EC Certification

PRODUCTION QUALITY ASSURANCE
Directive 93/42/EEC for Medical Devices, Annex V

We hereby declare that an examination of the under mentioned production quality assurance system - restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions - has been carried out following the requirements of the UK national legislation to which the undersigned is subjected, transposing Annex V of the Directive 93/42/EEC on medical devices. We certify that the production quality system conforms with the relevant provisions of the aforementioned legislation, and the result entitles the organization to use the CE 0473 marking on those products listed below.

SMITHS MEDICAL CZECH REPUBLIC a.s.

Olomoucká 306, 753 01 Hranice, Czech Republic

Obstetrics and Gynaecology Devices: Embryo Replacement Catheters and accessories
Directive 93/42/EEC for Medical Devices Class Is

Pain management devices: Correct Inject Cap
Directive 93/42/EEC for Medical Devices Class Is

Interventional Imaging Accessories
Directive 93/42/EEC for Medical Devices Class Is

Certificate Number: **1201-01 CE**
Initial Certification Date: **21 February 2014**
Certificate Effective Date: **03 March 2015**
Certificate Expiry Date: **20 February 2019**

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

The certification is subject to the organization maintaining their system in compliance with the regulations stated in this certificate, allowing regular assessments and following the contracted requirements of the Notified Body.
AMTAC Certification Services Limited is a Notified Body according to Directive 93/42/EEC for medical devices, with identification number 0473.

Certificare CE

Intertek

ASIGURAREA CALITĂŢII PRODUCŢIEI
Directiva 93/42/EEC privind dispozitivele medicale, Anexa V

Declarăm prin prezenta că o examinare a sistemului de asigurarea calităţii producţiei menţionate mai jos – limitată la aspectele de producţie aferente asigurării şi menţinerii condiţiilor sterile – a fost realizată conform cerinţelor legislaţiei naţionale britanice care ni se aplică, transpunând Anexa V din Directiva 93/42/EEC privind dispozitivele medicale. Confirmăm că sistemul de calitate a producţiei este conform prevederilor relevante din legislaţia sus-menţionată şi că rezultatele îndreptăţesc compania să folosească marcajul CE 0473 pe produsele menţionate mai jos.

SMITHS MEDICAL CZECH REPUBLICa.s.
Olomoucka 306, 753 01 Hranice, Republica Cehă

Dispozitive pentru obstetrică şi ginecologie: Catetere şi accesorii pentru înlocuirea embrionului
Directiva 93/42/EEC privind dispozitivele medicale, Clasa Is
Dispozitive pentru controlul durerii: Cap pentru injecţie corectă
Directiva 93/42/EEC privind dispozitivele medicale, Clasa Is
Accesorii pentru imagistică intervenţională
Directiva 93/42/EEC privind dispozitivele medicale, Clasa Is

Numărul certificatului: 1201-01 CE

Data primei certificări: 02.2014
Data efectivă a certificatului: 03.03.2015
Data expirării certificatului: 20.02.2019

Prin emiterea acestui certificat, Intertek nu îşi asumă responsabilitate decât faţă de client şi numai în conformitate cu contractul convenit pentru certificare. Valabilitatea acestui certificat depinde de menţinerea de către firmă a sistemului în conformitate cu cerinţele Intertek pentru certificarea sistemelor. Valabilitatea poate fi confirmată prin email la certificate.validation@intertek.com sau prin scanarea codului din partea dreaptă cu un telefon mobil. Acest certificat este destinat utilizării exclusive de către clientul AMTAC şi este emis conform contractului încheiat între AMTAC şi clientul său. Răspunderea şi responsabilitatea AMTAC sunt limitate la termenii şi condiţiile contractuale. AMTAC nu îşi asumă răspunderi decât către client, conform contractului, pentru pierderi, cheltuieli sau daune ocazionate de utilizarea acestui certificat. Numai clientul este autorizat să permită copierea sau distribuirea acestui certificat. Orice utilizare a numelui AMTAC sau a oricărei dintre mărcile sale pentru vânzare sau publicitatea materialelor, produselor sau serviciilor testate trebuie aprobată în prealabil de către AMTAC.
Certificatul rămâne proprietatea Intertek, căreia trebuie să îi fie returnat la cerere.

MATECIUC ALIN BOGDAN
TRADUCĂTOR AUTORIZAT
Nr. 2826

EC Certification

FULL QUALITY ASSURANCE SYSTEM
Directive 93/42/EEC for Medical Devices, Annex II excluding (4)

We hereby declare that an examination of the under mentioned full quality assurance system has been carried out following the requirements of the UK national legislation to which the undersigned is subjected, transposing Annex II (with the exemption of section 4) of the Directive 93/42/EEC on medical devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive, and the result entitles the organization to use the CE 0473 marking on those products listed below.

SMITHS MEDICAL CZECH REPUBLIC a.s.

Olomoucká 306, 753 01 Hranice, Czech Republic

Obstetrics and Gynaecology Devices
Ring Pessary Directive 93/42/EEC for Medical Devices Class IIb

Cardio Thoracic
Interventional Imaging Devices Directive 93/42/EEC for Medical Devices Class IIa

Oxygen & Humidity Management Devices
Thermovent T Directive 93/42/EEC for Medical Devices Class IIa

Pain Management Devices
Epidural Kits, catheters and accessory Devices Directive 93/42/EEC for Medical Devices Class IIa & IIb

Patient Pressure Monitoring, Invasive Pressure Monitoring Systems Directive 93/42/EEC for Medical Devices Class IIa & IIb

Portex Tracheostomy PDT Kits
Directive 93/42/EEC for Medical Devices Class IIa

Non-active devices for anaesthesia, emergency and intensive care
Blue Line Ultra Tracheostomy Kits uncuffed Directive 93/42/EEC for Medical Devices Class IIb
Tracheostomy tube inner cannula, Directive 93/42/EEC for medical devices Class IIb

Certificate Number: **1201-03 A CE**
Initial Certification Date: **27 May 2014**
Certificate Effective Date: **21 January 2015**
Certificate Expiry Date: **26 May 2019**

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

The certification is subject to the organization maintaining their system in compliance with the regulations stated in this certificate, allowing regular assessments and following the contracted requirements of the Notified Body.
AMTAC Certification Services Limited is a Notified Body according to Directive 93/42/EEC for medical devices, with identification number 0473.

Certificare CE

Intertek

SISTEM INTEGRAL DE ASIGURARE A CALITĂŢII
Directiva 93/42/CEE privind Dispozitivele Medicale, Anexa II, excluzând (4)

Declarăm prin prezenta faptul că o examinare a sistemului integral de asigurare a calităţii menţionat în acest document a fost efectuată cu respectarea cerinţelor legislaţiei naţionale din Regatul Unit, care guvernează funcţionarea societăţii în cauză, şi cu aplicarea Anexei II (cu excepţia secţiunii 4) la Directiva 93/42/CEE privind dispozitivele medicale. Certificăm faptul că sistemul integral de asigurare a calităţii este în conformitate cu prevederile relevante ale directivei mai sus menţionate, iar rezultatul conferă societăţii în cauză dreptul de a utiliza marcajul CE 0473 pe produsele enumerate mai jos.

SMITHS MEDICAL CZECH REPUBLIC a.s.

Olomoucká 306, 753 01 Hranice, Republica Cehă

Dispozitive pentru obstetrică şi ginecologie
Directiva 93/42/CEE privind Dispozitivele Medicale, Clasa IIb – pesare inelare

Utilizări cardiotoracice
Directiva 93/42/CEE privind Dispozitivele Medicale, Clasa IIa – Dispozitive de imagistică intervenţională

Dispozitive pentru gestiunea oxigenului şi a umidităţii
Directiva 93/42/CEE privind Dispozitivele Medicale, Clasa IIa - Thermovent T

Dispozitive pentru gestiunea durerilor
Directiva 93/42/CEE privind Dispozitivele Medicale, Clasa IIa şi IIb - kituri epidurale, catetere şi dispozitive accesorii

Sisteme de monitorizare a tensiunii pacientului, de monitorizare invazivă a tensiunii
Directiva 93/42/CEE privind Dispozitivele Medicale, Clasa IIa şi IIb

Kituri Portex PDT (drenaj postdural terapeutic) pentru traheostomie
Directiva 93/42/CEE privind Dispozitivele Medicale, Clasa IIa

Dispozitive non-active pentru anestezie, terapie de urgenţă şi intensivă
Directiva 93/42/CEE privind Dispozitivele Medicale, Clasa IIb – Kituri Blue Line Ultra fără manşon pentru traheostomie
Directiva 93/42/CEE privind Dispozitivele Medicale, Clasa IIb – canule interioare pentru tubul de traheostomie

Certificat Nr.: **1201-03 A CE**
Data certificării iniţiale: **27 mai 2014**
Data efectivă a certificatului: **21 ianuarie 2015**
Data de expirare a certificatului: **26 mai 2019**

Semnătură: [indescifrabil]
Brian Johnson
AMTAC Certification Services Limited, Milton Keynes, UK
Prezentul certificat este proprietatea AMTAC Certification Services Ltd

[Cod de scanat – Intertek]

Prin emiterea acestui certificat, Intertek nu îşi asumă răspunderea faţă de altă părţi, ci doar faţă de Client, şi în acel caz doar în conformitate cu Acordul de Certificare convenit. Validitatea prezentului certificat depinde de menţinerea de către societate a acestui sistem cu respectarea cerinţelor referitoare la certificarea sistemelor. Validitatea poate fi confirmată prin email la adresa certificate.validation@intertek.com sau prin scanarea codului din partea dreaptă folosind un telefon inteligent.
Prezentul Certificat este destinat utilizării sale exclusive de către clientul AMTAC şi se emite în baza acordului încheiat între AMTAC şi Clientul acesteia. Responsabilitatea şi răspunderea AMTAC sunt limitate la termenii şi condiţiile acordului. AMTAC nu îşi asumă răspunderea faţă de altă părţi, ci doar faţă de Client, în conformitate cu acordul, pentru orice pierdere, cheltuială sau daună ocazionată de utilizarea acestui Certificat. Clientul este unica entitate autorizată să permită copierea sau distribuţia acestui Certificat. Orice utilizare a denumirii AMTAC sau a uneia dintre mărcile sale pentru comercializarea sau publicitatea materialelor, produselor sau serviciilor testate trebuie să primească mai întâi aprobarea scrisă a companiei AMTAC.

Acest certificat rămâne proprietatea societăţii Intertek şi se va returna acesteia la cerere.

Certificarea face obiectul menţinerii de către societate a sistemului propriu în conformitate cu regulamentele prevăzute în acest certificat, permiţând evaluări regulate şi respectând cerinţele contractate ale organismului de certificare notificat.
AMTAC Certification Services Limited este un organism de certificare notificat în baza Directive 93/42/CEE privind dispozitivele medicale, având numărul de identificare 0473.

Certificare CE

Intertek

SISTEM INTEGRAL DE ASIGURARE A CALITĂŢII
Directiva 93/42/CEE privind Dispozitivele Medicale, Anexa II, excluzând (4)

Declarăm prin prezenta faptul că o examinare a sistemului integral de asigurare a calităţii menţionat în acest document a fost efectuată cu respectarea cerinţelor legislaţiei naţionale din Regatul Unit, care guvernează funcţionarea societăţii în cauză, şi cu aplicarea Anexei II (cu excepţia secţiunii 4) la Directiva 93/42/CEE privind dispozitivele medicale. Certificăm faptul că sistemul integral de asigurare a calităţii este în conformitate cu prevederile relevante ale directivei mai sus menţionate, iar rezultatul conferă societăţii în cauză dreptul de a utiliza marcajul CE 0473 pe produsele enumerate mai jos.

SMITHS MEDICAL CZECH REPUBLIC a.s.

