Thoracic Catheter, Straight, Radio-Opaque – 20F	200/815/200
Thoracic Catheter, Straight, Radio-Opaque – 24F	200/815/240
Thoracic Catheter, Straight, Radio-Opaque – 28F	200/815/280
Thoracic Catheter, Straight, Radio-Opaque – 32F	200/815/320
Thoracic Catheter, Straight, Radio-Opaque – 36F	200/815/360
Thoracic Catheter, Angled, Radio-Opaque – 32F	200/81/320
Thoracic Catheter, Straight, Soft, Radio-Opaque – 28F	209/810/280/700
Thoracic Catheter, Straight, Soft, Radio-Opaque – 32F	209/810/320/700

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

Date: **2017-06-28**

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

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Page 2 of 3

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

EC Design-Examination Certificate

Supplementary Information to CE 661326

Issued To:

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

Certificate History

Date	Reference Number	Action
Current	10166350	First issue. Transferred from another Notified Body

First Issued: **2017-06-28**Date: **2017-06-28**Expiry Date: **2022-06-27**

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Page 3 of 3

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

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A member of BSI Group of Companies.

Certificat CE de examinare a proiectului

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

Nr. CE 661326
Titular: **Smiths Medical International Ltd.**
Boundary Road
Hythe
Kent
CT21 6JL
Marea Britanie

Obiectul certificatului:

Catetere cardiotoracice.

BSI a examinat dispozitivele de mai sus conform cerintelor Directivei Consiliului 93/42/CEE, Anexa II, Secțiunea 4. Proiectul indeplinește cerințele Directivei. Pentru lansarea pe piață a acestor produse, este necesar certificatul menționat în Anexa II, excluzând Secțiunea 4.

Pentru și în numele BSI, organ de certificare în accepțiunea sus-menționatei Directive (Organ de certificare cu numărul 0086):



Stewart Brain, Șef compartiment conformitate și risc
Dispozitive medicale

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

Data: **2017-06-28**

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Data expirării: **2022-06-27**

Pagina 1 din 3

Valabilitatea prezentului certificat este condiționată de menținerea sistemului de calitate la cerințele Directivei dovedită de organul de certificare care supraveghează compania. Prezentă aprobare exclude toate produsele proiectate și/sau fabricate de o terță parte on în numele companiei care deține prezentul certificat, cu excepția unui acord contrar, încheiat cu BSI. Prezentul certificat a fost redactat electronic și este condiționat de respectarea caietului de sarcini.

Informații și contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000 BSI Assurance UK Limited, înregistrată în Anglia sub numărul 7805321 în 389 Chiswick High Road, Londra W4 4AL, UK. A membra a grupului BSI.



Certificat CE de examinare a proiectului

Informatii suplimentare pentru CE 661326

Titular:

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

Descriere produs	Cod produs
Cateter toracic, drept, moale, radio-opac– 10F	200/810/100
Cateter toracic, drept, moale, radio-opac– 12F	200/810/120
Cateter toracic, drept, moale, radio-opac– 16F	200/810/160
Cateter toracic, drept, moale, radio-opac– 20F	200/810/200
Cateter toracic, drept, moale, radio-opac– 24F	200/810/240
Cateter toracic, drept, moale, radio-opac– 28F	200/810/280
Cateter toracic, drept, moale, radio-opac– 32F	200/810/320
Cateter toracic, drept, moale, radio-opac– 36F	200/810/360
Cateter toracic, in unghi, moale, radio-opac– 10F	200/812/100
Cateter toracic, in unghi, moale, radio-opac– 12F	200/812/120
Cateter toracic, in unghi, moale, radio-opac– 16F	200/812/160
Cateter toracic, in unghi, moale, radio-opac– 20F	200/812/200
Cateter toracic, in unghi, moale, radio-opac– 24F	200/812/240
Cateter toracic, in unghi, moale, radio-opac– 28F	200/812/280
Cateter toracic, in unghi, moale, radio-opac– 32F	200/812/320
Cateter toracic, in unghi, moale, radio-opac– 36F	200/812/360
Cateter toracic, drept, radio-opac– 16F	200/815/160
Cateter toracic, drept, radio-opac– 20F	200/815/200
Cateter toracic, drept, radio-opac– 24F	200/815/240
Cateter toracic, drept, radio-opac– 28F	200/815/280
Cateter toracic, drept, radio-opac– 32F	200/815/320
Cateter toracic, drept, radio-opac– 36F	200/815/360
Cateter toracic, in unghi, radio-opac– 32F	200/81/320
Cateter toracic, drept, moale, radio-opac– 28F	209/810/280/700
Cateter toracic, drept, moale, radio-opac– 32F	209/810/320/700

