intertek
Total Quality. Assured.

# CERTIFICATE OF REGISTRATION

**Certificate Number:**
119-04 C

**Initial Certification Date:**
08 June 2004

**Date of Certification Decision:**
25 June 2018

**Issuing Date:**
25 June 2018

**Valid Until:**
24 June 2021

**This is to certify that the management system of:**

## SMITHS MEDICAL DEUTSCHLAND GmbH

**Bretonischer Ring 3, D-85630 Grasbrunn, Germany**

See appendix for additional sites and additional site scopes

**has been registered by Intertek as conforming to the requirements of:**

## EN ISO 13485:2016

### The management system is applicable to:

Design, manufacture, inspection, storage and distribution of Pressure Monitoring, Infusion Disposables, Interventional Imaging, Neurosurgery, Vascular Access.

The Servicing of active medical devices.

UKAS MANAGEMENT SYSTEMS
061

**Calin Moldovean**
President, Business Assurance

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

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

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

*Traducere din limba engleză*

## CERTIFICAT DE ÎNREGISTRARE

**Se certifică prin prezenta că sistemul de management al:**

# SMITHS MEDICAL DEUTSCHLAND GmbH

**Bretonischer Ring 3, D-85630 Grasbrunn, Germania**

Pentru locații și domenii suplimentare, vedeți anexa

**a fost înregistrată de către Intertek deoarece se conformează cerințelor:**

# EN ISO 13485:2016

**Certificat Număr:**
119-04 C

**Data Certificării Inițiale:**
08 Iunie 2004

**Data Deciziei Certificării:**
25 Iunie 2018

**Data Emiterii:**
25 Iunie 2018

**Valabil Până la:**
24 Iunie 2021

061

**Sistemul de management este aplicabil pentru:**

Proiectarea, fabricarea, inspectarea, depozitarea și distribuirea Dispozitivelor de Monitorizare a Tensiunii, a Dispozitivelor de Injectare de Unică Folosință, a Dispozitivelor pentru Intervenții, Imagistică, Neurochirurgie, Acces Vascular.

Service-ul dispozitivelor medicale active.

*Semnătura - indescifrabilă*
**Calin Moldovean**
Președinte, Business Assurance

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

"Prezentul Certificat este proprietatea AMTAC Certification Services Ltd sucursală deținută integral de către Intertek Holdings Ltd"

Intertek Certification Limited este organism acreditat UKAS conform graficului de Acreditare nr. 061

**********

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

Traducător autorizat
Nr. 2769/2015

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

S.C. CRAZY PRICE MEDICAL IMPORT EXPORT S.R.L. Conform cu originalul

În emiterea prezentului certificat, Intertek nu-și asumă nicio responsabilitate față de nicio parte, alta decât Clientul, și aceasta numai în conformitate cu Acordul de Certificare. Validitatea prezentului certificat se supune păstrării de către organizație a sistemului de management în conformitate cu cerințele Intertek cu privire la certificarea sistemelor. Validitatea acestuia poate fi confirmată prin email la certificate.validation@intertek.com sau prin scanarea codului din dreapta cu un smartphone. Certificatul rămâne proprietatea Intertek, căreia îi trebuie returnat la cerere.

# C-Fusor® - The pressure infusor


## A clear solution for Pressure Infusion, Transfusion and Flushing

- Secure fastening.
- Unique design ensures rapid set-up and fluid bag replacement.
- Accurate and easy-to-read pressure gauge.
- Crystal clear material allows maximum visibility of fluid levels.
- Allows for even pressure around the fluid container.
- Durable and easy to clean.
- Large squeeze bulb for rapid and reliable pressure control.
- Three-way stopcock prevents air leaks.
- 1000ml and 500ml sizes available.
- Extension sets available for two and three litre bags.

**C-Fusor® Products (Outside US Codes)**

| Code | Product Codes | Qty |
|---|---|---|
| MX 4805P1 | 500ml unit, complete with manometer, squeeze bulb and 3-way stopcock | 1 |
| MX 4810P1 | 1000ml unit, complete with manometer, squeeze bulb and 3-way stopcock | 1 |
| MX 4806 | C-Fusor® 500ml replacement bag only | 1 |
| MX 4830P1 | Expansion set for MX 4810, 3L fluid container | 1 |
| MX 1821-B | Squeeze bulb, male luer lock and 3-way stopcock | 1 |
| MX 1821-G | Pressure guage, 0-760mm Hg | 1 |

**C-Fusor® Products (US Codes)**

| Code | Product Codes | Qty |
|---|---|---|
| MX 4805 | 500ml unit, complete with manometer, squeeze bulb and 3-way stopcock | 1 |
| MX 4810 | 1000ml unit, complete with manometer, squeeze bulb and 3-way stopcock | 1 |
| MX 4830 | Expansion set for MX 4810, 3L fluid container | 1 |
| MX 1821-B | Squeeze bulb, male luer lock and 3-way stopcock | 1 |
| MX 1821-G | Pressure guage, 0-760mm Hg | 1 |



For further information please call your local Smiths Medical distributor or Smiths Medical on +44 (0)1303 260551

**Smiths Medical**
1500 Eureka Park, Ashford, Kent, TN25 4BF, UK
Tel: +44 (0)1303 260551 Fax: +44 (0)1303 266761

www.smiths-medical.com
**Smiths Medical, part of the global technology business Smiths Group**


Literature No. LIT/PV3124 10/2010

smiths medical

smiths medical
bringing technology to life

# C-Fusor®
# The pressure infusor


## PRESSURE MONITORING

medex™

smiths

## PRESSURE INFUSOR

# C-Fusor®

the pressure infusor




### A clear solution for Pressure Infusion, Transfusion and Flushing

- Secure fastening.
- Unique design ensures rapid set-up and fluid bag replacement.
- Accurate and easy-to-read pressure gauge.
- Crystal clear material allows maximum visibility of fluid levels.
- Allows for even pressure around the fluid container.
- Durable and easy to clean.
- Large squeeze bulb for rapid and reliable pressure control.
- Three-way stopcock prevents air leaks.
- 1000ml and 500ml sizes available.
- Extension sets available for two and three litre bags.

C-Fusor® Products

| Article | Description | Qty |
|---|---|---|
| MX 4805 | 500ml unit, complete with manometer, squeeze bulb and 3-way stopcock | 1 |
| MX 4810 | 1000ml unit, complete with manometer, squeeze bulb and 3-way stopcock | 1 |
| MX 4806 | C-Fusor® 500ml replacement bag only | 1 |
| MX 4811 | C-Fusor® 1000ml replacement bag only | 1 |
| MX 4830 | Expansion set for MX 4810, 3L fluid container | 1 |
| MX 1821-B | Squeeze bulb, male luer lock and 3-way stopcock | 1 |
| MX 1821-G | Pressure gauge, 0-760mm Hg | 1 |



For further information please call your local Smiths Medical distributor or Smiths Medical on +44 (0)1303 260551

smiths

**Smiths Medical International Ltd**

Hythe, Kent CT21 6JL UK
Tel: +44 (0)1303 260551 Fax: +44 (0)1303 266761
www.smiths-medical.com


Literature No. LIT/PV2590

smiths

Smiths Medical - a part of Smiths Group plc


**PRESSUREMONITORING**

**Organismo Notificato 0373**
*Notified Body 0373*

# *Istituto Superiore di Sanità*

| | | | | | |
|---|---|---|---|---|---|
| Certificato n° *Certificate no.* | **QPZ-1916-19** | Addendum n° *addendum no.* | //-// | Data prima emissione *First issue date* | **19.09.2019** |
| | | | | Data di emissione corrente *Current issue date* | **19.09.2019** |
| | | | | Data di scadenza *Expiry date* | **26.05.2024** |

## GARANZIA DELLA QUALITA' DELLA PRODUZIONE

secondo l'Allegato V della Direttiva Europea 93/42/CEE e successive modifiche ed integrazioni
*(recepita in Italia con il D.Lgs. n. 46 del 24.02.1997 e successive modifiche ed integrazioni)*

## *PRODUCTION QUALITY ASSURANCE*

according to Annex V of EC Directive 93/42/EEC and subsequent modifications and integrations
*(transposed in Italy by the D.Lgs. n. 46 issued on 24.02.1997 and subsequent modifications and integrations)*

**L'Istituto Superiore di Sanità, Organismo Notificato 0373, certifica che il sistema di garanzia della qualità della produzione attuato da**

*The Istituto Superiore di Sanità, Notified Body 0373, certifies that the production quality assurance enforced by*

***M.V. S.r.l.***

***Sede Legale/** Registered Office:*
***Via F.lli Cervi, 7 – 46023 Gonzaga loc. Palidano (MN) ITALIA***

*Altre sedi del Fabbricante /Other sites of the Manufacturer:*
***Sede Produttiva/** Production Site: **Via Don G. Dossetti , 5/7 – 46023 Gonzaga loc. Palidano (MN) ITALIA***

**per il dispositivo/i** *for the device(s)*

***(vedi allegato tecnico/ see technical sheet)****

**è conforme ai requisiti applicabili della Direttiva Europea 93/42/CEE e successive modifiche ed integrazioni.**

*is in compliance with the applicable requirements of Council Directive 93/42/EEC and subsequent modifications and integrations.*

**Il Direttore dell'Organismo Notificato**
*The Director of Notified Body*
**(Dott.ssa Roberta Marcoaldi)**

Roberta Marcoaldi

* **L'allegato tecnico è parte integrante del presente Certificato**
*The technical sheet is an integral part of this Certificate.*

**Organismo Notificato 0373**
*Notified Body 0373*

# *Istituto Superiore di Sanità*

## ALLEGATO TECNICO — TECHNICAL SHEET

Il Certificato n° / *The Certificate no.* **QPZ-1916-19**

Addendum n° / *addendum no.* *//-//*

*di cui il presente allegato tecnico è parte integrante, è da considerarsi riferito solo al/ai seguente/i prodotto/i soggetto/i a sorveglianza:*

*of which this technical sheet is an integral part, refers only to the following product(s) that are subject to surveillance:*

***Classe IIa** (Class IIa)*

| ***Nome prodotto*** *(Product name)* | ***Codice*** *(Code)* |
|---|---|
| *Aghi per mesoterapia, sterile/Mesotherapy needles, sterile* | *MXXYYYZZ*[1] |
| *Aghi per intralipoterapia/ Intralipotherapy needles, sterile* | *MILTXXYYY*[2] |
| *Aghi per elettrolipolisi, sterile/Electrolipolysis needles, sterile* | *MLPXXXY*[3] |
| *Raccordi multiniettori senza aghi, sterile/Multinjectors, sterile* | *MRYXXX*[4] |
| *Raccordi multiniettori con aghi, sterile/Multinjectors with needles, sterile* | *MRYYXXX*[5] |
| *Set per mesoterapia senza ago, sterile/Mesotherapy set, sterile* | *MDHNXXX*[6] |
| *Set per mesoterapia con ago, sterile/Mesotherapy set with needles,, sterile* | *MDHNXXYYZ*[7] |
| *Iniettore monouso per microterapia, sterile/Skin injection therapy, sterile* | *MSITXXXY*[8] |
| *Set "Bont Kit" con siringa, ago di prelievo e ago intradermico/"Bont Kit" set with syringe, drawing needle and intradermal needle* | *M03SBK* |