Olomoucká 306, 753 01 Hranice, Republica Cehă

Dispozitive pentru obstetrică şi ginecologie
Directiva 93/42/CEE privind Dispozitivele Medicale, Clasa IIb – pesare inelare

Utilizări cardiotoracice
Directiva 93/42/CEE privind Dispozitivele Medicale, Clasa IIa – Dispozitive de imagistică intervenţională

Dispozitive pentru gestiunea oxigenului şi a umidităţii
Directiva 93/42/CEE privind Dispozitivele Medicale, Clasa IIa - Thermovent T

Dispozitive pentru gestiunea durerilor
Directiva 93/42/CEE privind Dispozitivele Medicale, Clasa IIa şi IIb - kituri epidurale, catetere şi dispozitive accesorii

Sisteme de monitorizare a tensiunii pacientului, de monitorizare invazivă a tensiunii
Directiva 93/42/CEE privind Dispozitivele Medicale, Clasa IIa şi IIb

Kituri Portex PDT (drenaj postdural terapeutic) pentru traheostomie
Directiva 93/42/CEE privind Dispozitivele Medicale, Clasa IIa

Dispozitive non-active pentru anestezie, terapie de urgenţă şi intensivă
Directiva 93/42/CEE privind Dispozitivele Medicale, Clasa IIb – Kituri Blue Line Ultra fără manşon pentru traheostomie
Directiva 93/42/CEE privind Dispozitivele Medicale, Clasa IIb – canule interioare pentru tubul de traheostomie

Certificat Nr.:	**1201-03 A CE**
Data certificării iniţiale:	**27 mai 2014**
Data efectivă a certificatului:	**21 ianuarie 2015**
Data de expirare a certificatului:	**26 mai 2019**

Semnătură: [indescifrabil]
Brian Johnson
AMTAC Certification Services Limited, Milton Keynes, UK
Prezentul certificat este proprietatea AMTAC Certification Services Ltd

[Cod de scanat – Intertek]

Prin emiterea acestui certificat, Intertek nu îşi asumă răspunderea faţă de altă părţi, ci doar faţă de Client, şi în acel caz doar în conformitate cu Acordul de Certificare convenit. Validitatea prezentului certificat depinde de menţinerea de către societate a acestui sistem cu respectarea cerinţelor referitoare la certificarea sistemelor. Validitatea poate fi confirmată prin email la adresa certificate.validation@intertek.com sau prin scanarea codului din partea dreaptă folosind un telefon inteligent.
Prezentul Certificat este destinat utilizării sale exclusive de către clientul AMTAC şi se emite în baza acordului încheiat între AMTAC şi Clientul acesteia. Responsabilitatea şi răspunderea AMTAC sunt limitate la termenii şi condiţiile acordului. AMTAC nu îşi asumă răspunderea faţă de altă părţi, ci doar faţă de Client, în conformitate cu acordul, pentru orice pierdere, cheltuială sau daună ocazionată de utilizarea acestui Certificat. Clientul este unica entitate autorizată să permită copierea sau distribuţia acestui Certificat. Orice utilizare a denumirii AMTAC sau a uneia dintre mărcile sale pentru comercializarea sau publicitatea materialelor, produselor sau serviciilor testate trebuie să primească mai întâi aprobarea scrisă a companiei AMTAC.

Acest certificat rămâne proprietatea societăţii Intertek şi se va returna acesteia la cerere.

Certificarea face obiectul menţinerii de către societate a sistemului propriu în conformitate cu regulamentele prevăzute în acest certificat, permiţând evaluări regulate şi respectând cerinţele contractate ale organismului de certificare notificat.
AMTAC Certification Services Limited este un organism de certificare notificat în baza Directive 93/42/CEE privind dispozitivele medicale, având numărul de identificare 0473.

Subsemnatul SCARLATEANU GEORGE-RADU, traducator autorizat de Ministerul Justitiei cu numarul 26160/2009 certific exactitatea traducerii cu textul inscrisului in limba engleza care mi-a fost prezentat.

MINISTERUL JUSTITIEI
SCĂRLĂTEANU GEORGE RADU
NR. AUT. 26160/2009
TRADUCĂTOR SI INTERPRET
AUTORIZAT
LIMBA ENGLEZĂ

EC Certification

FULL QUALITY ASSURANCE SYSTEM
Directive 93/42/EEC for Medical Devices, Annex II excluding (4)

We hereby declare that an examination of the under mentioned full quality assurance system has been carried out following the requirements of the UK national legislation to which the undersigned is subjected, transposing Annex II (with the exemption of section 4) of the Directive 93/42/EEC on medical devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive, and the result entitles the organization to use the CE 0473 marking on those products listed below.

SMITHS MEDICAL CZECH REPUBLIC a.s.

Olomoucká 306, 753 01 Hranice, Czech Republic

Obstetrics and Gynaecology
Interventional Imaging Devices
Oxygen & Humidity Management Devices
Pain Management Devices
Invasive Patient Pressure Monitoring devices and Accessories
Tracheostomy Devices
Disposable Infusion Devices

As per the attached Product Schedule

Certificate Number: **1201-09 A CE**
Initial Certification Date: **27 May 2014**
Certificate Effective Date: **21 January 2016**
Certificate Expiry Date: **26 May 2019**

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

The certification is subject to the organization maintaining their system in compliance with the regulations stated in this certificate, allowing regular assessments and following the contracted requirements of the Notified Body.
AMTAC Certification Services Limited is a Notified Body according to Directive 93/42/EEC for medical devices, with identification number 0473.

PRODUCT SCHEDULE FOR CERTIFICATE 1201-09 A CE
SMITHS MEDICAL CZECH REPUBLIC a.s.

Obstetrics and Gynaecology: Ring Pessary devices
Directive 93/42/EEC for Medical Devices (Class IIb)

Interventional imaging Devices: Cardiothoracic HP lines & interventional imaging Devices and Accessories
Directive 93/42/EEC for Medical Devices (Class IIa)

Oxygen & Humidity Management Devices: Thermovent T
Directive 93/42/EEC for Medical Devices (Class IIa)

Pain Management Devices: Epidural Kits, Catheters and accessories
Directive 93/42/EEC for Medical Devices (Class IIb & IIa)

Invasive Patient Pressure Monitoring devices and Accessories
Directive 93/42/EEC for Medical Devices (Class IIb & IIa)

Tracheostomy Devices:
Directive 93/42/EEC for Medical Devices (Class IIb & IIa)

- Tracheostomy Tubes (Class IIb)
  - Blu Trachy Soft-Seal Cuff (6.0mm to 10.0mm)
  - Blu Trachy Soft-Seal Fenestrated (6.0mm to 10.0mm)
  - B/L Ultra Soft-Seal Cuff (6.0mm to 10.0mm) with smooth inner cannula
  - Blue Line Ultra Uncuffed (6.0mm to 10.0mm) with 15mm connector
  - B/L Ultra Soft-Seal Cuff (6.0mm to 10.0mm) with Fenestrated inner cannula
  - Blue Line Ultra Uncuffed (6.0mm to 10.0mm) with Fenestrated inner cannula
  - Blu Trachy Plain, Fenestrated, with Inner Cannula; Speak Valve (7.0mm)
  - B/L Ultra Suctionaid (6.0mm to 10.0mm)
  - B/L Ultra Suctionaid Soft-Seal Cuff (6mm, 7.5mm) with inner cannula
  - B/L Ultra Suctionaid (7mm to 10.0mm) with inner cannula
  - UniPerc Adjustable Flange Soft-Seal Cuff (7.0mm to 10.0mm)
  - UniPerc Adjustable Flange Uncuffed (7.0mm to 9.0mm)
- Portex PDT kits (Class IIa),
  - Percutaneous Dilation Kits without Forceps
  - Percutaneous Dilation Kits with Forceps
  - Percutaneous Kit Guidewire 100/544/000CZ
- UniPerc PDT kits (Class IIb)

Product Description	*Product Code(s)*
UniPerc Percutaneous Dilation Tracheostomy Kit with UniPerc Adjustable Flange Tracheostomy Tube, Soft-Seal Cuff - 7.0mm	*100/597/070CZ*
UniPerc Percutaneous Dilation Tracheostomy Kit with UniPerc Adjustable Flange Tracheostomy Tube, Soft-Seal Cuff - 8.0mm	*100/597/080CZ*
UniPerc Percutaneous Dilation Tracheostomy Kit with UniPerc Adjustable Flange Tracheostomy Tube, Soft-Seal Cuff - 9.0mm	*100/597/090CZ*

- UniPerc PDT kit Replacement Guidewire (Class IIa) 100/549/000CZ
- Blue Line Ultra kits / Uncuffed (Class IIb),
- Cricothyrotomy Kits (Class IIa)

Initial Certification Date: 27 May 2014
Certificate Effective Date: 21 January 2016

Brian Johnson ~ Authorized Signatory

PRODUCT SCHEDULE FOR CERTIFICATE 1201-09 A CE
SMITHS MEDICAL CZECH REPUBLIC a.s.

- Inner Cannula - Directive 93/42/EEC for medical devices Class IIb
  Blue Line Ultra Inner cannula (plain) 6.0 mm to 10.0 mm
  Blue Line Ultra Inner cannula (fenestrated) 6.0 mm to 10.0 mm
  UniPerc Replacement Inner cannula (straight) 7.0 mm to 9.0 mm

Disposable Infusion Devices
Directive 93/42/EEC for Medical Devices (Class IIa)

- Backcheck Valves,
- Caps / Connectors / Adaptors,
- Extension Sets w/Filters,
- Filters,
- Gravity Admin Sets,
- Injection Sites,
- Multi-Line Extension Sets,
- Single-Line Extension Sets,
- Stopcocks

The above products have been approved under the following AMTAC Certification projects:

G101864887 G101890178 G101785643 G101785610 G101847889 G101722797 G101802716 G101802729 CN866 CN865 CN869 CN920 CN1119 G102177198

Initial Certification Date: 27 May 2014
Certificate Effective Date: 21 January 2016

Brian Johnson ~ Authorized Signatory

Certificare CE

Intertek

SISTEMUL DE ASIGURAREA TOTALĂ A CALITĂŢII
Directiva 93/42/EEC privind dispozitivele medicale, Anexa II cu excluderea (4)

Declarăm prin prezenta că o examinare a sistemului sub-menţionat de asigurarea calităţii totale a fost realizată conform cerinţelor legislaţiei naţionale britanice care ni se aplică, transpunând Anexa II (cu excepţia secţiunii 4) din Directiva 93/42/EEC privind dispozitivele medicale. Confirmăm că sistemul de asigurarea calităţii totale este conform prevederilor relevante din directiva sus-menţionată şi că rezultatele îndreptăţesc compania să folosească marcajul CE 0473 pe produsele menţionate mai jos.

SMITHS MEDICAL CZECH REPUBLICa.s.
Olomoucka 306, 753 01 Hranice, Republica Cehă

Dispozitive de imagistică intervenţională pentru obstetrică şi ginecologie
Dispozitive de gestionare a oxigenului şi umidităţii
Dispozitive pentru controlul durerii
Dispozitive şi accesorii pentru monitorizarea invazivă a tensiunii pacientului
Dispozitive pentru traheostomie
Dispozitive pentru infuzie, de unică folosinţă
Conform Listei de produse ataşată

Numărul certificatului:	1201-09 A CE
Data primei certificări:	27.05.2014
Data efectivă a certificatului:	21.01.2016
Data expirării certificatului:	26.05.2019

Prin emiterea acestui certificat, Intertek nu îşi asumă responsabilitate decât faţă de client şi numai în conformitate cu contractul convenit pentru certificare. Valabilitatea acestui certificat depinde de menţinerea de către firmă a sistemului în conformitate cu cerinţele Intertek pentru certificarea sistemelor. Valabilitatea poate fi confirmată prin email la certificate.validation@intertek.com sau prin scanarea codului din partea dreaptă cu un telefon mobil. Acest certificat este destinat utilizării exclusive de către clientul AMTAC şi este emis conform contractului încheiat între AMTAC şi clientul său. Răspunderea şi responsabilitatea AMTAC sunt limitate la termenii şi condiţiile contractuale. AMTAC nu îşi asumă răspunderi decât către client, conform contractului, pentru pierderi, cheltuieli sau daune ocazionate de utilizarea acestui certificat. Numai clientul este autorizat să permită copierea sau distribuirea acestui certificat. Orice utilizare a numelui AMTAC sau a oricărei dintre mărcile sale pentru vânzare sau publicitatea materialelor, produselor sau serviciilor testate trebuie aprobată în prealabil de către AMTAC.
Certificatul rămâne proprietatea Intertek, căreia trebuie să îi fie returnat la cerere.

MATECIUC ALIN BOGDAN
TRADUCĂTOR AUTORIZAT
Nr. 2826

LISTA DE PRODUSE PENTRU CERTIFICATUL 1201-09 A CE
SMITHS MEDICAL CZECH REPUBLICa.s.