Prima editie: **2017-06-28**Data: **2017-06-28**Data expirarii: **2022-06-27**
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Pagina 2 din 3

Valabilitatea prezentului certificat este conditionata de mentinerea sistemului de 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 CE de examinare a proiectului

Informatii suplimentare pentru CE 661326

Titular:

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

Istoricul Certificatului

Data	Numar de referinta	Actiune
Curenta	10166350	Prima editie. Transferat de un alt organ de certificare.

Prima editie: 2017-06-28

Data: 2017-06-28

Data expirarii: 2022-06-27

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.

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 - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

No.**CE 661328****Issued To:**

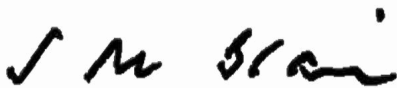
**Smiths Medical International Ltd.
Boundary Road
Hythe
Kent
CT21 6JL
United Kingdom**

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 V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III 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 661328

Certificate Scope:

The manufacture and final inspection of sterile:

Drainage Devices, Obstetrics and Gynaecology Devices, Oxygen and Humidity Management Devices, Intubation Systems, Infusion Disposables, Feeding Devices Accessories

The manufacture and final inspection of non-sterile:

Resuscitation Devices, Tracheostomy Tubes, Intubation Systems

Those aspects of annex V relating to the securing and maintaining of sterility of Vascular Access Device Accessories, Infusion Disposables, Intubation Systems, Obstetrics and Gynaecology 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 - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

List of Significant Subcontractors

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

Certificate No: **CE 661328**
 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 - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

List of Significant Subcontractors

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

Certificate No: **CE 661328**
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 - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

List of Significant Subcontractors

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

Certificate No: **CE 661328**
 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 - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

List of Significant Subcontractors

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

Certificate No: **CE 661328**
 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 - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

List of Significant Subcontractors

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

Certificate No: **CE 661328**
 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 - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

List of Significant Subcontractors

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

Certificate No: **CE 661328**
 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 - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

List of Significant Subcontractors

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

Certificate No: **CE 661328**
 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 - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

List of Significant Subcontractors

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

Certificate No: **CE 661328**
 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 - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

List of Significant Subcontractors

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

Certificate No: **CE 661328**
Date: **2017-06-28**
Issued To: **Smiths Medical International Ltd.**
Boundary Road
Hythe
Kent
CT21 6JL
United Kingdom

Subcontractor:**Service(s) supplied**

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 - Production Quality Assurance

Certificate History

Certificate No: **CE 661328**
Date: **2017-06-28**
Issued To: **Smiths Medical International Ltd.**
Boundary Road
Hythe
Kent
CT21 6JL
United Kingdom

Date	Reference Number	Action
Current	8693885 8603164	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.



By Royal Charter

Traducere din limba engleză

Certificat CE – Asigurarea Calității Producției

Directiva 93/42/CEE cu privire la Dispozitivele Medicale, Anexa V

Nr. **CE 661328**
Emis pentru: **Smith Medical International Ltd.**
Boundary Road
Hythe
Kent
CT21 6JL
Regatul Unit

Cu privire la:

Vedeți domeniul de certificare pe cealaltă pagină.