**Il Direttore dell'Organismo Notificato**
*The Director of Notified Body*
**(Dott.ssa Roberta Marcoaldi)**

Roberta Marcoaldi

Organismo Notificato 0373
*Notified Body 0373*

# *Istituto Superiore di Sanità*

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*of which this technical sheet is an integral part, refers only to the following product(s) that are subject to surveillance:*

***Classe IIa** (Class IIa)*

| ***Nome prodotto*** *(Product name)* | ***Codice*** *(Code)* |
|---|---|
| *Rubinetti / Stopcocks* | *AAXXYYYYYY*[9] |
| *Tappi di chiusura/ Closing cap* | *AAXXYYYYYY*[9]<br>*020440611000000*<br>*020440621000000* |
| *Rampe / Manifolds* | *AAXXYYYYYY*[9] |
| *Raccordi / Connectors* | *AAXXYYYYYY*[9] |
| *Valvole/ Valves* | *AAXXYYYYYY*[9] |
| *Prolunghe/Extension lines* | *AAXXYYYZZZZ*[10] |
| | *A15L150AA* |
| *Deflussori/ Infusion and transfusion sets* | *DXXXYYYY*[11] |

**Il Direttore dell'Organismo Notificato**
*The Director of Notified Body*
**(Dott.ssa Roberta Marcoaldi)**

Roberta Marcoaldi

Organismo Notificato 0373
*Notified Body 0373*

# *Istituto Superiore di Sanità*

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*of which this technical sheet is an integral part, refers only to the following product(s) that are subject to surveillance:*

***Classe IIa** (Class IIa)*

| ***Nome prodotto*** *(Product name)* | ***Codice*** *(Code)* |
|---|---|
| *Tubi di connessione per aspirazione, non sterile/ Aspiration tube, non sterile*<br>*Set tubi per apparecchiature di dermabrasione, sterile / Set tubes for dermabrasion equipment, sterile* | *EXXYYYYYY*[12] |
| *Drenaggio toracico, sterile/ Thoracic drainage, sterile* | *EXXYYYYYY*[12] |
| *Set per drenaggio toracico, sterile/ Thoracic drainage set, sterile* | *EXXYYYYYY*[12] |

**Il Direttore dell'Organismo Notificato**
*The Director of Notified Body*
**(Dott.ssa Roberta Marcoaldi)**

Roberta Marcoaldi

Organismo Notificato 0373
*Notified Body 0373*

# *Istituto Superiore di Sanità*

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*of which this technical sheet is an integral part, refers only to the following product(s) that are subject to surveillance:*

***Classe IIa** (Class IIa)*

| ***Nome prodotto*** *(Product name)* | ***Codice*** *(Code)* |
|---|---|
| *Catetere arterioso, sterile/ Arterial catheter, sterile* | *ACXXYYY*[13] |
| *Catetere arterioso con prolunga, sterile/ Arterial catheter with extension line, sterile* | *APXXYYY*[13] |

***Classe IIa** (Class IIa)*

| ***Nome prodotto*** *(Product name)* | ***Codice*** *(Code)* |
|---|---|
| *Cannula endotimpanica, sterile/ Endotympanic cannula,sterile* | *COXXCYY*[14] |
| *Mascherina nasale, sterile/ Nasal mask, sterile* | *COXXMYYS*[14] |
| *Mascherina nasale, non sterile/ Nasal mask, non sterile* | *COXXMYY*[14] |
| *Doccia nasale, non sterile/ Nasal irrigation, non sterile* | *COXXDYY*[14] |
| *Forcella nasale, non sterile/ Nasal fork, non sterile* | *COXXFYY*[14] |
| *Oliva nasale, non sterile/ Nasal olive, non sterile* | *COXXOYY*[14] |
| *Boccaglio, non sterile/ Mouthpiece, non sterile* | *COXXBYY*[14] |

[redacted]

*The Director of Notified Body*
**(Dott.ssa Roberta Marcoaldi)**

**Organismo Notificato 0373**
*Notified Body 0373*

# *Istituto Superiore di Sanità*

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*of which this technical sheet is an integral part, refers only to the following product(s) that are subject to surveillance:*

I codici di cui sopra hanno il seguente significato, come da criteri di codifica presentati dalla Ditta e conservati presso questo Organismo Notificato:

[1]M: lettera che individua il gruppo di appartenenza; XX: numeri che indicano la destinazione d'uso; YYY: campo alfanumerico che indica il diametro dell'ago; ZZ: numeri che indicano la lunghezza

[2]M: lettera che individua il gruppo di appartenenza; ILT: lettere che indicano la destinazione d'uso; XX: numeri che indicano il diametro dell'ago; YYY: numeri che indicano la lunghezza

[3]M: lettera che individua il gruppo di appartenenza; LP: lettere che indicano la destinazione d'uso; XXX: numeri che indicano la lunghezza; Y: lettera che indica eventuale zona di distribuzione

[4]M: lettera che individua il gruppo di appartenenza; R: lettera che indica il tipo; Y: lettera che indica il modello; XXX: numeri che indicano la configurazione

[5]M: lettera che individua il gruppo di appartenenza; R: lettera che indica il tipo; YY: lettere che indicano il modello; XXX: numeri che indicano la configurazione

[6]M: lettera che individua il gruppo di appartenenza; DHN: lettere che indicano il tipo; XXX: lettere che indicano il modello

[7]M: lettera che individua il gruppo di appartenenza; DHN: lettere che indicano il tipo; XX: numeri che indicano il diametro dell'ago; YY: numeri che indicano la lunghezza; Z: lettera che indica eventuale distributore;

[8]M: lettera che individua il gruppo di appartenenza; SIT: lettere che indicano il tipo; XXX: numeri che indicano il modello; Y: lettera che indica eventuale zona di distribuzione;

[9]AA: lettere che individuano il gruppo di appartenenza (Accessori); XX: numeri che definiscono il modello; YYYYYY: campo alfanumerico (variabile da 1 a 6 caratteri) che indica la configurazione;

[10]AA: lettere che individuano il gruppo di appartenenza (Prolunghe); XX: numeri che definiscono il modello; YYY: numeri che indicano la lunghezza; ZZZZ: campo alfanumerico (variabile da 0 a 4 caratteri) che indica la configurazione

[11]D: indica il gruppo di appartenenza (Deflussori); XXX: campo alfanumerico che indica il modello; YYYY: campo alfanumerico (variabile da 0 a 4 caratteri) che indica la configurazione;

[12]E: indica il gruppo di appartenenza; XX: numeri che indicano il modello; YYYYYY: campo alfanumerico (variabile da 4 a 6 caratteri) che indicano le varianti del modello;

[13]AC/AP: lettere che individuano il tipo; XX: numeri che indicano il diametro; YYY: campo alfanumerico che indica le varianti;

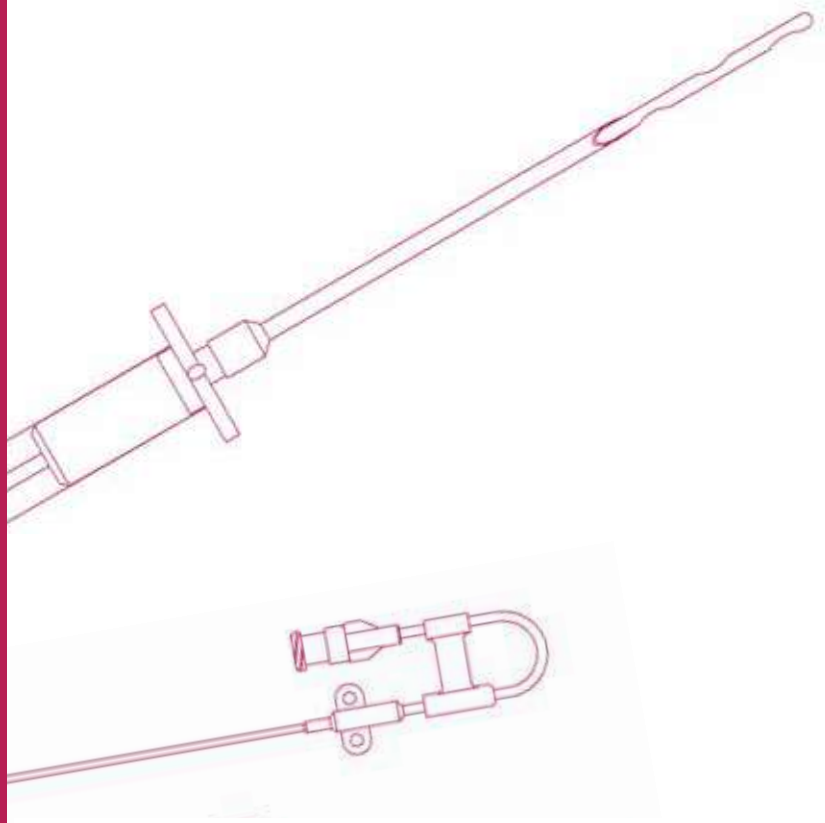
[14]CO: lettere che indicano il gruppo di appartenenza; XX: numeri che indicano il tipo; C: indica la cannula; M: indica la mascherina nasale; D: indica la doccia nasale; F: indica la forcella nasale; O: indica l'oliva nasale; B: indica il boccaglio; S: indica lo speculum; YY: lettere che indicano le varianti. Nel caso di mascherina nasale S indica sterile.

Valutazione della Conformità: vedi MOD-341-01-01 n. 343/19
*Conformity assessment: see MOD-341-01-01 n. 343/19*

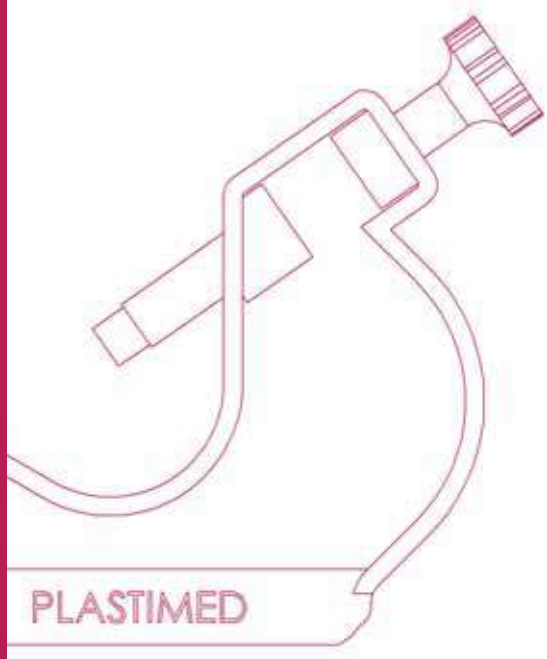
**Il Direttore dell'Organismo Notificato**
*The Director of Notified Body*
**(Dott.ssa Roberta Marcoaldi)**

Roberta Marcoaldi

Innovation & Technologie



# Plastimed®



Wir über uns

# Know How und Erfahrung = Spitzenqualität & Innovation

**Seit 1969** *produziert und vertreibt Plastimed die eigenen Produkte auf dem deutschen Markt. Spätestens seit der Markteinführung des Arteriellen Katheters nach Seldinger und des Katheters für Pleuradrainage steht Plastimed für Innovation und fortlaufende Anpassung von Produkten zur kontinuierlichen Erhöhung der Patienten- und Anwendersicherheit.*

## Unser Team:

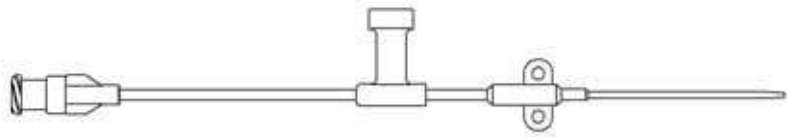
Unsere Produkte sind das Ergebnis eines modernen und innovativen Teamworks zwischen jungen und kreativen Mitarbeitern, erfahrenen und erprobten Experten sowie praktizierenden Ärzten.