Obstetrică şi ginecologie: Dispozitive pentru pesare inelare
Directiva 93/42/EEC privind dispozitivele medicale (Clasa IIb)

Dispozitive pentru imagistică intervenţională: Dispozitive şi accesorii pentru linii HP cardiotoracice şi imagistică intervenţională
Directiva 93/42/EEC privind dispozitivele medicale (Clasa IIa)

Dispozitive de gestionare a oxigenului şi umidităţii: Termovent T
Directiva 93/42/EEC privind dispozitivele medicale (Clasa IIa)

Dispozitive pentru controlul durerii: Kituri epidurale, catetere şi accesorii
Directiva 93/42/EEC privind dispozitivele medicale (Clasa IIb şi IIa)

Dispozitive şi accesorii pentru monitorizarea invazivă a tensiunii pacientului
Directiva 93/42/EEC privind dispozitivele medicale (Clasa IIb şi IIa)

Dispozitive pentru traheostomie:
Directiva 93/42/EEC privind dispozitivele medicale (Clasa IIb şi IIa)

- Tuburi pentru traheostomie (clasa IIb)
  Tub traheostoma Soft-Seal albastru (6-10 mm)
  Tub traheostoma Soft-Seal albastru cu apertură (6-10 mm)
  Tub B/L Ultra Soft-Seal (6-10 mm) cu canulă internă netedă
  Tub drept Blue Line Ultra (6-10 mm) cu conector de 15 mm
  Tub B/L Ultra Soft-Seal (6-10 mm) cu canulă internă cu apertură
  Tub drept Blue Line Ultra (6-10 mm) cu canulă internă cu apertură
  Tub drept traheostoma Blu cu canulă internă; valvă pentru vorbire (7 mm)
  Dispozitiv pentru aspiraţie B/L Ultra (6-10 mm)
  Tub B/L Ultra Soft-Seal pentru aspiraţie (6, 7,5 mm) cu canulă internă
  Dispozitiv pentru aspiraţie B/L Ultra (7-10 mm) cu canulă internă
  Tub Uniperc Soft-Seal reglabil (7-10 mm)
  Tub drept cu siste reglabil UniPerc (7-9 mm)
- Kituri Portex PDT (Clasa IIa),
  Kituri de dilataţie percutanată fără forceps
  Kituri de dilataţie percutanată cu forceps
  Ghid pentru kit traheostomie percutanată 100/544/000CZ
- Kituri UniPerc PDT (Clasa IIb)

MATECIUC ALIN BOGDAN
TRADUCĂTOR AUTORIZAT
Nr. 2826

Descrierea produsului	**Codul(urile) produsului**
Kit traheostomie pentru dilataţie percutanată UniPerc cu tub traheostoma reglabil UniPerc, tub Soft-Seal 7 mm	100/597/070CZ
Kit traheostomie pentru dilataţie percutanată UniPerc cu tub traheostoma reglabil UniPerc, tub Soft-Seal 8,0mm	100/597/080CZ
Kit traheostomie pentru dilataţie percutanată UniPerc cu tub traheostoma reglabil UniPerc, tub Soft-Seal 9,0mm	100/597/090CZ

- Kit UniPerc PDT, ghid pentru înlocuire (Clasa IIa) 100/549/000CZ
- Kituri Blue Line Ultra / drepte (Clasa IIb),
- Kituri pentru cricotirotomie (Clasa IIa)

Data primei certificări: 27.05.2014
Data efectivă a certificatului: 21.01.2016

MATECIUC ALIN BOGDAN
TRADUCĂTOR AUTORIZAT
Nr. 2826

LISTA DE PRODUSE PENTRU CERTIFICATUL 1201-09 A CE SMITHS MEDICAL CZECH REPUBLICa.s.

Intertek

- Canulă interioară – Directiva 93/42/EEC pentru dispozitive medicale, Clasa IIb
  Canulă interioară Blue Line Ultra (dreaptă) 6-10 mm
  Canulă interioară Blue Line Ultra (cu apertură) 6-10 mm
  Canulă interioară de înlocuire UniPerc (dreaptă) 7-9 mm

Dispozitive pentru infuzie, de unică folosinţă
Directiva 93/42/EEC privind dispozitivele medicale (Clasa IIa)

- Valve antireflux,
- Capete / Conectori / Adaptoare,
- Seturi de prelungire cu filtre,
- Filtre,
- Seturi de administrare prin gravitaţie
- Seturi pentru injecţii,
- Seturi pentru prelungire multi-line,
- Seturi pentru prelungire uni-line,
- Valve

Produsele de mai sus au fost avizate conform proiectelor de certificare AMTAC:

G101864887 G101890178 G101785643 G101785610 G101847889 G101722797 G101802716 G101802729 CN866 CN865 CN869 CN920 CN1119 G102177198

Data primei certificări: 27.05.14
Data efectivă a certificatului: 21.01.16

MATECIUC ALIN BOGDAN
TRADUCĂTOR AUTORIZAT
Nr. 2826

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

Certificat de Înregistrare

Intertek

Se certifică prin prezenta că sistemul de management al calității al

SMITHS MEDICAL CZECH REPUBLIC a.s.

Olomoucká 306, 753 01 Hranice, Republica Cehă

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, asamblarea, fabricarea, ambalarea și furnizarea de:

Dispozitive și Accesorii pentru Obstetrică și Ginecologie,
Dispozitive și Accesorii Intervenție Imagistică,
Dispozitive de Management al Oxigenului și Umidității,
Dispozitive și Accesorii de Management al Durerii,
Dispozitive și Accesorii Invazive de Monitorizare a Tensiunii Pacientului,
Dispozitive Traheotomie,
Dispozitive de Unică Folosință pentru Injecții,
Dispozitive Catetere Aspirare,
Sisteme de Dispozitive de Intubare.

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**

UKAS MANAGEMENT SYSTEMS
0671

Brian Johnson
AMTAC Certification Services Limited, Milton Keynes, UK
Acest Certificat este proprietatea AMTAC Certification Services Ltd

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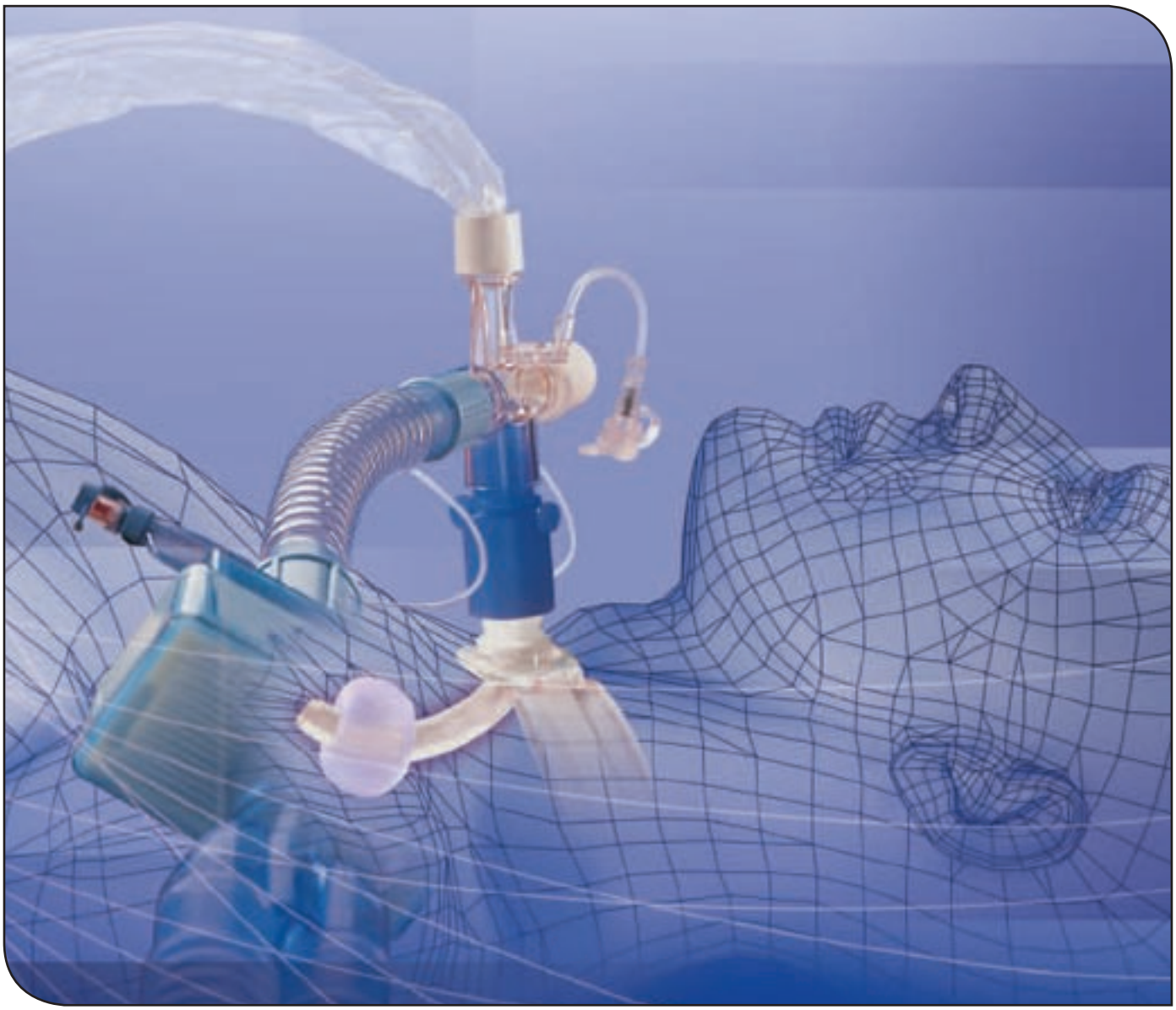
Subsemnata **MUSUROIA MIRELA,** traducator autorizat de Ministerul Justitiei, certific exactitatea acestei traducerii cu textul înscrisului original în limba engleza, ce a fost vizat de mine.

Traducător autorizat
Nr. 2769/2015

MINISTERUL JUSTIȚIEI
MUȘUROIA MIRELA
Aut. Nr. 2769
TRADUCĂTOR AUTORIZAT

smiths medical
bringing technology to life

Tracheostomy Supplement
Helping you sustain life



AIRWAY MANAGEMENT

PORTEX™

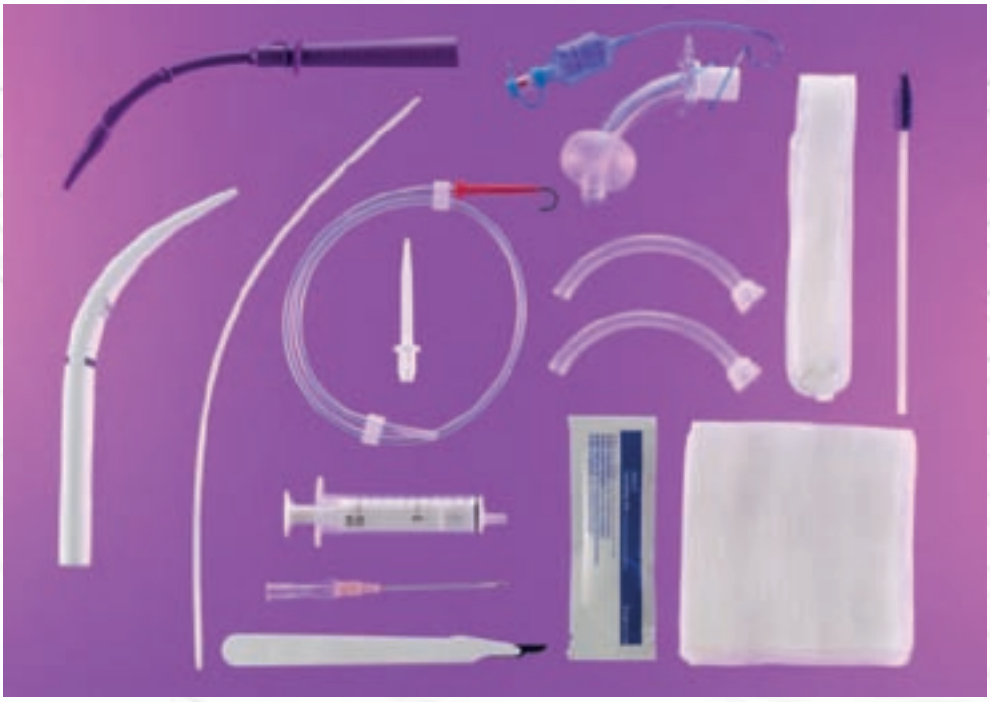
New ULTRAperc kits for percutaneous dilational tracheostomy

ULTRAperc provides the clinician with a range of totally integrated procedural kits for percutaneous dilational tracheostomy for use in Intensive Care or theatre.