În baza examinării efectuate de noi cu privire la sistemul de asigurare a calității conform cerințelor Directivei Consiliului 93/42/CEE, Anexa V. Sistemul de asigurare a calității îndeplinește cerințele directivei. Pentru plasarea pe piață a produselor clasa IIb și clasa III este necesar un certificat Anexa III.

Pentru și în numele BSI, Organism de Notificare pentru Directiva de mai sus (Număr Organism de Notificare 0086):

Semnătura – indescifrabilă

Stewart Brain, Director Conformitate și Risc
Dispozitive Medicale

Prima emitere: **28-06-2017**

Data: **28-06-2017**

Data expirării: **27-06-2022**

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Pagina 1 din 2

Valabilitatea acestui certificat este condiționată de menținerea sistemului de calitate în conformitate cu cerințele Directivei așa după cum s-a demonstrat prin activitățile solicitate Organismului de Notificare. Această aprobare exclude toate produsele proiectate și/sau fabricate de o terță parte în numele societății numită pe acest certificat, dacă nu s-a agreat în mod expres de către BSI.

Acest certificat a fost emis electronic și este în legătură cu condițiile contractuale.

Informații și Contact: BSI, Kitemark Court, Davy Avenue, Knowhill, Milton Keynes MK5 8PP, Tel.: +44 815 080 9000 BSI Assurance UK Limited, înregistrată în Anglia sub numărul 7805321 la 389 Chiswick High Road, Londra W4 4AL, UK
Membră a Grupului de Societăți BSI.





Certificat Nr.: CE 661328

Domeniu Certificat:

Fabricarea și inspecția finală a următoarelor produse sterile:

Dispozitive Drenaj, Dispozitive pentru Obstetrică și Ginecologie, Dispozitive Management Oxigen și Umiditate, Sisteme de Intubare, Dispozitive de Perfuzie de Unică Folosință, Accesorii Dispozitive pentru Alimentare.

Fabricarea și inspecția finală a următoarelor produse non-sterile:

Dispozitive de Resuscitare, Tuburi Traheostomie, Sisteme de Intubare.

Acele aspecte din Anexa V cu privire la securitatea și menținerea sterilității Accesoriiilor pentru Dispozitivele de Acces Vascular, Dispozitive de Perfuzie de Unică Folosință, Sisteme de Intubare, Dispozitive pentru Obstetrică și Ginecologie.

Prima emitere: **28-06-2017**

Data: **28-06-2017**

Data expirării: **27-06-2022**

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Pagina 2 din 2

Valabilitatea acestui certificat este condiționată de menținerea sistemului de calitate în conformitate cu cerințele Directivei așa după cum s-a demonstrat prin activitățile solicitate Organismului de Notificare. Această aprobare exclude toate produsele proiectate și/sau fabricate de o terță parte în numele societății numită pe acest certificat, dacă nu s-a agreat în mod expres de către BSI.

Acest certificat a fost emis electronic și este în legătură cu condițiile contractuale.

Informații și Contact: BSI, Kitemark Court, Davy Avenue, Knowhill, Milton Keynes MK5 8PP, Tel.: +44 815 080 9000 BSI Assurance UK Limited, înregistrată în Anglia sub numărul 7805321 la 389 Chiswick High Road, Londra W4 4AL, UK
Membră a Grupului de Societăți BSI.