## Qualität:

Qualitätssicherung gehört zu unseren Prioritäten, unsere Produkte sind ISO 13485 02/04 zertifiziert und entsprechen den EU-Richtlinie 93/42/EEC des Rats zu Medizinprodukten.

## Produkte:

Die flexiblen Strukturen des Unternehmens sowie unsere fundierten Kenntnisse, ermöglichen eine bedarfsgerechte Entwicklung spezifischer Produkte, die an die besonderen Bedürfnisse der Kunden angepasst sind.



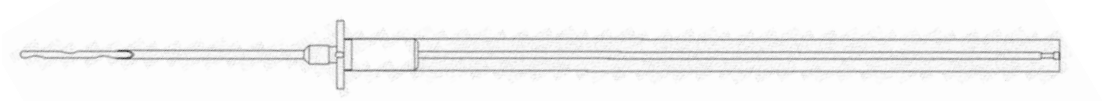
## Innovation & Know How:

### → Einsatz der neuartigsten Kunststoffen

Als einziger Hersteller verwenden wir die drei Kunststoffe:
- **PTFE** für die arterielle Druckmessung
- **Alyphatisches PUR** für die ZVD
- **Lipidfestes Polymethylpenten** für unsere Hähne-,bzw. Hahnbänke-Linie

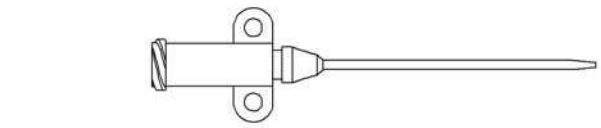
### → Sicherheit garantiert !

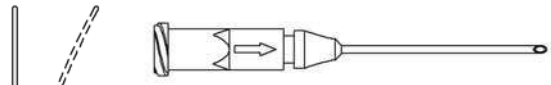
Wir wenden die technisch hochwertigsten und innovativsten Produktionsverfahren an.
Mit der Thermoplasteschweißtechnik beherrschen wir seit 35 Jahren eine Einspritzmethode, die alle Sicherheitsprobleme in der Katheterherstellung löst.



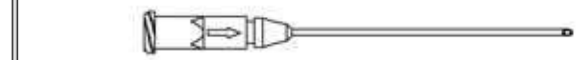
# Inhaltsverzeichnis

# ARTERIO-SELD KATHETER

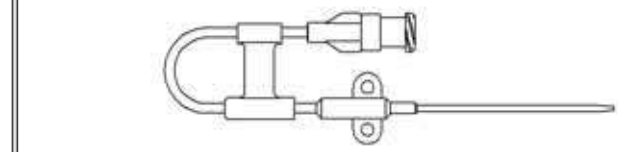


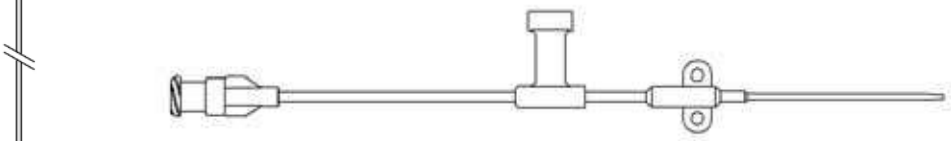


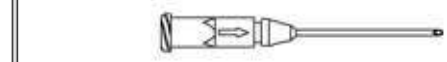
ARTERIO-SELD 40 x 1.3 mm 4F
+ Führungsdraht 0.60 x 220 mm



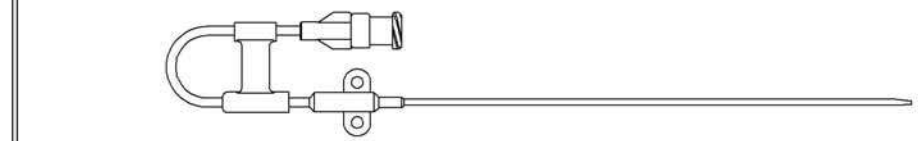
ARTERIO-SELD 110 x 1.3mm 4F
+ Führungsdraht 0.60 x 300 mm

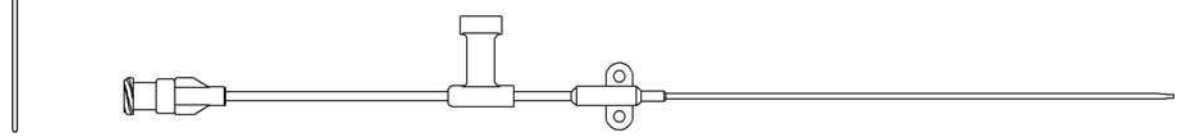


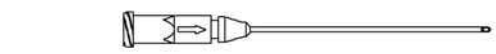




ARTERIO-SELD 40 x 1.3 mm 4F mit Zuleitung und Klipp-Halterung
+ Führungsdraht 0.60 x 220 mm



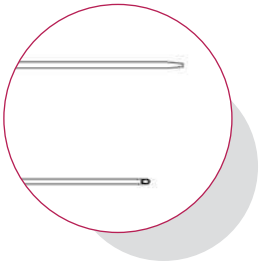




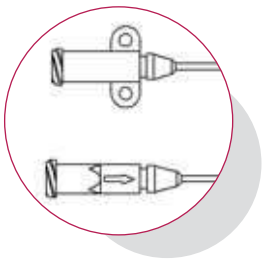
ARTERIO-SELD 110 x 1.3 mm 4F mit Zuleitung und Klipp-Halterung
+ Führungsdraht 0.60 x 300 mm

# Arterio-Seld®

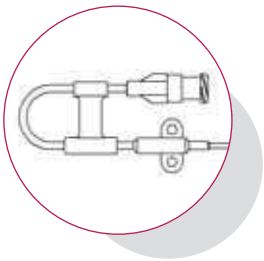
## SELDINGER KATHETER für die ARTERIELLE DRUCKMESSUNG



**1.** Röntgendichter Katheterschlauch aus PTFE zur optimalen Druckübertragung ("Blutlinieneffekt"). Die langverdünnte Spitze erlaubt ein einwandfreies Einlegen des Katheters.



**2.** Patentierter durchsichtiger Katheter-, bzw. Kanülansatz aus exklusivem Thermoplast, mit Doppelfixierungsflügel und -ring. Optimale Einführung des Führungsdrahtes.



**3.** Das exklusive Zuleitungsbesteck zum 180° Kippen mit Klipp-Halterung erlaubt eine für den Patienten schonende Anwendung des Katheters und vermindert (auf beträchtlicher Weise) jedes Infektionsrisiko.

### Paediatrie

| PTFE Katheter | | Führungsdraht | Kanüle | Artikel Nr. | |
|---|---|---|---|---|---|
| L.mm | AD.mm F | ADxL. mm | ADxL. mm | Standard | Mit Zuleitung |
| 20 | 0.7 2F | 0.48 x 220 | 0.7 x 19 22G | 422 022 | 422R022 |
| 20 | 1.0 3F | 0.48 x 220 | 0.9 x 19 20G | 422 023 | 422R023 |
| 30 | 0.7 2F | 0.48 x 220 | 0.7 x 19 22G | 422 032 | 422R032 |
| 40 | 1.0 3F | 0.48 x 220 | 0.9 x 30 20G | 422 043 | 422R043 |
| 40 | 1.3 4F | 0.59 x 220 | 1.1 x 30 19G | 422 044 | 422R044 |
| 60 | 1.0 3F | 0.48 x 220 | 0.9 x 30 20G | 422 063 | 422R063 |
| 60 | 1.3 4F | 0.59 x 220 | 1.1 x 30 19G | 422 064 | 422R064 |

### Erwachsene

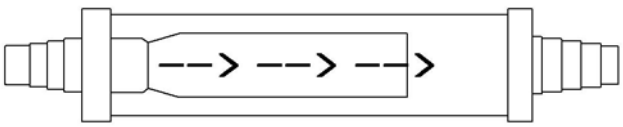
| L.mm | AD.mm F | ADxL. mm | ADxL. mm | Standard | Mit Zuleitung |
|---|---|---|---|---|---|
| 80 | 1.0 3F | 0.48 x 220 | 0.9 x 50 20G | 422 083 | 422R083 |
| 80 | 1.3 4F | 0.59 x 220 | 1.1 x 50 19G | 422 084 | 422R084 |
| 110 | 1.0 3F | 0.48 x 300 | 0.9 x 50 20G | 422 113 | 422R113 |
| 110 | 1.3 4F | 0.59 x 300 | 1.1 x 50 19G | 422 114 | 422R114 |
| 110 | 1.7 5F | 0.88 x 300 | 1.4 x 50 17G | 422 115 | 422R115 |
| 140 | 1.0 3F | 0.48 x 300 | 0.9 x 50 20G | 422 143 | 422R143 |
| 140 | 1.3 4F | 0.59 x 300 | 1.1 x 50 19G | 422 144 | 422R144 |
| 200 | 1.3 4F | 0.59 x 440 | 1.1 x 75 19G | 422 204 | 422R204 |
| 200 | 1.7 5F | 0.88 x 440 | 1.4 x 75 17G | 422 205 | 422R205 |
| 200 | 2.0 6F | 1.14 x 440 | 1.6 x 75 16G | 422 206 | 422R206 |

*1 VE = 20 St. Doppel-Peelpackung. Weitere Modelle auf Anfrage.*

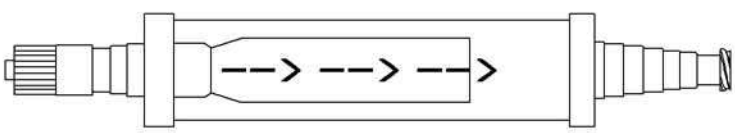
THORAKATH "Standard" Ausführung:
Röntgendichter PE Katheter mit seitlichen Löchern
+sterile Hülse, Punktionskanüle, 3-Wege-Hahn, Ansatz MLL/Konus 6-13 mm

THORAKATH "Safe": gleiche Komponenten
Mit Anti-Knick System zur sicheren Handhabung

Als komplettes "Set" erhältlich: gleiche Komponenten
+2L Beutel, 50 ml SpritzeLL,Gummi-Ansatz, Rückschlagventil M/W LL

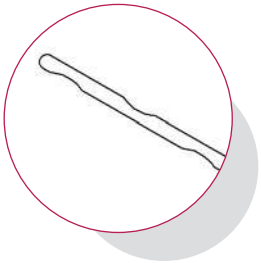


Heimlich Ventil
Einfaches Modell mit Stufen-Ansätzen 6 -10 mm

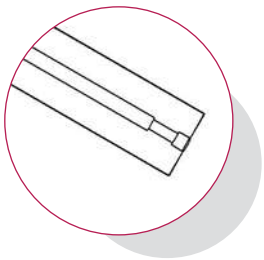


HEIMLICH VENTIL
Einfaches Modell mit LuerLock Ansätzen

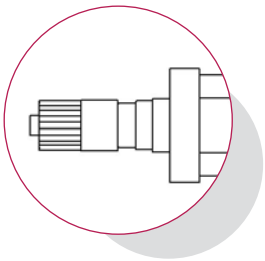
# Thorakath® & Heimlich Ventil



**1.** Kleinlumiger starkkontrastgebender PE Katheter mit dünnwandiger Punktionskanüle. Die Pleuraschneidfläche wird durch den Schirmeffekt geschützt.