Only ULTRAperc kits include every component required from initial incision to final tube insertion using a purpose designed introducer. Also, because ULTRAperc kits are available with Blue Line Ultra, by using ULTRAperc you will gain all the added benefits of this innovative and popular range of tracheostomy tubes.

ULTRAperc is produced with the meticulous attention to detail and quality you expect from Smiths Medical, and offers the clinician:

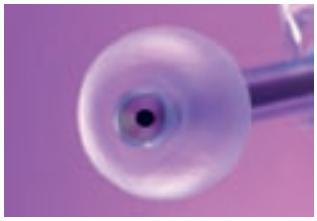
- Totally integrated components, with unique introducer
- The advantages of Blue Line Ultra
- A wide choice of kits to meet individual requirements
- A convenient package including everything required for the procedure
- Ergonomic design for ease of use
- Cost-effective kits



ULTRAperc

PERCUTANEOUS TRACHEOSTOMY KITS

A close fit - the ULTRAperc introducer is tailor made for Blue Line Ultra tracheostomy tubes. The tapered tube tip fits the introducer to minimise trauma on insertion.



A convenient package - Only Smiths Medical ULTRAperc PDT kits can offer the option of the unique introducer and Blue Line Ultra tracheostomy tube all in one kit, avoiding the compromise of mis-matched components.

An ergonomic design - the handle of the ULTRAperc single stage dilator has a chevron-style design, giving a good grip when use of lubricant jelly makes for slippery handling.

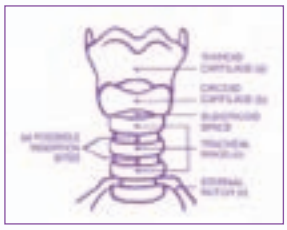
The benefits of Blue Line Ultra - ULTRAperc PDT kits with Blue Line Ultra include all the advantages of this tube range: Soft-Seal cuff, flexible flange, tapered tip, thermo-sensitive PVC material for patient comfort and is suitably radio-opaque for x-ray visualisation.

Also available - Smiths Medical has produced supporting educational material for users of the ULTRAperc kit. The 'How To Guide: Percutaneous Tracheostomy' is produced in association with Care of the Critically Ill. The educational video demonstrates the technique for inserting Blue Line Ultra tubes using the ULTRAperc system.

ULTRAperc kits for percutaneous dilational tracheostomy

Using Ultraperc single dilation technique

1. With the patient in the supine position, hyperextend the neck using a suitable support.



2. Locate and mark the anatomical landmarks. Prepare patient for surgery. Suction pharynx and (if present) re-establish airway with the tracheal tube cuff above the vocal cords to avoid the risk of damaging the tube. If appropriate, inject the site with local anaesthetic.

3. Make a horizontal incision (1.5-2cm) at the chosen insertion site.

4. Insert the needle and cannula (with the syringe attached). Advance the needle until aspiration of air confirms entry into the trachea.

5. Ease the guidewire introducer out from its sheath and straighten the 'J' tip, leaving a sufficient length of exposed guidewire (2-3cm) to enable its dispensing with the forefinger and thumb.

6. Using the introducer, feed the guidewire into the trachea.

7. Pass the dilator over the guidewire towards the trachea and push the dilator forward to penetrate the tracheal wall and at the same time dilate both the tissues and the tracheal wall.

8. Pass the long guiding catheter over the guidewire into the trachea in the direction of the arrow marked on the catheter (safety stop end first) until the safety stop on the guiding catheter is located at the skin. Align the proximal end of the guiding catheter with the proximal band mark on the guidewire to determine the depth of insertion.

9. Immediately prior to insertion, immerse the distal end of the "single stage" dilator in sterile water or saline to activate the lubricious coating on the dilator. Pass the dilator over the guiding catheter until it reaches the "safety stop". In this position, the proximal mark on the guiding catheter will just be visible at the handle end of the dilator.

10. Whilst stabilising the guidewire and guiding catheter to ensure they remain stable and in position in the trachea, insert and partially remove the dilator several times in order to slightly over-dilate the trachea to a size appropriate for the tracheostomy tube to be inserted. The dilator is marked, for guidance, with 38FR and maximum insertion depth.

11. Insert the lubricated tracheostomy tube located on its lubricated introducer over the guiding catheter through the stoma with a slight twisting motion.

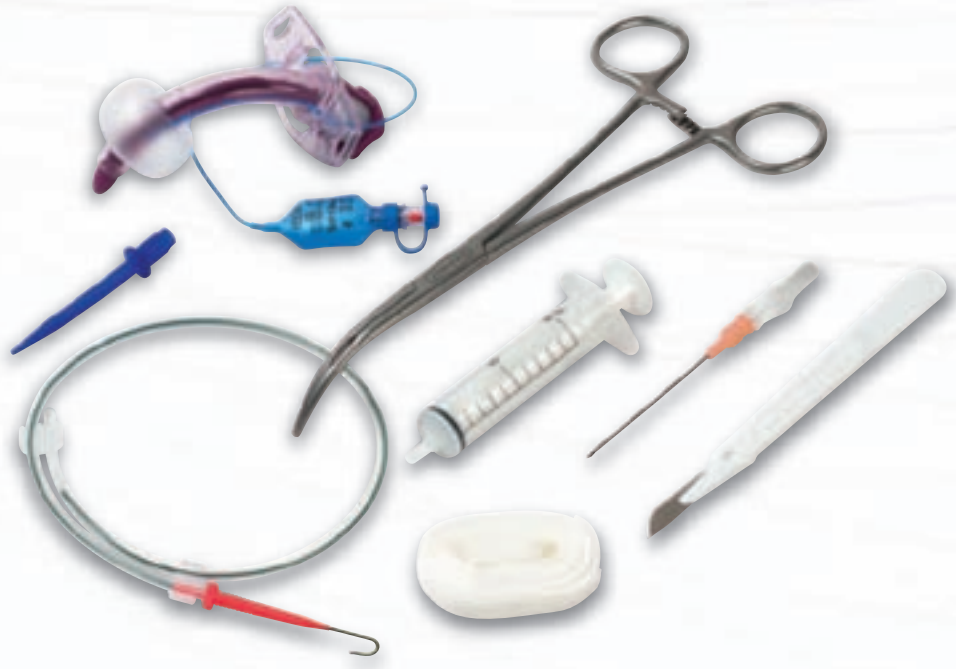
Griggs dilating forceps kits for percutaneous tracheostomy

Based on the widely accepted Seldinger guidewire technique, these kits incorporate the unique and patented Griggs guidewire dilating forceps.

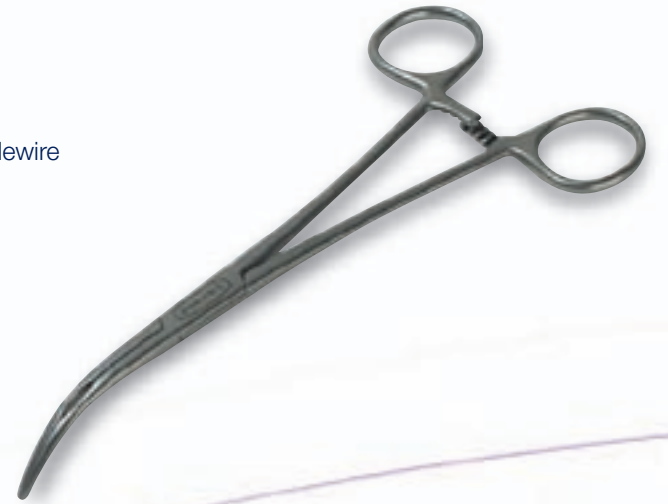
The design of the Griggs forceps permits:

- Single step dilation
  - No need for repeated insertions
  - Minimises tracheal trauma
  - One instrument for a wide range of adult sizes
- Retention of guidewire in situ throughout procedure
  - Maintains accuracy and safety

Smiths Medical kits for Griggs technique percutaneous tracheostomy provide the option for immediate minimally invasive and minimally disruptive treatment, at the bedside or in theatre, which has been shown to have lower complications and morbidity rates versus the traditional surgical technique. [1,2]



References:
1: Griggs WM, Myburgh JA, Worthley LIG. A prospective comparison of a percutaneous tracheostomy technique with standard surgical tracheostomy. Int Care Med 1991; **17**: 261-263.
2: Leinhardt DJ, Mughal M, Bowles B, Glew R, Kishen R et al. Br J Surg 1992; **79**: 255-258.



Only Smiths Medical kits include the unique, patented Griggs guidewire dilating forceps:

- Lock over guidewire for easy, atraumatic insertion
- Allow single step dilation
- Minimise tracheal trauma
- Re-usable to ensure cost-effectiveness

Smiths Medical kits provide what you need:

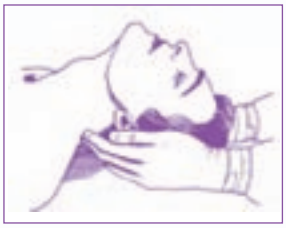
- Full procedure pack (excluding drapes) - avoids delay and inconvenience
- Kits available with or without guidewire dilating forceps - for flexible economy
- Include a Smiths Medical tracheostomy tube with unique guidewire obturator - to ensure convenience and compatibility
- Choice of three tracheostomy tube sizes - to suit a wide range of patients

Kits are also available with the Adjustable Flange Tracheostomy Tube:

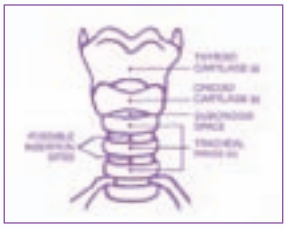
- Moveable flange to facilitate stoma hygiene
- Suitable for patients with deep-set tracheas
- Tapered tube tip and tapered obturator which clips onto bonded connector aid tube insertion
- Siliconised PVC eases passage of suction catheter

Kits for Griggs technique percutaneous tracheostomy

Using the Griggs technique



1. With the patient in the supine position, hyperextend the neck using a suitable support.



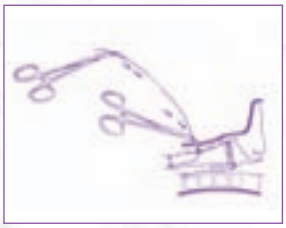
2. Locate and mark the anatomical landmarks. Prepare patient for surgery. Suction pharynx and (if present) re-establish airway with the tracheal tube cuff above the vocal cords to avoid the risk of damaging the tube. If appropriate, inject the site with local anaesthetic.

3. Make a horizontal incision (1.5-2cm) at the chosen insertion site.

4. Insert the needle and cannula (with the syringe attached). Advance the needle until aspiration of air confirms entry into the trachea.

5. Using the introducer, feed the guidewire into the trachea.

6. Pass the dilator over the guidewire towards the trachea and push the dilator forward to penetrate the tracheal wall and at the same time dilate both the tissues and the tracheal wall.



7. Thread the guidewire through the clamped Guidewire Dilating Forceps and advance the forceps until the anterior tracheal wall is reached. Dilate the pre tracheal tissues by opening the forceps and remove the forceps in the open position.

8. Re-thread the forceps as described and now advance through the tracheal wall. Raise forceps handles into the vertical position so that the forceps jaws further penetrate the tracheal wall and lie longitudinally in the trachea. Dilate the trachea by opening forceps. Remove forceps in the open position.

9. Thread the guidewire through the obturator of the tracheostomy tube and advance both into the trachea. Remove obturator and guidewire.