Certificat CE – Asigurarea Calității Producției
Directiva 93/42/CEE cu privire la Dispozitivele Medicale, Anexa V

Lista Principalilor Subantreprenori

Recunoscuți ca fiind implicați în serviciile legate de produsul acoperit de:

Certificat Nr.: **CE 661328**
Data: **28-06-2017**
Emis pentru: **Smith Medical International Ltd.**
Boundary Road
Hythe
Kent
CT21 6JL
Regatul Unit

Subantreprenor	Servicii furnizate
Brightwake Limited Lowmoor Business Park Kirby-in-Ashfield Nottinghamshire NG17 7JZ Regatul Unit	Fabricare
GaleMed Corporation Nr. 87, Li-Gong 2nd Road Wu-Jia YILAN 268 Taiwan	Fabricare
GE Medical Pollards Wood Nightingales Lane Chalfont Saint Giles HP8 4SP Regatul Unit	Fabricare

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Pagina 1 din 9

Informații și Contact: BSI, Kitemark Court, Davy Avenue, Knowhill, Milton Keynes MK5 8PP, Tel.: +44 815 080 9000 BSI Assurance UK Limited, înregistrată în Anglia sub numărul 7805321 la 389 Chiswick High Road, Londra W4 4AL, UK
Membră a Grupului de Societăți BSI.





Certificat CE – Asigurarea Calității Producției
Directiva 93/42/CEE cu privire la Dispozitivele Medicale, Anexa V

Lista Principalilor Subantreprenori

Recunoscuți ca fiind implicați în serviciile legate de produsul acoperit de:

Certificat Nr.: **CE 661328**
Data: **28-06-2017**
Emis pentru: **Smith Medical International Ltd.**
Boundary Road
Hythe
Kent
CT21 6JL
Regatul Unit

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

Pentair Filtration Solutions 1350 Hammond Road, St. Paul Minnesota 55110 SUA	Furnizor Principal
---	--------------------

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

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Pagina 2 din 9

Informații și Contact: BSI, Kitemark Court, Davy Avenue, Knowhill, Milton Keynes MK5 8PP, Tel.: +44 815 080 9000 BSI Assurance UK Limited, înregistrată în Anglia sub numărul 7805321 la 389 Chiswick High Road, Londra W4 4AL, UK
Membră a Grupului de Societăți BSI.





Certificat CE – Asigurarea Calității Producției
Directiva 93/42/CEE cu privire la Dispozitivele Medicale, Anexa V

Lista Principalilor Subantreprenori

Recunoscuți ca fiind implicați în serviciile legate de produsul acoperit de:

Certificat Nr.: **CE 661328**
Data: **28-06-2017**
Emis pentru: **Smith Medical International Ltd.**
Boundary Road
Hythe
Kent
CT21 6JL
Regatul Unit

Subantreprenor	Servicii furnizate
Smiths Healthcare Manufacturing SA de CV Avenida Calidad Nr. 4 Parque, Industrial Internacional Tijuana 22425 Mexic	Fabricare
Smiths Healthcare Manufacturing SA de CV Carretera Miguel Aleman km 21.7 Parque Industrial Monterrey Apodaca Nuevo Leon 66603 Mexic	Fabricare

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Pagina 3 din 9

Informații și Contact: BSI, Kitemark Court, Davy Avenue, Knowhill, Milton Keynes MK5 8PP, Tel.: +44 815 080 9000 BSI Assurance UK Limited, înregistrată în Anglia sub numărul 7805321 la 389 Chiswick High Road, Londra W4 4AL, UK
Membră a Grupului de Societăți BSI.





Certificat CE – Asigurarea Calității Producției
Directiva 93/42/CEE cu privire la Dispozitivele Medicale, Anexa V

Lista Principalilor Subantreprenori

Recunoscuți ca fiind implicați în serviciile legate de produsul acoperit de:

Certificat Nr.: **CE 661328**
Data: **28-06-2017**
Emis pentru: **Smith Medical International Ltd.**
Boundary Road
Hythe
Kent
CT21 6JL
Regatul Unit

Subantreprenor

Servicii furnizate

Smiths Medical ASD Inc. 10 Bowman Dr. Fabricare
Keene, New Hampshire, 03431
SUA

Smiths Medical ASD Inc., 1265 Grey Fox Road, St. Paul, Minnesota 55112
Fabricare
SUA

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

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Pagina 4 din 9

Informații și Contact: BSI, Kitemark Court, Davy Avenue, Knowhill, Milton Keynes MK5 8PP, Tel.: +44 815 080 9000 BSI Assurance UK Limited, înregistrată în Anglia sub numărul 7805321 la 389 Chiswick High Road, Londra W4 4AL, UK
Membră a Grupului de Societăți BSI.