**2.** Dichte sterile Einführungshülse für eine saubere und sichere Orientierung im Pleuraraum. Keine chirugische Drainagelegung erforderlich, umfangreicher Anwendungsbereich : Intensivstation, Pneumologie, Interne Medizin, Onkologie, Neonatologie, usw…



**3.** Exklusiver M-LuerLock Ansatz des Doppel-Heimlich Ventils.

## Paediatrie

## Erwachsene

| PE Katheter | | Seitliche | Artikel Nr. | | |
|---|---|---|---|---|---|
| L.mm | AD.mm F | Löcher | Standard | Mit Anti-Knick | SET |
| 300 | 2.0 6F | 4 auf 3cm | 301 306 | 301S306 | 301K306 |
| 400 | 2.7 8F | 5 auf 4cm | 301 408 | 301S408 | 301K408 |
| 500 | 2.7 8F | 10 auf 9 cm | 301 508 | 301S508 | 301K508 |
| 500 | 3.3 10F | 10 auf 9 cm | X | 301S510 | 301K510 |

*1 VE = 20 St. Peelpackung. Weitere Modelle auf Anfrage.*

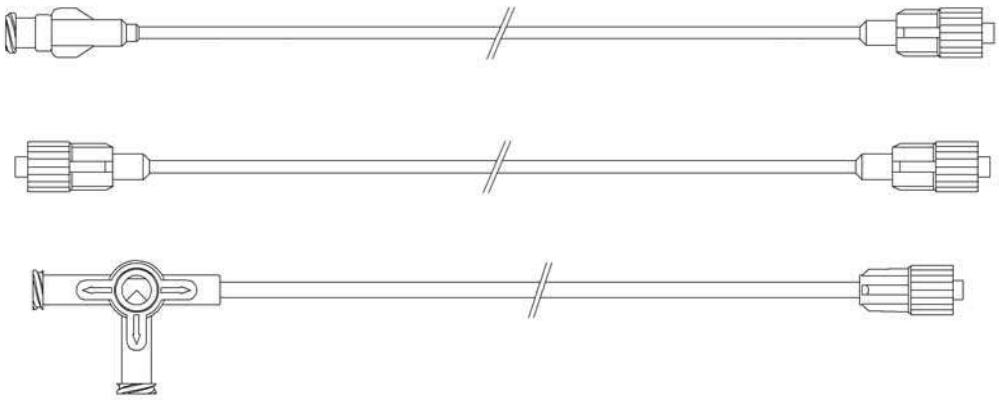
## Heimlich Ventil

| | Artikel Nr. | |
|---|---|---|
| Beschreibung | Einfach | Doppel |
| Ventil mit LuerLock Ansätzen | 691 512 | 691 522 |
| Ventil mit Stufen-Ansätzen 6-10mm | 691 514 | 691 524 |
| Ventil mit Gummi-Ansätzen | 691 516 | 691 526 |

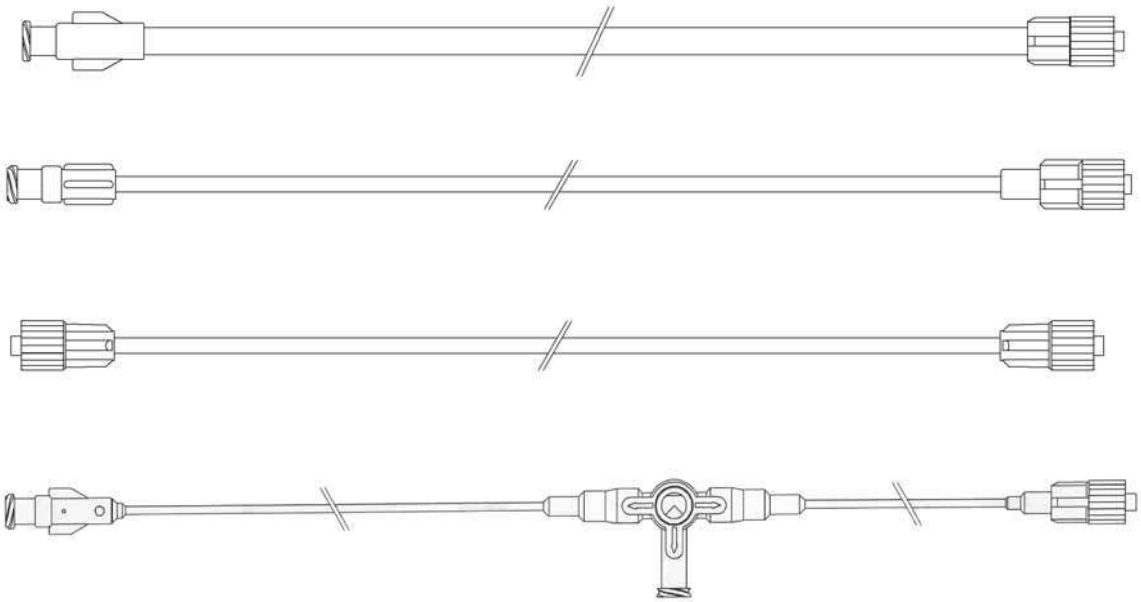
*1 VE = 10 St. Peelpackung. Weitere Modelle auf Anfrage.*

# VERLÄNGERUNGEN

PE VERLÄNGERUNGEN erhältlich in verschiedenen Durchmessern:
M/W , M/M , M/4Wege-Hahn , SPIRAL LuerLock mit loser Überwurfmutter

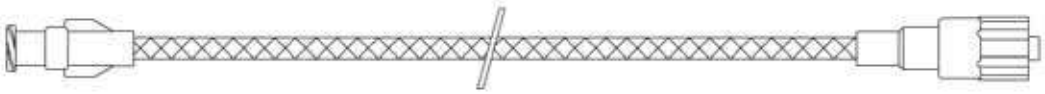


PVC VERLÄNGERUNGEN erhältlich in verschiedenen Durchmessern:
M/W , M/M , M/4Wege-Hahn , SPIRAL LuerLock mit loser Überwurfmutter

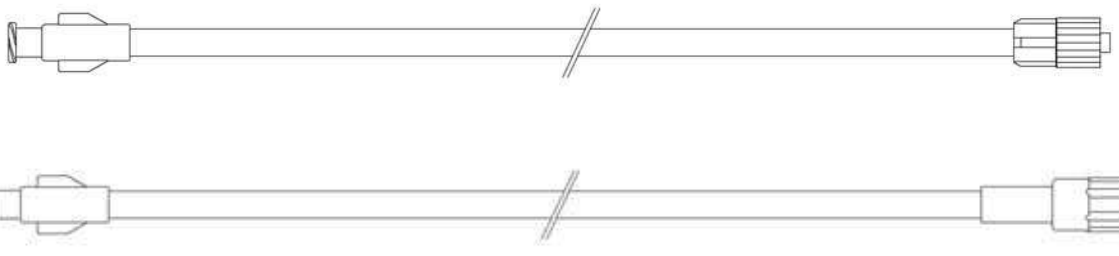


HOCHDRUCK- VERLÄNGERUNGEN 1200PSI:

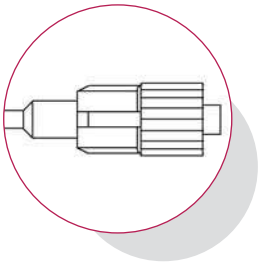
a. aus verstärktem PUR mit loser, bzw. rotativer Überwurfmutter



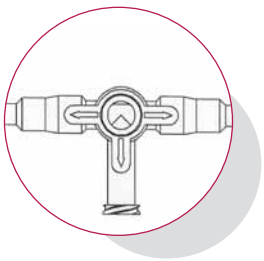
b. aus PVC mit loser, bzw. rotativer Überwurfmutter



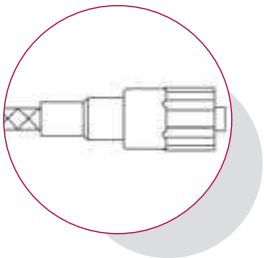
# Verlängerungen



**1.** Kleinlumiger PE Schlauch mit loser Überwurfmutter / Besonders geeignet für die Druckübertragung. Lieferbar mit Farbstreifen.