Ordering information

Smiths Medical **Blue Line Ultra** Percutaneous Tracheostomy kit with Guidewire Dilating Forceps

Description	Product Code
Kit with 7mm I.D. tracheostomy tube	100/541/070
Kit with 8mm I.D. tracheostomy tube	100/541/080
Kit with 9mm I.D. tracheostomy tube	100/541/090

Smiths Medical **Blue Line Ultra Suctionaid** Percutaneous Tracheostomy kit with Guidewire Dilating Forceps

Description	Product Code
Kit with 7mm I.D. tracheostomy tube	100/891/070
Kit with 8mm I.D. tracheostomy tube	100/891/080
Kit with 9mm I.D. tracheostomy tube	100/891/090

Smiths Medical **Blue Line Ultra** Percutaneous Tracheostomy kit without Guidewire Dilating Forceps

Description	Product Code
Kit with 7mm I.D. tracheostomy tube	100/543/070
Kit with 8mm I.D. tracheostomy tube	100/543/080
Kit with 9mm I.D. tracheostomy tube	100/543/090

Smiths Medical **Blue Line Ultra Suctionaid** Percutaneous Tracheostomy kit without Guidewire Dilating Forceps

Description	Product Code
Kit with 7mm I.D. tracheostomy tube	100/893/070
Kit with 8mm I.D. tracheostomy tube	100/893/080
Kit with 9mm I.D. tracheostomy tube	100/893/090


100/541


100/543


100/891


100/893

Smiths Medical **Blue Line** Percutaneous Tracheostomy kit with Guidewire Dilating Forceps

Description	Product Code
Kit with 7mm I.D. tracheostomy tube	100/540/070
Kit with 8mm I.D. tracheostomy tube	100/540/080
Kit with 9mm I.D. tracheostomy tube	100/540/090

Smiths Medical **Adjustable Flange** Tracheostomy kit with Guidewire Dilating Forceps

Description	Product Code
Kit with 7mm I.D. tracheostomy tube	100/545/070
Kit with 8mm I.D. tracheostomy tube	100/545/080
Kit with 9mm I.D. tracheostomy tube	100/545/090

Smiths Medical **Blue Line** Percutaneous Tracheostomy kit without Guidewire Dilating Forceps

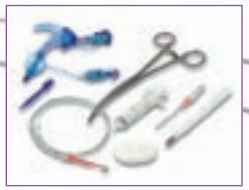
Description	Product Code
Kit with 7mm I.D. tracheostomy tube	100/542/070
Kit with 8mm I.D. tracheostomy tube	100/542/080
Kit with 9mm I.D. tracheostomy tube	100/542/090

Smiths Medical **Adjustable Flange** Tracheostomy kit without Guidewire Dilating Forceps

Description	Product Code
Kit with 7mm I.D. tracheostomy tube	100/546/070
Kit with 8mm I.D. tracheostomy tube	100/546/080
Kit with 9mm I.D. tracheostomy tube	100/546/090


100/540


100/542

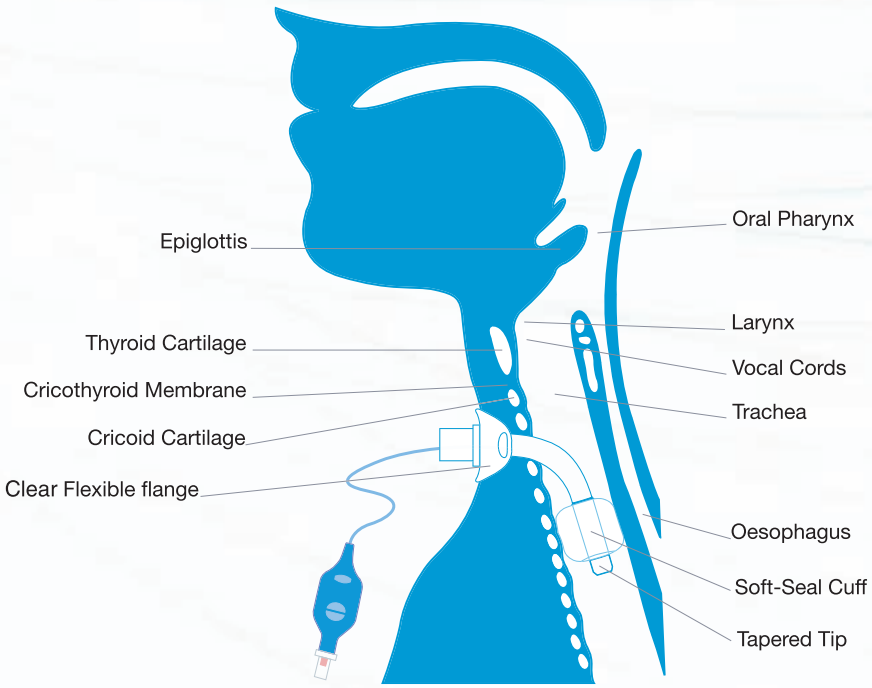

100/545


100/546

Blue Line Ultra with inner cannula

The benefits of the Blue Line Ultra inner cannula system

- Inner cannula designed to be robust and easy to use. Clicks into place to confirm correct insertion. Can be used for up to 30 days
- Ring-pull design aids smooth insertion and removal from tube, minimising patient trauma
- Size of inner cannula indicated to avoid errors in use
- 15mm ISO termination is permanent part of the tube, patient can be ventilated with or without inner cannula in place
- A cleaning brush is supplied for cleaning inner cannula. Brush features soft nylon filaments and smooth brush tip
- Fenestrated inner cannula is coloured red for ease of identification of use
- Multiple fenestrations match those of tracheostomy tube and minimise risk of blockages
- Provided with two reusable inner cannulae and tube holder to secure tube



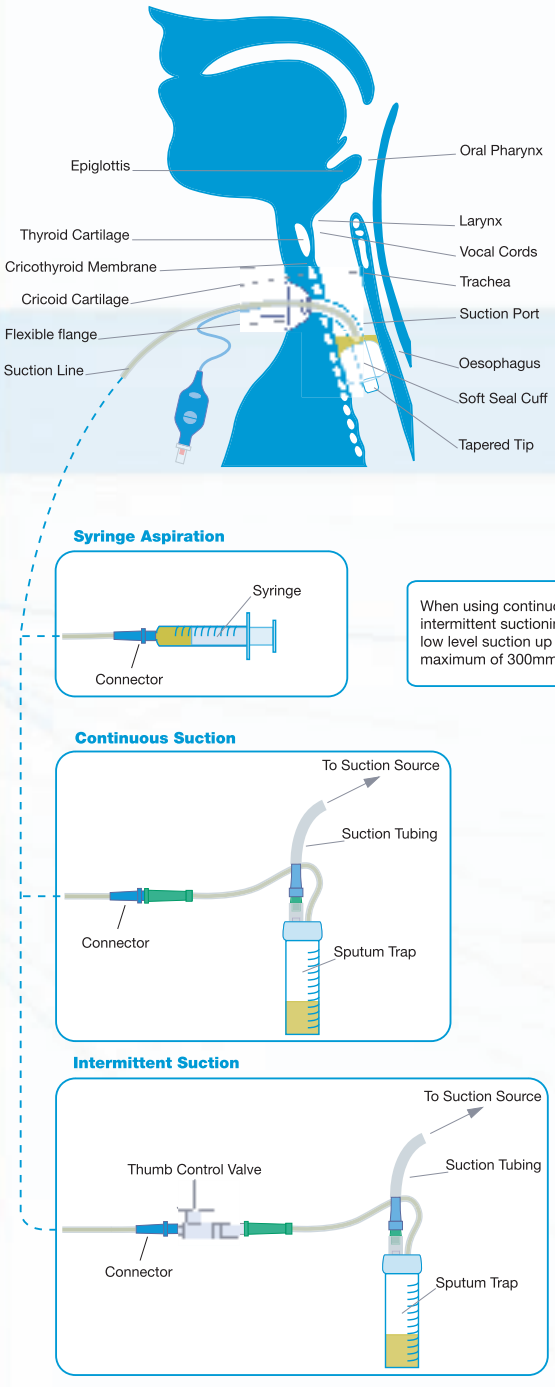
Blue Line Ultra tracheostomy tubes

When caring for a patient with a tracheostomy, you need to choose the tracheostomy tube that best suits the specific clinical need. The Blue Line Ultra range has many benefits:

- Comprehensive range - available with or without inner cannula, cuffed or uncuffed, rigid or thermosensitive, fenestrated or unfenestrated
- Thermosensitive PVC tubes provides sufficient rigidity for initial insertion, and then softens at body temperature to accommodate individual patient anatomy
- Soft-Seal cuff - low pressure, high volume cuff for minimal trauma whilst providing an effective seal. When deflated, cuff relaxes smoothly to tube minimising discomfort on insertion and removal. Velvet soft material with larger cuff resting diameter
- Clear markings on pilot balloon provide relevant information
- Flange is soft for maximum patient comfort, and clear to ensure aesthetic acceptability
- Tube material is suitably radio-opaque to enable confirmation of tube position
- Multiple fenestrations to minimise risk of occlusions
- Obturator provides rigidity for tube insertion. Rounded obturator tip for insertion with minimal trauma
- Special clip design minimises obturator tip movement during tube insertion

New Blue Line Ultra Suctionaid

A new addition to the Blue Line Ultra range, the Blue Line Ultra Suction Aid is ideal for improving patient well-being by maintaining a clean, hygienic and unobstructed airway and having the ability to remove secretions from above the cuff.

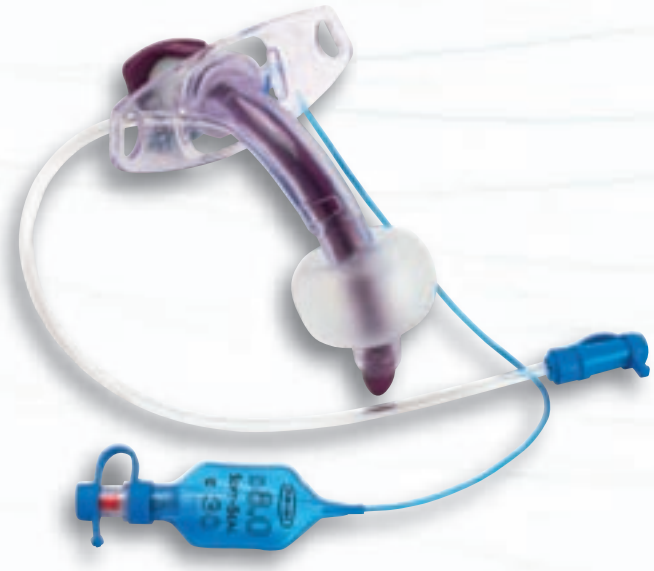


Reducing the potential risk of infection

Accumulation and stasis of contaminated mucus and subglottic secretions above the cuff of tracheostomy tubes can be uncomfortable for patients and provides an ideal growth medium for pathogens. The integral suction lumen of Blue Line Ultra Suctionaid allows removal of these pooled secretions.

Reducing the risk of aspiration

However good the cuff, microaspiration of contaminated material can potentially lead to pulmonary infection. Maintaining tracheostomy hygiene and regular removal of secretions with Blue Line Ultra Suctionaid can help reduce this aspiration.



Blue Line tracheostomy tubes

The comprehensive range of Blue Line tracheostomy tubes meets the varying needs of different departments and different patients.

In Surgery the primary requirement is for ventilation, which needs an atraumatic tube with a good cuff seal against air and liquid. These needs are met by Blue Line cuffed, thermosensitive tubes.

In Intensive Care the patient also needs to be weaned off ventilation, and to restart vocalisation. Tubes for this setting, as well as being atraumatic with a good cuff seal against air and liquid, need to permit airflow to the larynx. Blue Line cuffed, thermosensitive, fenestrated tubes fulfil this requirement.

On the Ward spontaneous breathing obviates the need for the cuff, while vocalisation demands airflow to the larynx. For these patients Blue Line uncuffed thermosensitive tubes are ideal.

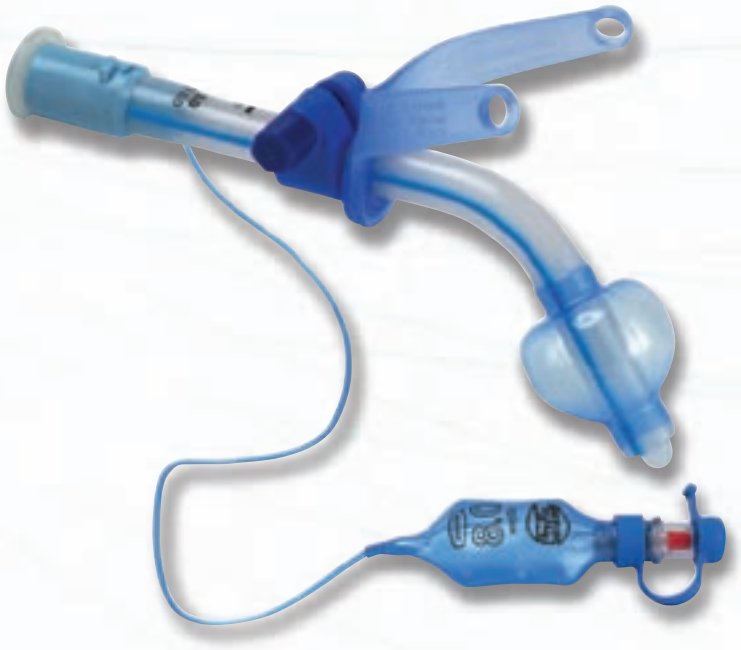
In the Home, patients who still require a tracheostomy although they are breathing spontaneously and vocalising want a tube which is unobtrusive, as well as atraumatic and permitting a good airflow to the larynx. For them the solution is a Blue Line uncuffed, thermosensitive, fenestrated tube with no 15mm connector.