Certificat CE – Asigurarea Calității Producției
Directiva 93/42/CEE cu privire la Dispozitivele Medicale, Anexa V

Lista Principalilor Subantreprenori

Recunoscuți ca fiind implicați în serviciile legate de produsul acoperit de:

Certificat Nr.: **CE 661328**
Data: **28-06-2017**
Emis pentru: **Smith Medical International Ltd.**
Boundary Road
Hythe
Kent
CT21 6JL
Regatul Unit

Subantreprenor	Servicii furnizate
Smiths Medical ASD Inc., 6250 Shier Rings Road, Dublin, Ohio 43016 SUA	Fabricare
Smiths Medical ASD Inc., 9124 Polk Lane, Suite 101 Olive Branch, Mississippi 38654 SUA	Distribuție
Smiths Medical Czech Republic a.s. Olomoucka 306, 753 01 Hranice Republica Cehă	Fabricare

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Informații și Contact: BSI, Kitemark Court, Davy Avenue, Knowhill, Milton Keynes MK5 8PP, Tel.: +44 815 080 9000 BSI Assurance UK Limited, înregistrată în Anglia sub numărul 7805321 la 389 Chiswick High Road, Londra W4 4AL, UK
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Emis pentru: **Smith Medical International Ltd.**
Boundary Road
Hythe
Kent
CT21 6JL
Regatul Unit

Subantreprenor	Servicii furnizate
Smiths Medical Gary, 5700 W 23rd Ave Gary, Indiana 46406 SUA	Fabricare
Smiths Medical International Ltd., 52 Grayhill Rd., Cumbernauld, Glasgow G68 9HQ Regatul Unit	Fabricare
Smiths Medical International Nijmegen Bijsterhuizen 22-08, 6604 LD Wijchen Olanda	Distribuție

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Emis pentru: **Smith Medical International Ltd.**
Boundary Road
Hythe
Kent
CT21 6JL
Regatul Unit

Subantreprenor	Servicii furnizate
Smiths Medical Italia Srl, Via della Stazione, Ambalare 2 Latina Scalo, 04100 Italia	

Sterigenics Belgium (Petit-Rechain) SA Zoning Industriel de Petit-Rechain, Avenue Andre Ernst 21, B-4800 Verviers Belgia	Sterilizare ETO
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Sterigenics UK Limited, Cotes Park Estate, Somercotes Alfreton, DE55 4NJ Regatul Unit	Sterilizare ETO
--	-----------------

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Pagina 7 din 9

Informații și Contact: BSI, Kitemark Court, Davy Avenue, Knowhill, Milton Keynes MK5 8PP, Tel.: +44 815 080 9000 BSI Assurance UK Limited, înregistrată în Anglia sub numărul 7805321 la 389 Chiswick High Road, Londra W4 4AL, UK
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Certificat CE – Asigurarea Calității Producției
Directiva 93/42/CEE cu privire la Dispozitivele Medicale, Anexa V

Lista Principalilor Subantreprenori

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Certificat Nr.: **CE 661328**
Data: **28-06-2017**
Emis pentru: **Smith Medical International Ltd.**
Boundary Road
Hythe
Kent
CT21 6JL
Regatul Unit

Subantreprenor	Servicii furnizate
Sterigenics US, LLC 344 Bonnie Circle, Corona, California 92880 SUA	Sterilizare Gamma

Sterigenics LLC, 1700 College Blvd., West Memphis, Arkansas 72301 SUA	Sterilizare Gamma
--	-------------------

Sterilization Services of Tennessee, Inc., 2396 Florida Street, Memphis, Tennessee 38109 SUA	Sterilizare ETO
---	-----------------

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Pagina 8 din 9

Informații și Contact: BSI, Kitemark Court, Davy Avenue, Knowhill, Milton Keynes MK5 8PP, Tel.: +44 815 080 9000 BSI
Assurance UK Limited, înregistrată în Anglia sub numărul 7805321 la 389 Chiswick High Road, Londra W4 4AL, UK
Membră a Grupului de Societăți BSI.