**2.** Direkt am Schlauch eingeschweißter 4-Wege-Hahn. Spezielles Modell für das Druck-Monitoring.



**3.** Rotativer Adapter/Überwurfmutter bei Hochdruck PUR Verlängerung.

## PE Perfusion

| Länge in cm | ID x AD in mm | Artikel Nr. | ID x AD in mm | Artikel Nr. |
|---|---|---|---|---|
| 13 | 1 X 2 | 117 40131 | 1.5 X 2.5 | 117 40132 |
| 50 | 1 X 2 | 117 40501 | 1.5 X 2.5 | 117 40502 |
| 100 | 1 X 2 | 117 41001 | 1.5 X 2.5 | 117 41002 |
| 150 | 1 X 2 | 117 41501 | 1.5 X 2.5 | 117 41502 |
| 200 | 1 X 2 | 117 42001 | 1.5 X 2.5 | 117 42002 |

## PE MLL/4-Wege-Hahn

| Länge in cm | ID x AD in mm | Artikel Nr. | ID x AD in mm | Artikel Nr. |
|---|---|---|---|---|
| 10 | 1 X 2 | 117 50101 | | |
| 50 | 1 X 2 | 117 50501 | | |
| 150 | 1 X 2 | 117 51501 | 1 X 2 | 117 61501 |
| 200 | 1 X 2 | 117 52001 | 1 X 2 | 117 62001 |

## Hochdruck

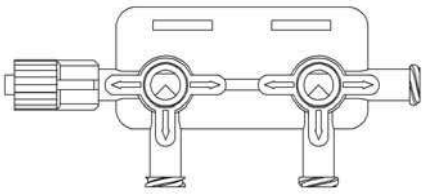
| Länge in cm | ID x AD in mm | Artikel Nr. | ID x AD in mm | Artikel Nr. |
|---|---|---|---|---|
| 30 | 2 X 4 | 111 30304 | 2.5 X 5 | 111 30305 |
| 60 | 2 X 4 | 111 30604 | 2.5 X 5 | 111 30605 |
| 90 | 2 X 4 | 111 30904 | 2.5 X 5 | 111 30905 |
| 120 | 2 X 4 | 111 31204 | 2.5 X 5 | 111 31205 |

## PE M/W LL SPIRAL

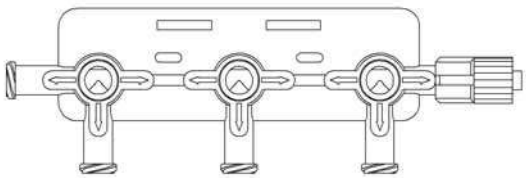
| Länge in cm | ID x AD in mm | Artikel Nr. | ID x AD in mm | Artikel Nr. |
|---|---|---|---|---|
| 200 | 1 X 2 | 117S42001 | 1.5 X 2.5 | 117S42002 |
| 300 | 1 X 2 | 117S43001 | 1.5 X 2.5 | 117S43002 |
| 400 | 1 X 2 | 117S44001 | 1.5 X 2.5 | 117S44002 |

*1 VE = 20 St. Peelpackung. Weitere Modelle auf Anfrage : PVC, Licht-undurchlässlich, mit Farbstreifen, M/M LL, W/W LL, andere Durchmesser, usw...*

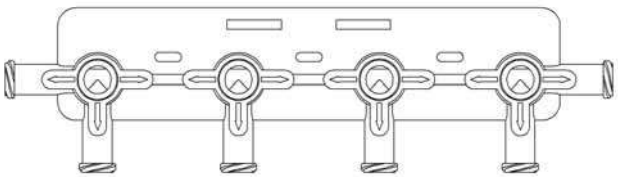
# Hähne und Hahnbänke: Lipidofeste Produkte



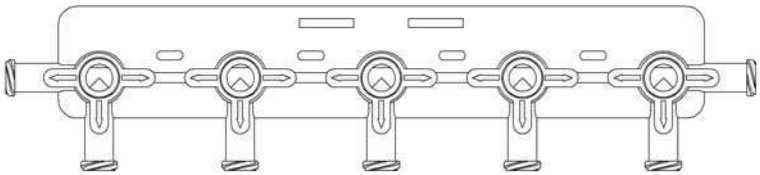
2-fach HAHNBANK: (rot/blau)
lose Überwurfmutter links



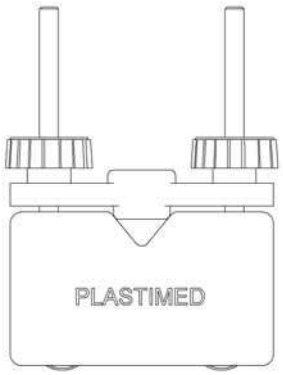
3-fach HAHNBANK: (rot/blau/gelb)
lose Überwurfmutter rechts



4-fach HAHNBANK: (rot/blau/gelb/grün)
6 W LuerLock Ansätze

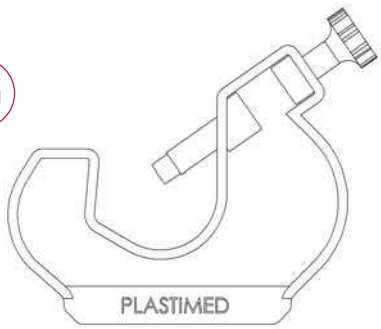


5-fach HAHNBANK (rot/blau/gelb/grün/grau)
7 W LuerLock Ansätze

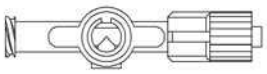



Universalhalter

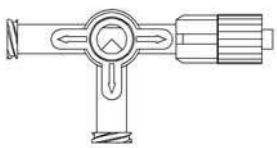
Neu




Einweghalter



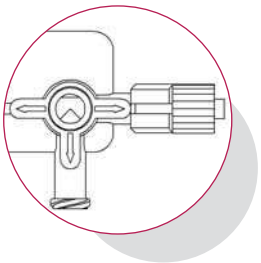
2-Wege Hahn mit loser Überwurfmutter



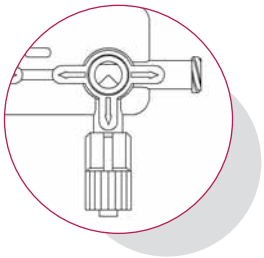
4-Wege Hahn mit loser Überwurfmutter

# Hähne und Hahnbänke / Halter

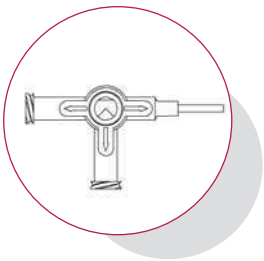
## Alle Produkte aus lipidofestem Polymethylpenten



**1.** Lose Überwurfmutter links, bzw. rechts der Hahnbänke.



**2.** Lose Überwurfmutter vorne an der Monitoring-Hahnbank.



**3.** 4-Wege-Hahn mit eingeschweißtem Rohransatz zur Schlauchkupplung. In verschiedenen Durchmessern lieferbar.

## Hahnbänke

| BESCHREIBUNG / MODELL | Artikel Nr. | | | |
|---|---|---|---|---|
| | 2fach | 3fach | 4fach | 5fach |
| Alle W LuerLock Ansätze | 602 000 | 603 000 | 604 000 | 605 000 |
| Mit loser Überwurfmutter links | 602 004 | 603 004 | 604 004 | 605 004 |
| Mit loser Überwurfmutter rechts | 602 006 | 603 006 | 604 006 | 605 006 |
| Mit Verlängerung M/M LL | | | | |
| 2X3,2 mm - 50 cm | 602 050 | 603 050 | 604 050 | 605 050 |
| 100 cm | 602 100 | 603 100 | 604 100 | 605 100 |
| 150 cm | 602 150 | 603 150 | 604 150 | 605 150 |
| 200 cm | 602 200 | 603 200 | 604 200 | 605 200 |

*Peelpackung 1VE = 20 St. Weitere Modelle auf Anfrage*

## Hähne

| BESCHREIBUNG / MODELL | ARTIKEL Nr. |
|---|---|
| 2-Wege-Hahn mit loser Überwurfmutter | 601 220 |
| 4-Wege-Hahn mit loser Überwurfmutter | 601 320 |
| 4-Wege-Hahn mit Rohransatz für Katheter 1.7 mm | 613 508 |

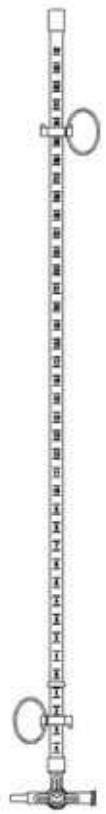
*Peelpackung 1VE = 20 St. Weitere Modelle auf Anfrage*

## Halter für Hahnbänke

| BESCHREIBUNG / MODELL | | ARTIKEL Nr. |
|---|---|---|
| Exklusiver Einweghalter für PLASTIMED Hahnbänke | Neu | 666 100 |
| Universalhalter | | 666 200 |

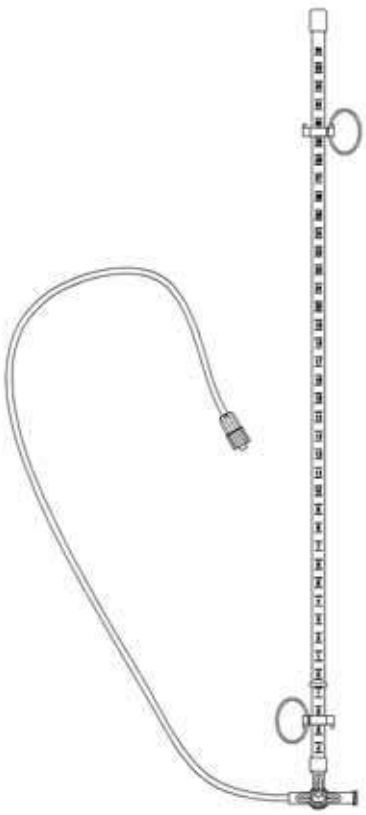
# Manometer für Zentralvenendruck





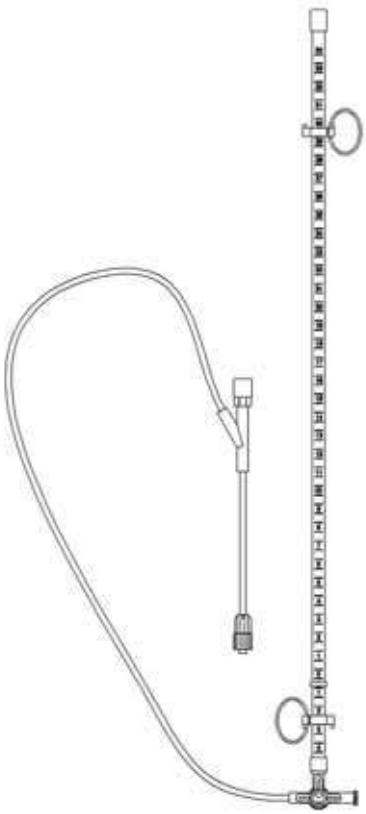
Einfache Ausführung:
graduierter - 4/+33 cm steifer Messrohr mit Kugelanzeiger + 1 3 Wegehahn und 2 Stativfixierungen

Artikel Nr.: 671 000



Ausführung mit PVC Verlängerung:
gleiche Komponenten + Verlängerung 150 cm

Artikel Nr.: 671 150



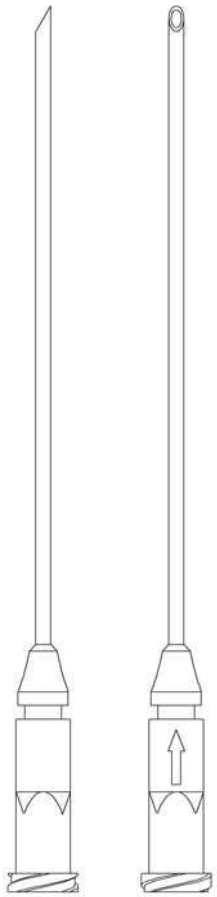
Ausführung mit PVC Verlängerung & Y INT: gleiche Komponenten + Verlängerung 150 cm und Y-Injektion-Ansatz