The Blue Line range is also broad and flexible enough to cover the enormous variation in individual patient anatomy by offering customised tubes (see pages 56-62).

Blue Line tracheostomy tubes

Blue Line tubes are designed to meet all your needs.

- Thermosensitive material
  - Initial rigidity for easy intubation
  - Flexibility at body temperature to adapt to the individual patient's anatomy
- Atraumatic design
  - Anatomical tube shape
  - Smooth contours for maximum comfort
  - Non-toxic siliconised PVC tube
  - Low pressure, high volume Profile cuff
- Large choice of tubes
  - Cuffed or uncuffed, fenestrated or unfenestrated, with or without 15mm connector
  - Specialised products for specific needs



Blue Line tracheostomy tubes

Ordering information

Cuffed tubes

Product	Sizes (I.D.mm)	Pack size	Product Codes
Profile cuff tube	6-10	10	100/518/060 - 100/518/100
Double cuff tube	7-10	10	100/512/070 - 100/512/100
Vocalaid tube	6-10	10	100/517/060 - 100/517/100

Uncuffed tubes

Product	Sizes (I.D.mm)	Pack size	Product Codes
Uncuffed tube	3-10	10	100/506/030 - 100/506/100
Uncuffed single fenestrated tube	3-10	10	100/536/030 - 100/536/100
Uncuffed double fenestrated tube	6-10	10	100/537/060 - 100/537/100

Uncuffed tubes without 15mm connector

Product	Sizes (I.D.mm)	Pack size	Product Codes
Uncuffed tube	3-10	10	100/505/030 - 100/505/100
Uncuffed fenestrated tube	3-10	10	100/535/030 - 100/535/100

Adjustable flange tubes

Product	Sizes (I.D.mm)	Pack size	Product Codes
Profile cuff tube	6-10	2	100/523/060 - 100/523/100
Uncuffed tube	6-10	2	100/526/060 - 100/526/100

The last 3 digits indicate the correct tube size e.g. for a size 8.0mm I.D. tube, the product code is 100/518/080

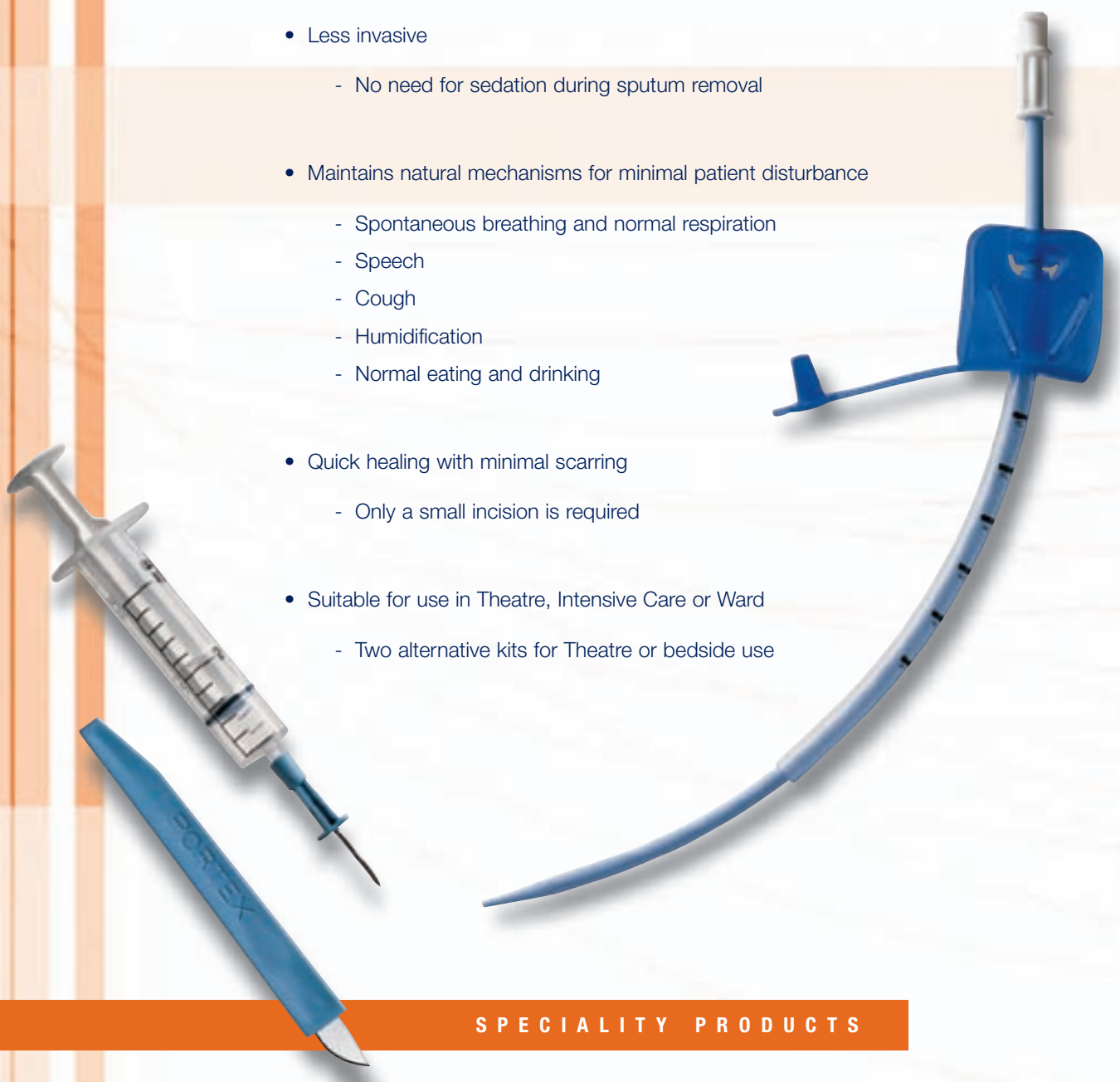
No inner cannulae are available for these products.

100/505 products are available single packed. To order replace '0' with '1' - e.g. 100/505/130.
Code for size 10mm tube as single item is 100/505/110.

Mini-Trach II minitracheotomy kits

After surgery, infection or injury, sputum retention can be a real problem which, if not effectively treated can lead to significant morbidity and even death. When there is the risk that natural sputum removal by coughing, with or without physiotherapy, will not be adequate, prophylactic minitracheotomy can prevent the problem arising and offers many advantages over conventional techniques for managing sputum retention: [4,5,6,7]

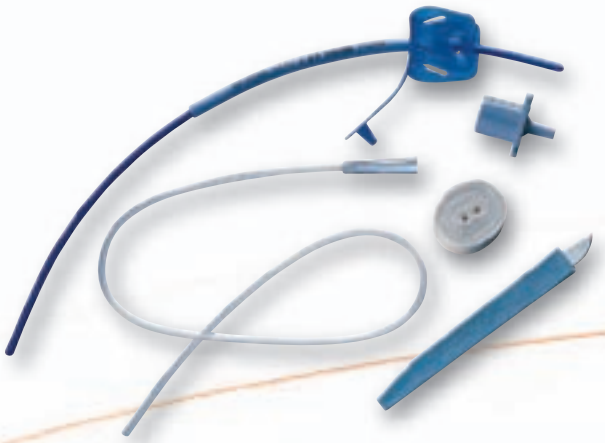
- Constant tracheal access
  - No need for tracheal intubation or tracheostomy
- Less invasive
  - No need for sedation during sputum removal
- Maintains natural mechanisms for minimal patient disturbance
  - Spontaneous breathing and normal respiration
  - Speech
  - Cough
  - Humidification
  - Normal eating and drinking
- Quick healing with minimal scarring
  - Only a small incision is required
- Suitable for use in Theatre, Intensive Care or Ward
  - Two alternative kits for Theatre or bedside use



4: HR Matthews, RB Hopkinson "Treatment of sputum retention by mini tracheostomy" Brit J Surg 1984: 71: 147-150
5: Mini tracheostomy and the control of sputum, HR Matthews. Surgeon Annual 1998. Appleton & Lange, USA P39-59
6: P Bonde, I Papachristos, A McCraith, B Kelly, C Wilson, JA McGuigon, K McManus, "Sputum Retention after Lung Operation: Randomised trial shows superiority of prophylachc minitracheostomy in high-risk patients" Ann Thoracic Surg 2002; 74: 196-203
7: P Bonde, K McManus, M McMnespie, J MuGuigon "Lung Surgery: identifing the subgroup at risk for sputum retention" European Journal of Cardio-Thoracic Surgery 22(2002) 18-22

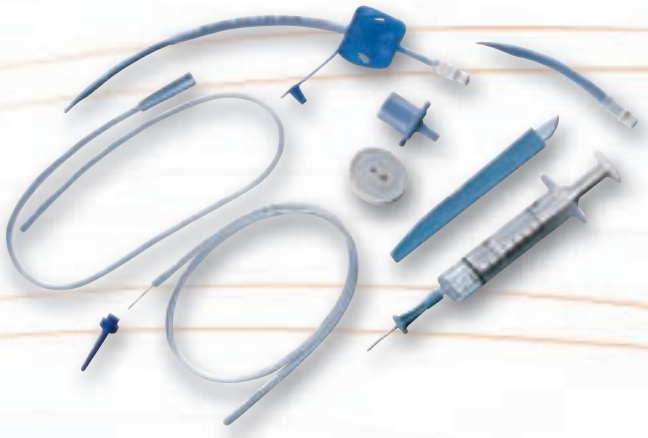
Mini-Trach II kit for surgical insertion in Theatre

- Guarded scalpel allows the correct incision to be made without risk of damage to the posterior wall of the trachea
- Introducer guides the cannula into the trachea
- 4.0mm ID soft PVC cannula provides access to the trachea both as an airway and for suctioning
- 15mm connector allows standard connection to breathing systems. 10F low friction suction catheter allows immediate initial suctioning following cannulation



Mini-Trach II Seldinger kit for therapeutic insertion in Theatre, Intensive Care or Ward

- Guarded scalpel to make initial midline skin incision
- 16G bevelled needle allows simple puncture of the cricothyroid membrane
- Aspirating syringe allows confirmation of correct needle placement
- Flexible tipped guidewire helps introduction of dilator without trauma to posterior tracheal wall
- Curved dilator expands the opening to permit smooth insertion of the Mini-Trach cannula
- Introducer guides the cannula into the trachea
- 4.0mm ID soft PVC cannula provides access to the trachea both as an airway and for suctioning
- 15mm connector allows standard connection to breathing systems
- 10F low friction suction catheter allows immediate initial suctioning following cannulation



Mini-Trach II minitracheotomy kits

Using the Mini-Trach II Seldinger kit

1. The patient is positioned supine with head, neck and chin fully extended. The operator stands above the patient's head facing the patient's feet.

2. The skin is cleansed and the position of the cricothyroid membrane located by palpation and marked.

3. A midline vertical 1cm skin incision is made using the guarded scalpel.

4. The 16G bevelled needle is fitted to the syringe. With the trachea immobilised the bevelled needle is inserted vertically (with the opening of the needle facing caudally) through the cricothyroid membrane. Correct placement is confirmed by aspiration of air.

5. The syringe is removed carefully, keeping the needle in position. The flexible tip of the guidewire is inserted through the bevelled needle into the trachea.

6. The bevelled needle is removed carefully while holding the guidewire to ensure that the guidewire is not moved out of position.

7. The curved dilator is fed onto the guidewire and passed through the cricothyroid membrane.

8. The dilator is removed carefully while holding the guidewire to ensure that the guidewire is not moved out of position. The curved introducer with the premounted Mini-Trach cannula is then fed onto the guidewire and introduced into the trachea with firm pressure.