Certificat CE – Asigurarea Calității Producției
Directiva 93/42/CEE cu privire la Dispozitivele Medicale, Anexa V

Lista Principalilor Subantreprenori

Recunoscuți ca fiind implicați în serviciile legate de produsul acoperit de:

Certificat Nr.: **CE 661328**
Data: **28-06-2017**
Emis pentru: **Smith Medical International Ltd.**
Boundary Road
Hythe
Kent
CT21 6JL
Regatul Unit

Subantreprenor

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

Servicii furnizate

Velcro USA Inc., 95 Sundial Avenue, Furnizor principal
Manchester,
New Hampshire 03103-7206
SUA

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Pagina 9 din 9

Informații și Contact: BSI, Kitemark Court, Davy Avenue, Knowhill, Milton Keynes MK5 8PP, Tel.: +44 815 080 9000 BSI Assurance UK Limited, înregistrată în Anglia sub numărul 7805321 la 389 Chiswick High Road, Londra W4 4AL, UK
Membră a Grupului de Societăți BSI.





Certificat CE – Asigurarea Calității Producției

Istoric Certificat

Certificat Nr.: **CE 661328**
Data: **28-06-2017**
Emis pentru: **Smith Medical International Ltd.**
Boundary Road
Hythe
Kent
CT21 6JL
Regatul Unit

Data	Număr Referință	Acțiune
Curentă	8693885 8603164	Prima emitere. Transferat de la un alt Organism de Notificare. Reînnoire certificat.

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Pagina 1 din 1

Valabilitatea acestui certificat este condiționată de menținerea sistemului de calitate în conformitate cu cerințele Directivei așa după cum s-a demonstrat prin activitățile solicitate Organismului de Notificare. Această aprobare exclude toate produsele proiectate și/sau fabricate de o terță parte în numele societății numită pe acest certificat, dacă nu s-a agreat în mod expres de către BSI.

Acest certificat a fost emis electronic și este în legătură cu condițiile contractuale.

Informații și Contact: BSI, Kitemark Court, Davy Avenue, Knowhill, Milton Keynes MK5 8PP, Tel.: +44 815 080 9000 BSI Assurance UK Limited, înregistrată în Anglia sub numărul 7805321 la 389 Chiswick High Road, Londra W4 4AL, UK Membră a Grupului de Societăți BSI.

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

Traducător autorizat
Nr. 2769/2015



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



061



Brian Johnson

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. AMTAC Certification Services Limited is owned by AMTAC Certification Services Holdings Limited, which is a wholly owned subsidiary of Intertek UK Holdings Limited. AMTAC Certification Services Limited is an accredited body registered under UKAS with the identification number of 061. In the issuance of this certificate, AMTAC assumes no liability to any party other than to the Client and then only in accordance with the agreed Terms and Conditions.