Artikel Nr.: 671Y150

*Peelpackung 1VE = 10St. Weitere Modelle auf Anfrage.*

# Seldinger Kanülen: Intro-Seld

Die Referenzkanüle seit 30 Jahren

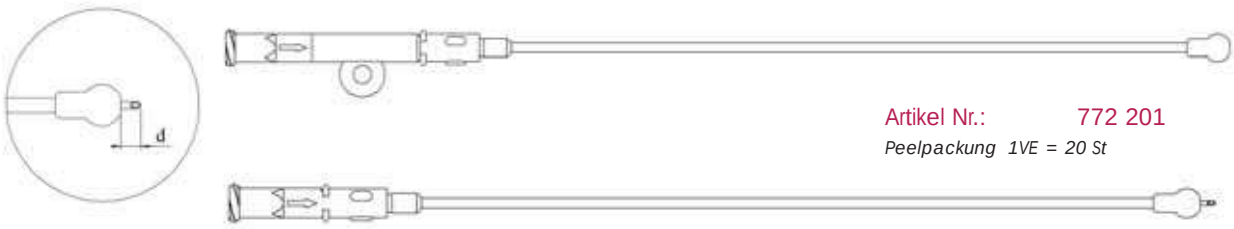


| L.mm | ID mm | AD mm | G | Führungsdraht AD inch | Artikel Nr. |
|---|---|---|---|---|---|
| 19 | 0.51 | 0.71 | 22 | .018 " | 242 007 |
| 30 | 0.62 | 0.92 | 20 | .019 " | 243 010 |
| 50 | 0.62 | 0.92 | 20 | .019 " | 245 010 |
| 30 | 0.82 | 1.12 | 19 | .024 " | 243 013 |
| 50 | 0.82 | 1.12 | 19 | .024 " | 245 013 |
| 75 | 0.82 | 1.12 | 19 | .024 " | 248 013 |
| 75 | 1.12 | 1.42 | 17 | .035 " | 248 017 |
| 75 | 1.32 | 1.62 | 16 | .045 " | 248 020 |

*Peelpackung 1VE = 50 St. Weitere Modelle auf Anfrage.*

# Besteck für Para-Uterine Blockade

für lokale Anaesthesie mit Schutzkugel



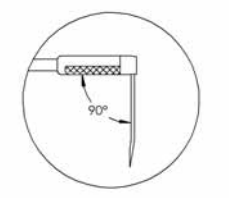

Artikel Nr.: 772 201

*Peelpackung 1VE = 20 St*

20 cm x 1.0 mm
Metallkanüle

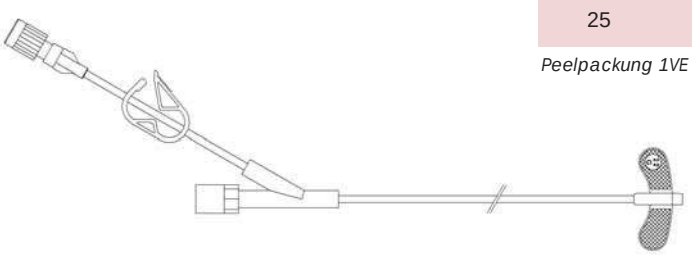
# HUBER Nadeln mit Verlängerung

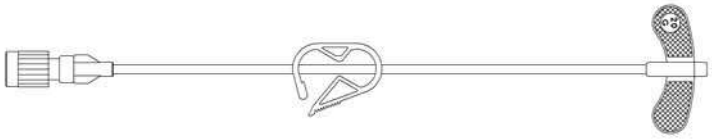
Ausführung mit Verlängerung & Y INT: gleiche Komponenten Verlängerung 20 cm und Y-Injektionsansatz




| L.mm | AD mm | G | Artikel Nr. Ohne Y-INT | Artikel Nr. Mit Y-INT |
|---|---|---|---|---|
| 20 | 0.71 | 22 | 745 222 | 745Y222 |
| 25 | 0.71 | 22 | 745 322 | 745Y322 |
| 20 | 0.92 | 20 | 745 220 | 745Y220 |
| 25 | 0.92 | 20 | 745 320 | 745Y320 |
| 20 | 1.12 | 19 | 745 219 | 745Y219 |
| 25 | 1.12 | 19 | 745 319 | 745Y319 |

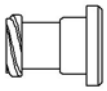
*Peelpackung 1VE = 50St. Weitere Modelle auf Anfrage.*



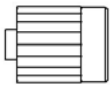


# Ansätze / Stopfen / Verschlüsse

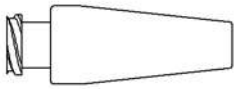




STOPFEN W LuerLock
Artikel Nr. 695 055

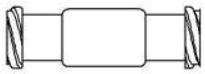


STOPFEN M LuerLock
Artikel Nr. 695 011

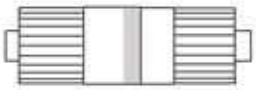


ANSATZ WLL/Konus 6 - 13 mm
Artikel Nr. 695 053

ANSATZ: MLL / KONUS 6 - 13mm
Artikel Nr. 695 013

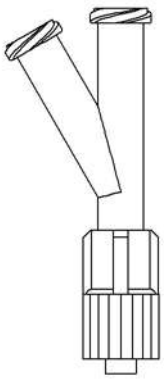


ANSATZ W/W LuerLock
Artikel Nr. 695 524



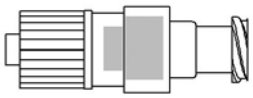
ANSATZ M/M LuerLock rotativ
Artikel Nr. 695 226

ANSATZ M/M LuerLock
Artikel Nr. 695 224



Y-ANSATZ mit loser Überwurfmutter
Artikel Nr. 695 789

Y-ANSATZ mit rotativer Überwurfmutter
Artikel Nr. 695 797



ANSATZ M/W LuerLock
Artikel Nr. 695 465
mit integriertem Rückschlag-Ventil

*Alle Produkte: Peelpackung 1VE = 25St. Weitere Komponenten auf Anfrage*

# Bestell Nr. & Maßeinheiten

| ARTIKEL Nr. | SEITE | ARTIKEL Nr. | SEITE |
|---|---|---|---|
| 111 30304 | 7 | 422 113 | 3 |
| 111 30604 | 7 | 422 114 | 3 |
| 111 30904 | 7 | 422 115 | 3 |
| 111 31204 | 7 | 422 143 | 3 |
| 111 30305 | 7 | 422 144 | 3 |
| 111 30605 | 7 | 422 204 | 3 |
| 111 30905 | 7 | 422 205 | 3 |
| 111 31205 | 7 | 422 206 | 3 |
| 117 40131 | 7 | 422R083 | 3 |
| 117 40501 | 7 | 422R084 | 3 |
| 117 41001 | 7 | 422R113 | 3 |
| 117 41501 | 7 | 422R114 | 3 |
| 117 42001 | 7 | 422R115 | 3 |
| 117 40132 | 7 | 422R143 | 3 |
| 117 40502 | 7 | 422R144 | 3 |
| 117 41002 | 7 | 422R204 | 3 |
| 117 41502 | 7 | 422R205 | 3 |
| 117 42002 | 7 | 422R206 | 3 |
| 117 50101 | 7 | 601 220 | 9 |
| 117 50501 | 7 | 601 320 | 9 |
| 117 51001 | 7 | 602 000 | 9 |
| 117 51501 | 7 | 602 004 | 9 |
| 117 61001 | 7 | 602 006 | 9 |
| 117 61501 | 7 | 602 050 | 9 |
| 117S42001 | 7 | 602 100 | 9 |
| 117S43001 | 7 | 602 150 | 9 |
| 117S44001 | 7 | 602 200 | 9 |
| 117S42002 | 7 | 603 000 | 9 |
| 117S43002 | 7 | 603 004 | 9 |
| 117S44002 | 7 | 603 006 | 9 |
| 242 007 | 11 | 603 050 | 9 |
| 243 010 | 11 | 603 100 | 9 |
| 245 010 | 11 | 603 150 | 9 |
| 243 013 | 11 | 603 200 | 9 |
| 245 013 | 11 | 604 000 | 9 |
| 248 013 | 11 | 604 004 | 9 |
| 248 017 | 11 | 604 006 | 9 |
| 248 020 | 11 | 604 050 | 9 |
| 301 306 | 5 | 604 100 | 9 |
| 301 408 | 5 | 604 150 | 9 |
| 301 508 | 5 | 604 200 | 9 |
| 301 510 | 5 | 605 000 | 9 |
| 301K306 | 5 | 605 004 | 9 |
| 301K408 | 5 | 605 006 | 9 |
| 301K508 | 5 | 605 050 | 9 |
| 301K510 | 5 | 605 100 | 9 |
| 301S508 | 5 | 605 150 | 9 |
| 301S510 | 5 | 605 200 | 9 |
| 422 022 | 3 | 613 508 | 9 |
| 422 023 | 3 | 666 100 | 9 |
| 422 032 | 3 | 666 200 | 9 |
| 422 043 | 3 | 671 000 | 10 |
| 422 044 | 3 | 671 150 | 10 |
| 422 063 | 3 | 671Y150 | 10 |
| 422 064 | 3 | 691 512 | 5 |
| 422R022 | 3 | 691 514 | 5 |
| 422R023 | 3 | 691 516 | 5 |
| 422R032 | 3 | 691 522 | 5 |
| 422R063 | 3 | 691 524 | 5 |
| 422R064 | 3 | 691 526 | 5 |
| 422 083 | 3 | 745 alle Ø | 11 |
| 422 084 | 3 | 745Y alle Ø | 11 |
| 422 085 | 3 | 772 201 | 11 |

**ÄQUIVALENZ DER AUßENDURCHMESSER**

| Nadel / Kanüle / Führungsdraht | | |
|---|---|---|
| US Gauge = G | Inch " | mm |
| 30 | .012 | 0.31 |
| 29 | .013 | 0.33 |
| 28 | .014 | 0.36 |
| 27 | .016 | 0.41 |
| 26 | .018 | 0.46 |
| 25 | .020 | 0.51 |
| 24 | .022 | 0.56 |
| 23 | .025 | 0.63 |
| 22 | .028 | 0.71 |
| 21 | .032 | 0.81 |
| 20 | .035 | 0.89 |
| 19 | .042 | 1.10 |
| 18 | .049 | 1.24 |
| 17 | .058 | 1.47 |
| 16 | .065 | 1.65 |
| 15 | .072 | 1.83 |
| 14 | .083 | 2.11 |
| 13 | .095 | 2.41 |
| 12 | .109 | 2.77 |
| 11 | .120 | 3.05 |
| 10 | .134 | 3.40 |

| KATHETER | | |
|---|---|---|
| CH=FG=F | Inch " | mm |
| 1 | .013 | 0.33 |
| 1.5 | .019 | 0.51 |
| 2 | .028 | 0.70 |
| 2.5 | .035 | 0.89 |
| 3 | .039 | 1.00 |
| 3.5 | .045 | 1.14 |
| 4 | .052 | 1.33 |
| 4.5 | .059 | 1.50 |
| 5 | .066 | 1.67 |
| 5.5 | .071 | 1.80 |
| 6 | .079 | 2.00 |
| 6.5 | .085 | 2.16 |
| 7 | .092 | 2.33 |
| 7.5 | .098 | 2.49 |
| 8 | .105 | 2.67 |
| 8.5 | .111 | 2.83 |
| 9 | .118 | 3.00 |
| 10 | .131 | 3.31 |
| 11 | .144 | 3.67 |
| 12 | .157 | 4.00 |
| 13 | .170 | 4.33 |
| 14 | .184 | 4.67 |
| 15 | .197 | 5.00 |

| Inch " | mm |
|---|---|
| .039 | 1.00 |
| 1 | 25.4 |
| 12 = 1 foot | 305 |
| 3 feet = 1 yard | 901 |

| **Schlauchinnenräume** | |
|---|---|
| Innen Ø | Wert/10 cm Länge |
| 1,0 mm | 0,08 ml |
| 1,5 mm | 0,15 ml |
| 2,0 mm | 0,31 ml |
| 2,5 mm | 0,49 ml |