9. The introducer and guidewire are removed holding the cannula flange in place against the skin.

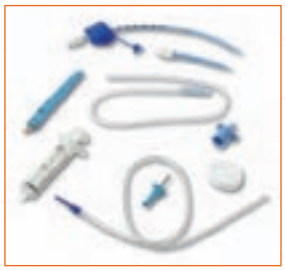
10. The cannula is fixed in place with neck tapes.

11. The suction catheter is passed immediately to remove any existing blood and secretions.

Ordering information

Mini-Trach II

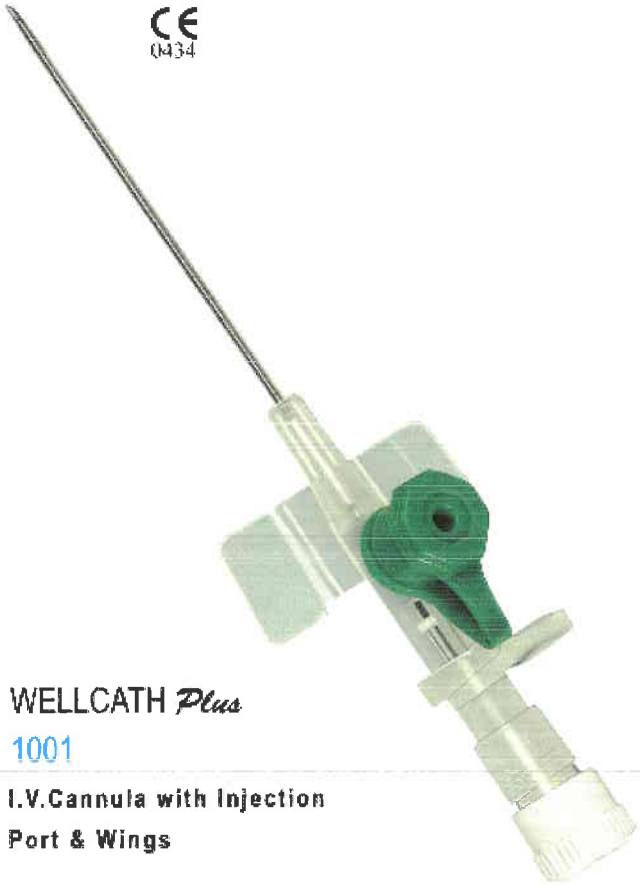
Description	Pack Size	Product Code
Seldinger kit	5	100/461/000
Non-Seldinger kit	10	100/462/000



100/461

I.V.Cannula

CE 0434



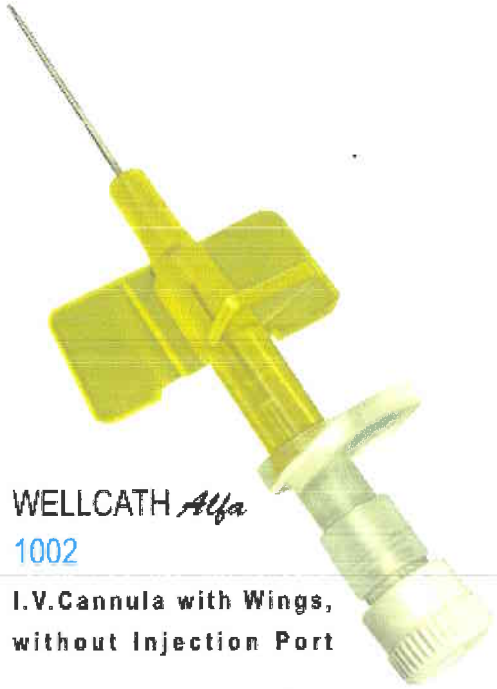
WELLCATH *Plus*

1001

I.V.Cannula with Injection Port & Wings

- Injection Port with unidirectional valve for facilitating extra medication and preventing back flow.
- Specially engineered recessed plug with ring, to avoid risk of contamination
- Angled & grooved wings for easy cannulation and to prevent rolling of cannula over patient's body.
- Colour coded cap for easy identification of gauge size.
- Needle Hub designed for proper grip during insertion.
- Flash Back chamber allows easy visualization of blood, confirming correct placement of Catheter
- Optional Hydrophobic filter/Porous plug in Flash back chamber available on demand

CE 0434



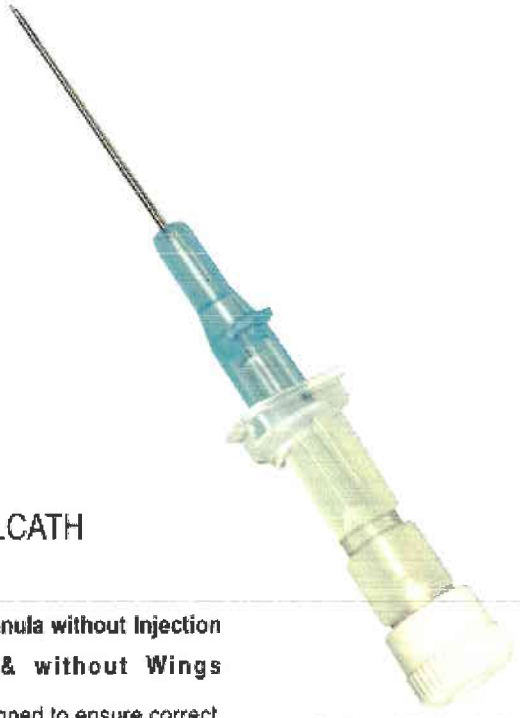
WELLCATH *Alfa*

1002

I.V.Cannula with Wings, without Injection Port

- Angled & grooved wings for easy cannulation and to prevent rolling of cannula over patient's body.
- Colour coded body for easy identification of gauge size.
- Needle Hub designed for proper grip during insertion.
- Flash Back chamber allows easy visualization of blood, confirming correct placement of Catheter.
- Optional Hydrophobic filter/Prorous plug in Flash back chamber available on demand

CE 0434



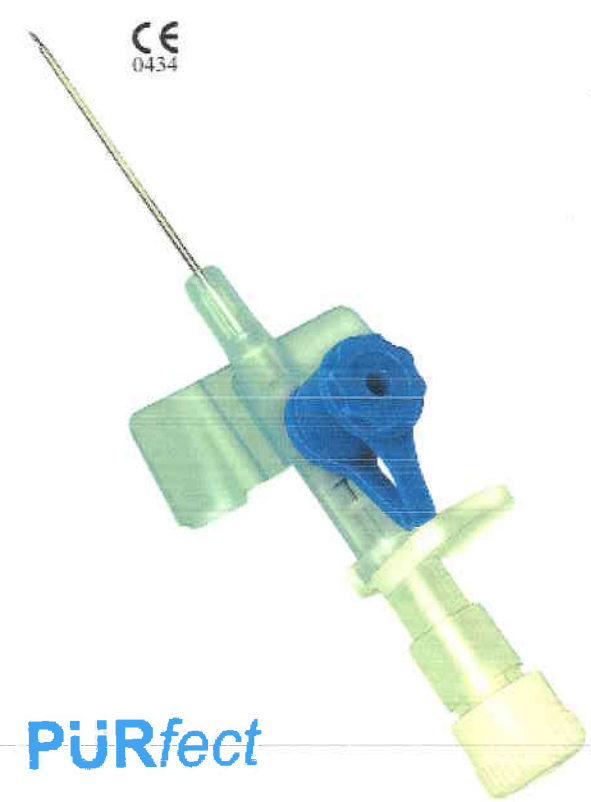
WELLCATH

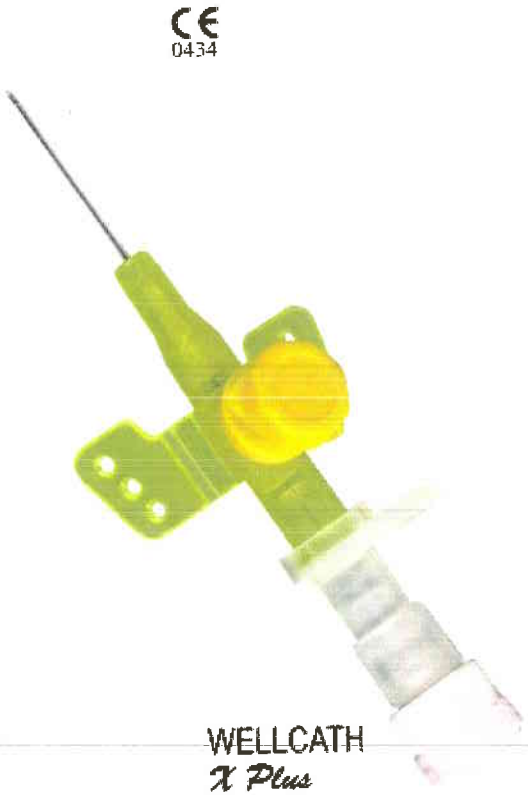
1003

I.V.Cannula without Injection Port & without Wings

- Designed to ensure correct Orientation of needle bevel & better control during cannulation.
- Needle Cover designed for safe disposal of needle after Catheterization.
- Colour coded body for gauge size identification.
- Needle Hub designed for proper grip during insertion.
- Flash Back chamber allows easy visualization of blood, confirming correct placement of Catheter
- Optional Hydrophobic filter/Prorous plug in Flash back chamber available on demand

.V.Cannula





PÜRfect

I.V.Cannula range with Polyurethane as catheter material

- PÜRfect Plus (I.V.Cannula with Injection Port and Wings). Ref.: 1001 P
- PÜRfect X Plus (I.V.Cannula with Injection Port and Suturable Wings) Ref.: 1001XP
- PÜRfect Alfa (I.V.Cannula with Wings and Without Port). Ref.: 1002 P
- PÜRfect Cath (I.V.Cannula without Injection Port and without Wings) Ref.: 1003 P
- Pencath PÜRfect (I.V.Cannula without Injection Port and without Wings) Ref.: 1006 P
- Neo PÜRfect (I.V.Cannula with Wings for Neonates).Ref.: 1004P

WELLCATH *X Plus*

- Ergonomically designed wings tofacilitate longer usage
- Wings providedwith holes for fixation of I.V. Cannula with suture on patient's body
- Colour coded body for ease of size identification
- Snap fit port cap
- Flip type Port cap also optionally available which increases patient comfort as the protective cap of Injection Port opens and closes almost effortlessely

IV Cannula Specifications

Size	Colour	Int./Ext. (ø in mm)	Length* (in mm)	Water Flow Rate (in ml./min)
14G	Orange	1.72/2.1	45	280
16G	Grey	1.3/1.8	45	200
17G	White	1.15/1.5	45	130
18G	Green	0.95/1.30	45	95
20G	Pink	0.75/1.1	32	61
22G	Blue	0.6/0.9	25	36
24G	Yellow	0.48/0.72	19	20
26G	Violet	0.44/0.6	19	13

- **Shorter length available on demand**

Management System Certificate

Certificate No.:	Project No.:	Initial Certification Date:	Valid Until:
247997-2017-AQ-IND-NA-PS Rev. 1.0	**PRJC-166238-2009-MSC-IND**	**24 OCTOBER 2017**	**21 JUNE 2021**

This is to certify that the management system of:

Wellmed International Industries Pvt. Ltd.

A-176 & 177, Sector - 63, Noida -201301, U.P., India.

Complies with the requirements of:

ISO 13485:2016/NS-EN ISO 13485:2016

The Certificate is valid for the following scope:

Development, Manufacture, Marketing of Disposable Medical Devices for Infusion, Gastroenterology, Urology, Surgery, Anaesthesia and Allied Applications.

Place and Date:
Høvik, 22 May 2018

NORWEGIAN ACCREDITATION
MSYS 018

For:
DNV GL NEMKO PRESAFE AS

Eugenie Winger Husebye

The Certificate has been digitally signed.
See www.presafe.com/digital_signatures for more info

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

DNV BUSINESS ASSURANCE

EC CERTIFICATE - FULL QUALITY ASSURANCE SYSTEM

Certificate No. 94308-2011-CE-IND-NA 1.0
This Certificate consists of 4 pages

This is to certify that the Quality Management System of

Wellmed International Industries Pvt. Ltd.

A- 176 & 177 Sector 63 Noida 201301 U.P India

for design, production and final product inspection/testing of

Sterile Medical Disposable Devices

has been assessed with respect to
the conformity assessment procedure described in Article 11.3.a and Annex II excluding section 4 (Module H) of Council Directive 93/42/EEC on Medical Devices, as amended, and found to comply

Further details are given overleaf

Place and date:
Høvik, 01 April 2016

For DNV GL BUSINESS ASSURANCE
NORWAY AS

Tone Kolpus
Certification Manager

NORWEGIAN ACCREDITATION
PROD 002

Notified Body No.:
0434

This Certificate is valid until:
11 April 2021

Aud Løken Eiklid
Technical Reviewer

This Certificate has been digitally signed. See www.dnv.com/digitalsignatures for more info

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as 'Forskrift for Medisinsk Utstyr' by the Norwegian Ministry of Health and Care Services.