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

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:

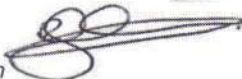
Sistemelor de Respirat, Dispozitivelor de Drenaj, Dispozitivelor de Alimentare, Dispozitivelor de Filtrare, Infuzoare de Unică Folosință, Sisteme de Intubare, Dispozitive de Obstetrică și Ginecologie, Dispozitive de Management al Oxigenului și Umidității, Dispozitive de Monitorizare a Presiunii, Dispozitive 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

Brian Johnson



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

În emiterea acestui certificat, Intertek nu-și asumă nicio răspundere față de altă Parte în afară de Client, și aceasta, numai în conformitate cu Acordul de Certificare agreat. Validitatea acestui certificat depinde de păstrarea de către organizație a sistemului în conformitate cu cerințele Intertek pentru sistemele de certificare. Validitatea poate fi confirmată prin email la certificate.validation@intertek.com sau prin scanarea codului din dreapta cu un. AMTAC Certification Services Limited este deținută de AMTAC Certification Services Holdings Limited, care este o sucursală deținută integral de Intertek UK Holdings Limited. AMTAC Certification Services Limited este un organism acreditat înregistrat la UKAS cu numărul de identificare 061. În emiterea acestui certificat, AMTAC nu-și asumă nicio responsabilitate față de nicio parte, alta decât Clientul, și aceasta numai în conformitate cu Termenii și Condițiile agreate. Certificatul rămâne proprietatea Intertek, căreia îi trebuie returnat la cerere.

CT-ISO 9001:2008-UKAS-EN-LT-P-04.jan.12

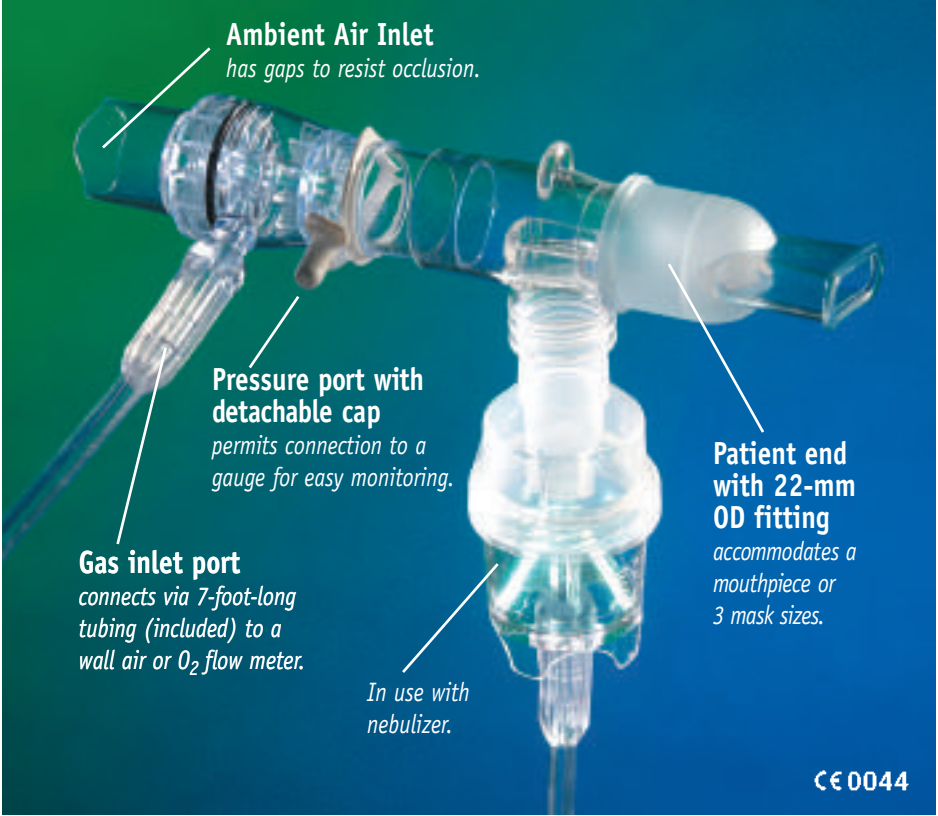


061



Intertek Intertek Intertek Intertek Intertek

Lung Expansion Products.



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 O₂ for enhanced FiO₂), 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)



EzPAP shown with mask



EzPAP with disposable manometer



Large, medium & pediatric mask

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 O₂ 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. O₂ 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



CE 0044



CE 0044