# Kontaktadresse

Plastimed GmbH
Lebacherstr. 4
66113 Saarbrücken
Tel.: 0681-99 63368
Fax: 0681-99 63 111
E-Mail: info@plastimed-gmbh.de

GMED
GROUPE LNE

**ATTESTATION** / *CERTIFICATE* **N° 23818 rev. 10**
**Délivrée à Paris le 21 février 2019**
*Issued in Paris on February 21st, 2019*

# ATTESTATION CE / *EC CERTIFICATE*

**Approbation du Système Complet d'assurance Qualité**/ *Approval of full Quality Assurance System*
**ANNEXE II excluant le point 4 Directive 93/42/CEE relative aux dispositifs médicaux**
*ANNEX II excluding section 4 Directive 93/42/EEC concerning medical devices*
**Pour les dispositifs de classe III, un certificat CE de conception est requis**
**For class III devices, a EC design certificate is required**

**Fabricant** / *Manufacturer*

**PRODIMED**
**6 rue Louis Armand**
**95130 LE PLESSIS BOUCHARD FRANCE**

**Catégorie du(des) dispositif(s)** / *Device(s) category*

**Dispositifs médicaux stériles comprenant des dispositifs pour l'accès vasculaire, l'accès gastro-intestinal, le drainage, le prélèvement, la gynécologie et l'obstétrique.**

*sterile medical devices including devices for vascular access, gastro-intestinal access, drainage and sampling, gynaecological and obstetric procedures.*

Voir détails sur addendum / See attachment for additional information

**GMED atteste qu'à l'examen des résultats figurant dans le rapport référencé P600032, le système d'assurance qualité - pour la conception, la production et le contrôle final - des dispositifs médicaux énumérés ci-dessus est conforme aux exigences de l'annexe II excluant le point 4 de la Directive 93/42/CEE.**

*GMED certifies that, on the basis of the results contained in the file referenced P600032, the quality system - for design, manufacturing, and final inspection - of medical devices listed here above complies with the requirements of the Directive 93/42/EEC, annex II excluding section 4*

La validité du présent certificat est soumise à une vérification périodique ou imprévue
The validity of the certificate is subject to periodic or unexpected verification

**Début de validité** / *Effective date :* **February 21st, 2019 (included)**
**Valable jusqu'au** / *Expiry date :* **August 15th, 2022 (included)**

GMED SAS GMED SAS

**On behalf of the President**
**Béatrice LYS**
**Technical Director**

GMED_0293-F-V9-07-2016

GMED - 23818 rev. 10
Renouvelle le certificat 23818-9

GMED
GROUPE LNE

**Addendum au certificat n° 23818 rev. 10** **page 1/1**
*Addendum of the certificate n° 23818 rev. 10*
Dossier / *File* N° P600032

## Identification des dispositifs / *Identification of devices*

**Version française :**
**Dispositifs médicaux stériles comprenant des dispositifs pour l'accès vasculaire, l'accès gastro-intestinal, le drainage, le prélèvement, la gynécologie et l'obstétrique.**

- **Cathéters artériels périphériques stériles à usage unique**
- **Cathéters veineux périphériques stériles à usage unique**
- **Cathéters veineux périphériques à aiguille stériles à usage unique**
- **Aiguilles stériles à usage unique**
- **Drainage abdominal et thoracique stériles à usage unique**

***Version anglaise :***
***Sterile medical devices including devices for vascular access, gastro-intestinal access, drainage and sampling, gynaecological and obstetric procedures.***

- ***Sterile single use arterial catheters for peripheral use***
- ***Sterile single use peripheral venous catheters***
- ***Sterile single use peripheral venous catheters with needle***
- ***Sterile single use needles***
- ***Sterile single use abdominal and thoracic drainage devices***

**Les produits couverts par ce certificat sont référencés sur la liste des produits de PRODIMED (3 pages) datée du 14 février 2019, authentifiée par GMED en date du 19 février 2019**

***Medical devices covered by this certificate are referenced on the PRODIMED's list of products (3 pages) dated February 14th, 2019, authenticated by GMED on February 19th, 2019***

**Ce certificat couvre le site et les activités suivants**
*This certificate covers the following site and activities*

- **PRODIMED – 6 rue Louis Armand 95130 LE PLESSIS BOUCHARD FRANCE**
  **Siège social – Activités de conception, de fabrication et de contrôle final** / *Headquarters – Design, manufacturing and final inspection activities*

GMED | 0459

**On behalf of the President**
**Béatrice LYS**
**Technical Director**

**LISTE DES PRODUITS/LIST OF PRODUCTS**
**Annexe II excluant le point 4 Directive 93/42/CEE**
**Annex II excluding section 4 Directive 93/42/EEC**

PRODIMED

Cathéters **artériels** (ombilicaux) périphériques stériles à usage **unique**
Cathéters **veineux** (ombilicaux) périphériques stériles à usage **unique**

**Sterile** single use arterial **(umbilical)** catheter for peripheral use
Sterile single use **peripheral venous** (umbilical) catheter

| REFERENCE | DESIGNATION | CLASSE |
|---|---|---|
| 1183.12 | OMBILICATH 3,5 F | II b |
| 1194.12 | OMBILICATH 3,5F PU 40 cmx 1,2 mm | II b |
| 11621.13 | OMBILICATH 4F - 2L PU 15 cm x 1,3 mm | II b |
| 11622.13 | OMBILICATH 4F - 2L PU 20 cm x 1,3 mm | II b |
| 11623.13 | OMBILICATH 4F - 2L PU 30 cm x 1,3 mm | II b |
| 1183.17 | OMBILICATH 5F | II b |
| 11623.17 | OMBILICATH 5F - 2L PU 30 cm x 1,7 mm | II b |
| 1194.17 | OMBILICATH 5F PU 40 cm x 1,7 mm | II b |
| 1183.23 | OMBILICATH 7F PU 30 cm x 2,3 mm | II b |

Cathéters veineux périphériques à aiguille stériles à usage unique

Sterile single use Peripheral venous catheters with needle

| REFERENCE | DESIGNATION | CLASSE |
|---|---|---|
| 1244.13 | ENDOCATH 40CM X 1.3MM 4F | II b |
| 1246.13 | ENDOCATH 60CM X 1.3MM 4F | II b |
| 1246.15 | ENDOCATH 60CM X 1.5MM 4.5F | II b |

GMED (0459) reconnait que son certificat CE
est valide pour les dispositifs médicaux décrits
..... 19 FEV. 2019
GMED (0459) recognizes that its EC certificate
is valid for the medical devices listed

14/02/2019



PRODIMED S.A.S. ETABLISSEMENT SECONDAIRE
ZAE, 6 rue Louis Armand - 95130 LE PLESSIS BOUCHARD France - Tél. 33 (0)1 34 44 15 15 - Fax 33 (0)1 30 72 22 08
Siret : 324 918 283 00031
PRODIMED S.A.S. SIEGE SOCIAL
ZI, 4 avenue de l'Europe - 60530 NEUILLY EN THELLE - France - Tél. 33 (0)3 44 26 63 46 - Fax 33 (0)3 44 26 93 37
Site Internet : www.prodimed.com e-mail : contact@prodimed.com
S.A.S. au capital de 728 000 euros - RCS Compiègne B 324 918 283 - Code APE 3250A - Siret : 324 918 283 00023
PRODUCTION DE MATERIEL MEDICO - CHIRURGICAL

**LISTE DES PRODUITS/LIST OF PRODUCTS**
**Annexe II excluant le point 4 Directive 93/42/CEE**
**Annex II excluding section 4 Directive 93/42/EEC**

PRODIMED

Cathéters artériels périphériques stériles à usage unique

Sterile single use Arterial catheters for peripheral use

GMED (0459) reconnait que son certificat CE est valide pour les dispositifs médicaux décrits 19 FEV. 2019

GMED (0459) recognizes that its EC certificate is valid for the medical devices listed

| REFERENCE | DESIGNATION | CLASSE |
|---|---|---|
| 3842.09 | SELDICATH PU EXTENSION 4CM 20G 0.9MM | II b |
| 3843.09 | SELDICATH PU EXTENSION 6CM 20G 0.9MM | II b |
| 3843.12 | SELDICATH PU EXTENSION 6CM 18G 1.2MM | II b |
| 3844.09 | SELDICATH PU EXTENSION 8CM 20G 0.9MM | II b |
| 3844.12 | SELDICATH PU EXTENSION 8CM 18G 1.2MM | II b |
| 3846.09 | SELDICATH PU EXTENSION 11CM 20G 0.9MM | II b |
| 3846.12 | SELDICATH PU EXTENSION 11CM 18G 1.2MM | II b |
| 3848.12 | SELDICATH PU EXTENSION 15CM 18G 1.2MM | II b |
| 3849.12 | SELDICATH PU EXTENSION 20CM 18G 1.2MM | II b |
| 3871.07 | SELDICATH FEP 2CM 22G 0.7MM | II b |
| 3871.10 | SELDICATH PTFE 2CM 20G 1.0MM | II b |
| 3872.07 | SELDICATH FEP 3CM 22G 0.7MM | II b |
| 3872.10 | SELDICATH PTFE 4CM 20G 1.0MM | II b |
| 3872.13 | SELDICATH PTFE 4CM 18G 1.3MM | II b |
| 3873.10 | SELDICATH PTFE 6CM 20G 1.0MM | II b |
| 3873.13 | SELDICATH PTFE 6CM 18G 1.3MM | II b |
| 3874.10 | SELDICATH PTFE 8CM 20G 1.0MM | II b |
| 3874.13 | SELDICATH PTFE 8CM 18G 1.3MM | II b |
| 3874.17 | SELDICATH PTFE 8CM 16G 1.7MM | II b |
| 3874C10 | SELDICATH PTFE 8CM 20G 1.0MM AIG.COURTE | II b |
| 3876.10 | SELDICATH PTFE 11CM 20G 1.0MM | II b |
| 3876.13 | SELDICATH PTFE 11CM 18G 1.3MM | II b |
| 3876.17 | SELDICATH PTFE 11CM 16G 1.7MM | II b |
| 3876.20 | SELDICATH PTFE 11CM 14G 2.0MM | II b |
| 3881.10 | SELDICATH PTFE 15CM 20G 1.0MM | II b |
| 3881.13 | SELDICATH PTFE 15CM 18G 1.3MM | II b |
| 3881.13L | SELDICATH PTFE 15CM 18G 1.3MM AIG.LONG | II b |
| 3882.10 | SELDICATH PTFE 20CM 20G 1.0MM | II b |
| 3882.13 | SELDICATH PTFE 20CM 18G 1.3MM | II b |
| 3882.17 | SELDICATH PTFE 20CM 16G 1.7MM | II b |
| 3882.20 | SELDICATH PTFE 20CM 14G 2.0MM | II b |
| 3883.10 | SELDICATH PTFE 30CM 20G 1.0MM | II b |
| 3883.13 | SELDICATH PTFE 30CM 18G 1.3MM | II b |
| 3883.17 | SELDICATH PTFE 30CM 16G 1.7MM | II b |
| 3883.20 | SELDICATH PTFE 30CM 14G 2.0MM | II b |