Certificate history

Revision	Description	Issue Date
0	Original certificate	2011-04-11
1	**Recertification Audit**	**2016-04-11**

Products covered by this Certificate

Product Description	Product	Class
Sterile Disposable Medical Devices		
Transfusion & Infusion:		
I.V Cannula	I.V. Cannula with/without Injection port & with/without wings Size: 14,16,17,18,20,22,24 & 26 G I.V. Cannula with wings & without Injection port for Neonates with & without wing holder Size: 24 & 26 G I.V. Cannula with Suturable wings & Flip Type port Size: 14,16,17,18,20,22,24 & 26 G I.V. Cannula with wings & Three Way Size: 14,16,17,18,20,22,24 & 26 G I.V. Cannula Pen Type with & without rigid plastic enclosure Size: 14,16,17,18,20,22,24 & 26 G SAFETY I.V. Cannula with needle bevel enclosure & with complete needle enclosure Size: 14,16,17,18,20,22,24 & 26 G	IIa
Three Way Stop Cock	Normal Pressure, High Pressure, Normal Pressure with Ext. Line, High Pressure with Ext. Line	IIa
Three Way Stop Cock (Lipid Resistant)	Normal Pressure, High Pressure, Normal Pressure with Ext. Line, High Pressure with Ext. Line	IIa
I.V Flow Regulator	Standard	IIa
Obtuator	Size: 14,16,17,18,20,22,24 & 26 G	IIa
Heparin Port/ Injection Stopper	Latex/ Silicone Transparent and Opaque	IIa
Luer Lock/ Threaded Stopper/ Luer Cap	Standard	IIa

I.V Set	Burette Type: 110, 150 ml Vented: Micro/Macro Drop Non Vented: Micro/Macro Drop	IIa
Extension Tube	Extension Tube(Normal) , High Pressure	IIa
Gynaecology:		
Amniotic Sac Perforator	Standard	IIa
Umbilical Cord Clamp		Is
Urology:		
Foley Balloon Catheter	Two Way / Three way Size FG 06 to 24	IIa
Nelaton Catheter	FG: 8 to 22	IIa
Gastroenterology:		
	Ryle's Tube: FG: 8,10,12,14,16,18,20,22 Levins Tube FG: 8,10,12,14,16,18,20,22,24 Infant Feeding Tube FG: 4,5,6,7,8,10	IIa
Anaesthesia & Respiratory		
	Endotracheal Tube with/ without Cuff 02 to 11 m.m Nebulizer: with /without Face Mask(Adult and Child) Suction Catheter: Plain, Finger Tip Control, Thumb Control FG: 6 to 22 Nasal Oxygen Catheter FG: 06 to 22 Mucus Extractor Size: FG 10 to 14	IIa
Anaesthesia & Respiratory	Face Mask: (Adult and Child), Face Mask with NRB(Adult & Child) Twin Bore Nasal Oxygen Set: (Adult& Child) Guedal Airway Size: 000,00,0,1,2,3,4,5,6	Is
Surgery& Wound Drainage		
Chest Drainage Catheter(Thoracic Drainage Catheter)	Straight, Curved FG: 06 to 40	IIa
Chest Drainage Catheter with Trocar(Thoracic Drainage Catheter with Trocar)	FG: 06 TO 40	IIa
Closed Wound Suction Drainage Set:	FG:8 ,10,12,14,16,18 with Bellow capacity 50 ml,400 ml, 800 ml	IIa

Redon Drain	Size FG: 8 to 20	IIa
Yankauer Suction Set	Standard/ Crown Tip with or Without Vacuum Control	IIa
Corrugated Drainage Sheet	Size: 25x 250 m.m	IIa
A.V. Fistula Needle	Fixed and Rotating Wings Size: 15 to 17 G	IIa

The complete list of devices is filed with the Notified Body.

Sites covered by this certificate

Site Name	Address
Wellmed International Industries Pvt. Ltd.	A- 176 & 177 Sector 63 Noida 201301 U.P India

EU Representative : CMC Medical Devices & Drugs S. L.
C/Horacio Lengo, N^{0} 18 CP 29006, Málaga, Spain
Ph: + 34951214054

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform the local DNV Office of any intended updating of the quality system and DNV will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system DNV reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of DNV.

END OF CERTIFICATE

DNV BUSINESS ASSURANCE

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

CERTIFICAT CE – SISTEM COMPLET DE ASIGURARE A CALITĂȚII
Certificat Nr. 94308-2011-CE-IND-NA 1.0

Acest Certificat conține 4 pagini
Se certifică prin prezenta că Sistemul de Management al Calității al companiei

Wellmed International Industries Pvt. Ltd.

A- 176 & 177 Sector 63 Noida 201301 U.P India

pentru proiectare, producție și inspecție/ testare finală de

Dispozitive medicale sterile de unică folosință

a fost evaluat cu privire la
procedura de evaluare a conformității, descrisă în Articolul 11.3.a și Anexa II, excluzând secțiunea 4 (Modul H) la Directiva Consiliului 93/42/CEE pentru Dispozitive Medicale, amendată, și s-a constatat că este în conformitate

Detalii suplimentare pe verso

Locul și data:
Høvik, 01 Aprilie 2016

Ptr. DNV GL BUSINESS ASSURANCE
NORWAY AS

NORWEGIAN ACCREDITATION
PROD 002

CE

Acest Certificat este valabil până la:
11 Aprilie 2021

Tone Kolpus
Director Certificare

Organism Notificat nr:
0434

Aud Løken Eiklid
Revizor Tehnic

Acest Certificat poartă semnătura digitală. vezi www.dnv.com/digitalsignatures pentru mai mult informații

Aviz: Certificatul este supus termenilor și condițiilor de pe verso. Orice schimbări semnificative în design și construcție pot anula acest certificat.

Det Norske Veritas AS, Veritasveien 1, 1322 Høvik, Norvegia. Tel: +47 67 57 9900 Fax: +47 6757 9911 www.dnv.com

Jurisdicție

Aplicarea Directivei Consiliului 93/42/CEE din 14 Iunie 1993, adoptată ca 'Forskrift for Medisinsk Utstyr' Ministerul Sănătății și Serviciilor Medicale din Norvegia.

Istoric Certificat

Revizie	Descriere	Data eliberării
0	Certificat Original	11.04.2011
1	**Audit pentru recertificare**	**11.04.2016**

Produse acoperite de acest Certificat

Descrierea produsului	Produs	Clasa
Dispozitive medicale sterile de unică folosință		
Transfuzie & Infuzie:		
I.V Canulă	I.V. Canulă cu/ fără port de injecție & cu/ fără aripioare Mărime: 14,16,17,18,20,22,24 & 26 G I.V. Canulă cu aripioare & fără port de injecție pentru nou-născuți cu & fără suport cu aripioară Mărime: 24 & 26 G I.V. Canulă cu aripioare suturabile & port tip flip Mărime: 14,16,17,18,20,22,24 & 26 G I.V. Canulă cu aripioare & cu trei căi Mărime: 14,16,17,18,20,22,24 & 26 G I.V. Cannula tip stilou cu & fără carcasă de plastic rigidă Mărime: 14,16,17,18,20,22,24 & 26 G Canulă de siguranță I.V. cu carcasă teșită pentru ac & cu carcsă completă pentru ac Mărime: 14,16,17,18,20,22,24 & 26 G	IIa
Robinet cu trei căi	Presiune normală, Presiune ridicată, Presiune normală cu prelungitor, Presiune ridicată cu prelungitor	IIa
Robinet cu trei căi (rezistent la lipide)	Presiune normală, Presiune ridicată, Presiune normală cu prelungitor, Presiune ridicată cu prelungitor	IIa
Dispozitiv de reglare a fluxului I.V.	Standard	IIa
Obturator	Mărime: 14,16,17,18,20,22,24 & 26 G	IIa
Port heparină / Opritor injecție	Latex/ Silicon, Transparent și Opac	IIa
Sistem de închidere Luer Lock/ Opritor filetat/ Capac Luer	Standard	IIa

Set I.V.	Tip biuretă: 110, 150 ml Ventilat: Cu micro/macro-picătură Neventilat: Cu micro/macro-picătură	IIa
Tub extensie	Tub extensie (Normal), Presiune ridicată	IIa
Ginecologie:		
Perforator sac amniotic	Standard	IIa
Clemă cordon ombilical		Is
Urologie:		
Cateter cu balon Foley	Două căi/ Trei căi Mărime FG 06 la 24	IIa
Cateter Nelaton	FG: 8 la 22	IIa
Gastroenterologie:		
	Tub Ryle: FG: 8,10,12,14,16,18,20,22 Tub Levins FG: 8,10,12,14,16,18,20,22,24 Tub alimentare sugar FG: 4,5,6,7,8,10	IIa
Anestezie & Respirator		
	Tub endotraheal cu/ fără garnitură 02 la 11 m.m Nebulizator: cu / fără mască (Adulți și Copii) Cateter absorbție: Drept, Control vârf deget, Control degetul mare FG: 6 la 22 Cateter nazal pt oxigen FG: 06 la 22 Extractor mucus, Mărime: FG 10 la 14	IIa
Anestezie & Respirator	Mască: (Adulți și Copii), Mască cu NRB (Adulți și Copii) Set nazal pt oxigen cu dublu orificiu: (Adulți și Copii) dispozitiv pentru căile respiratorii Guedel, Mărime: 000,00,0,1,2,3,4,5,6	Is
Chirurgie & Drenaj plagă		
Cateter drenaj toracic (Cateter toracic)	Drept, curbat FG: 06 la 40	IIa
Cateter drenaj toracic cu Trocar (Cateter toracic cu Trocar)	FG: 06 la 40	IIa
Set de drenaj închis cu aspirația plăgii:	FG:8 ,10,12,14,16,18 cu capacitate Bellows 50 ml,400 ml, 800 ml	IIa

Tub dren Redon	Mărime FG: 8 la 20	IIa
Set de absorbție Yankauer	Vârf standard/ coroană cu sau fără control vid	IIa
Foaie corugată de drenaj	Mărime: 25x 250 m.m	IIa
Ac fistulă A.V.	Aripioare fixe și rotative Mărime: 15 la 17 G	IIa

Lista completă a dispozitivelor este depusă la Organismul Notificat.

Unități acoperite de acest certificat

Denumire unitate	Adresa
Wellmed International Industries Pvt. Ltd.	A- 176 & 177 Sector 63 Noida 201301 U.P India

Representanță UE : CMC Medical Devices & Drugs S. L.
C/Horacio Lengo, N^0 18 CP 29006, Málaga, Spania,

Tel: + 34951214054

Termeni și condiții

Certificatul este supus următoarelor condiții și termeni:

- Orice producător (vezi 2001/95/CE pentru o definiție exactă) este responsabil pentru daunele cauzate de un defect în produsul(ele) său(sale), în conformitate cu Directiva 85/374/CEE, amendată, privind răspunderea produselor defecte.
- Certificatul este valabil doar pentru produsele și/ sau unitățile de producție specificate mai sus.
- Producătorul va îndeplini obligațiile rezultate din sistemul de calitate aprobat și va menține acest sistem adecvat și eficient.
- Producătorul va informa Oficiul local DNV cu privire la orice actualizare intenționată a sistemului de calitate și DNV va evalua schimbările și va decide asupra valabilității certificatului.
- Vor fi efectuate audituri periodice pentru a verifica dacă Producătorul menține și aplică sistemul de calitate. DNV își rezervă dreptul, pe baza unui motiv precis sau în urma unei suspiciuni, de a efectua vizite neanunțate.

Următoarele pot anula acest Certificat:

- Schimbări în sistemul de calitate, care afectează producția.
- Auditurile periodice nu sunt efectuate în intervalul permis.

Declarație de conformitate și marcarea produsului

Dacă sunt întrunite condițiile și termenii de mai sus, producătorul poate întocmi o declarație de conformitate CE și poate aplica legal marca CE urmată de numărul de identificare DNV al Organismului Notificat.

SFÂRȘITUL CERTIFICATULUI

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