Vu

14/02/2019



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Site Internet : www.prodimed.com e-mail : contact@prodimed.com
S.A.S. au capital de 728 000 euros - RCS Compiègne B 324 918 283 - Code APE 3250A - Siret : 324 918 283 00023

PRODUCTION DE MATERIEL MEDICO - CHIRURGICAL

**LISTE DES PRODUITS/LIST OF PRODUCTS**
**Annexe II excluant le point 4 Directive 93/42/CEE**
**Annex II excluding section 4 Directive 93/42/EEC**

PRODIMED

Aiguilles stériles à usage unique

Sterile single use needles

| REFERENCE | DESIGNATION | CLASSE |
|---|---|---|
| 1915.10 | MICRODARD 55MM POUR CATHETER 1.0MM | II a |
| 1917.20 | MICRODARD 75MM POUR CATHETER 2.0MM | II a |
| 1935.07 | MICRODARD 5CM DIA.INT 0.7MM | II a |
| 1938.10 | MICRODARD 8CM DIA.INT 1.0MM | II a |
| 1938.13 | MICRODARD 8CM DIA.INT 1.3MM | II a |
| 2917.10 | MICRODARD 7CM MANDRIN INOX 1.0MM | II a |
| 8752.10 | DISP BLOC PARA-CERVICAL DEPASST AIG46MM | II a |
| 8755.10 | DISP BLOC PARA-CERVICAL DEPASST AIG 6MM | II a |

Drainage abdominal stérile à usage unique

Sterile single use Abdominal drainage devices

| REFERENCE | DESIGNATION | CLASSE |
|---|---|---|
| 6837.10 | MICRODARD PONCTION D'ASCITE 7CM | II a |

Drainage thoracique stérile à usage unique

Sterile single use thoracic drainage devices

| REFERENCE | DESIGNATION | CLASSE |
|---|---|---|
| 5323.20 | PLEUROCATH NEONATAL 30CM X 2.0MM 6F | II a |
| 5324.27 | PLEUROCATH PEDIATRIE 40CM X 2.7MM 8F | II a |
| 5325.27 | PLEUROCATH ADULTES 50CM X 2.7MM 8F | II a |
| 5325.33 | PLEUROCATH ADULTES 50CM X 3.3MM 10F | II a |
| 5325P33 | PLEUROCATH ADULTES 50CM X 3.3MM 10F | II a |
| 5334.27 | PLEUROCATH SAMU 40CM X 2.7MM 8F | II a |
| 5343.20 | PLEUROCATH SELDINGER 25CM X 2MM 6F | II a |
| 5344.27 | PLEUROCATH SELDINGER 40CM X 2.7MM 8F | II a |
| 5344.33 | PLEUROCATH SELDINGER 40CM X 3.3MM 10F | II a |
| 5344.40 | PLEUROCATH SELDINGER 40CM X 4.0MM 12F | II a |
| 5354.40 | PLEUROCATH SELDINGER 40CM 12F/AIG TUOHY | II a |
| 5375.27 | PLEUROCATH GUIBOUT 50CM X 2.7MM 8F | II a |

GMED (0459) recognizes that its EC certificate is valid for the medical devices listed
GMED (0459) reconnaît que son certificat CE est valide pour les dispositifs médicaux écrits
19 FEV. 2019



14/02/2019

PRODIMED S.A.S. ETABLISSEMENT SECONDAIRE
ZAE, 6 rue Louis Armand - 95130 LE PLESSIS BOUCHARD France - Tél. 33 (0)1 34 44 15 15 - Fax 33 (0)1 30 72 22 08
Siret : 324 918 283 00031

PRODIMED S.A.S. SIEGE SOCIAL
ZI, 4 avenue de l'Europe - 60530 NEUILLY EN THELLE - France - Tél. 33 (0)3 44 26 63 46 - Fax 33 (0)3 44 26 93 37
Site Internet : www.prodimed.com e-mail : contact@prodimed.com
S.A.S. au capital de 726 000 euros - RCS Compiègne B 324 918 283 - Code APE 3250A - Siret : 324 918 283 00023

PRODIMED

## EC DECLARATION OF CONFORMITY

Manufacturer's Name: **PRODIMED**

Address : 6, Rue Louis Armand
95130 Le Plessis Bouchard
France

Declares that the medical device ranges described hereafter (details below):

**Sterile single-use arterial catheter for peripheral use**
**Seldicath®**

- are in conformity with the essential requirements and provisions of European Directive 93/42/EEC dated June 14th 1993 transcribed in French law by the Decrees n° 95-292, n° 2009-482 and n° 2010-270,

- are subjected to the procedure in Annex II (excluding Section 4) of European Directive 93/42/EEC under the supervision of Notified Body Number 0459 :

  LNE – G-MED
  Laboratoire National de Métrologie et d'Essais
  1, rue Gaston Boissier
  75724 PARIS Cedex15

This declaration is based on various elements as:

- **V63** technical record information demonstrates the conformity with essential requirements of the 93/42/CEE directive.

- The certificate N° **23831** issued by our notified body (LNE-GMed) certifies Quality Management System developed by PRODIMED complies with the requirements of the international standards ISO 13485: 2003 – NF EN ISO 13485 : 2012.

- The certificate N° **23818** issued by our notified body (LNE-GMed) certifies that Quality System for design, manufacturing and final inspection complies with the requirements of the Directive 93/42/EEC, Annex II excluding section 4.

Le Plessis Bouchard, January 4th 2018

Patrick CHAULET
General Manager



**PRODIMED S.A.S. ETABLISSEMENT SECONDAIRE**
ZAE, 6 rue Louis Armand - 95130 LE PLESSIS BOUCHARD France - Tél. 33 (0)1 34 44 15 15 - Fax 33 (0)1 30 72 22 08
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**PRODIMED S.A.S. SIEGE SOCIAL**
ZI, 4 avenue de l'Europe - 60530 NEUILLY EN THELLE - France - Tél. 33 (0)3 44 26 63 46 - Fax 33 (0)3 44 26 93 37
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S.A.S. au capital de 728 000 euros - RCS Compiègne B 324 918 283 - Code APE 3250A - Siret : 324 918 283 00023
PRODUCTION DE MATERIEL MEDICO - CHIRURGICAL

PRODIMED

Déclaration CE de conformité / **EC Declaration of conformity**

| Référence commerciale | Désignation | Classe |
|---|---|---|
| 3842.09 | Seldicath PU 4 cm x 0,9 mm : 20G | II b |
| 3843.09 | Seldicath 0,9 mm PU 6 cm x 0,9 mm : 20G | II b |
| 3843.12 | Seldicath | II b |
| 3844.09 | Seldicath | II b |
| 3844.12 | Seldicath | II b |
| 3846.09 | Seldicath 0,9 mm PU 11 cm x 0,9 mm : 20G | II b |
| 3846.12 | Seldicath 1,2 mm PU 11 cm x 1,2 mm : 18G | II b |
| 3848.12 | Seldicath PU 15 cm x 1,2 mm : 18G | II b |
| 3849.12 | Seldicath 1,2 PU 20 cm x 1,2 mm 18G | II b |
| 3854 10 | Seldicath PU 8 cm x 0,9 mm : 20G | II b |
| 3854 13 | Seldicath PU 8 cm x 1,2 mm : 18G | II b |
| 3856 10 | Seldicath PU 11 cm x 0,9 mm : 20G | II b |
| 3856 13 | Seldicath PU 11 cm x 1,2 mm | II b |
| 3871.07 | Seldicath 2F FEP 2 cm x 0,7 mm | II b |
| 3871.10 | Seldicath 3F PTFE 2 cm x 1,0 mm | II b |
| 3872.07 | Seldicath 2F FEP 3 cm x 0,7 mm | II b |
| 3872.10 | Seldicath 3F PTFE 4 cm x 1,0 mm | II b |
| 3872.13 | Seldicath 4F PTFE 4 cm x 1,3 mm | II b |
| 3873.10 | Seldicath 3F PTFE 6 cm x 1,0 mm | II b |
| 3873.13 | Seldicath 4F PTFE 6 cm x 1,3 mm | II b |
| 3874.10 | Seldicath 3F PTFE 8 cm x 1,0 mm | II b |
| 3874.13 | Seldicath 4F PTFE 8 cm x 1,3 mm | II b |
| 3874.17 | Seldicath 5F PTFE 8 cm x 1,7 mm | II b |
| 3874C10 | Seldicath 3F PTFE 8 cm x 1,0 mm | II b |
| 3874S10 | Seldicath 3F PTFE 8 cm x 1,0 mm | II b |
| 3876.10 | Seldicath 3F PTFE 11 cm x 1,0 mm | II b |
| 3876.13 | Seldicath 4F PTFE 11 cm x 1,3 mm | II b |
| 3876.17 | Seldicath 5F PTFE 11 cm x 1,7 mm | II b |
| 3876.20 | Seldicath 6F PTFE 11 cm x 2,0 mm | II b |
| 3881.10 | Seldicath 3F PTFE 15 cm x 1,0 mm | II b |
| 3881.13 | Seldicath 4F PTFE 15 cm x 1,3 mm | II b |
| 3881.13L | Seldicath 4F PTFE 15 cm x 1,3 mm | II b |
| 3882.10 | Seldicath 3F PTFE 20 cm x 1,0 mm | II b |
| 3882.13 | Seldicath 4F PTFE 20 cm x 1,3 mm | II b |
| 3882.17 | Seldicath 5F PTFE 20 cm x 1,7 mm | II b |
| 3882.20 | Seldicath 6F PTFE 20 cm x 2,0 mm | II b |
| 3883.10 | Seldicath 3F PTFE 30 cm x 1,0 mm | II b |
| 3883.13 | Seldicath 4F PTFE 30 cm x 1,3 mm | II b |
| 3883.17 | Seldicath 5F PTFE 30 cm x 1,7 mm | II b |
| 3883.20 | Seldicath 6F PTFE 30 cm x 2,0 mm | II b |



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# 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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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**

# 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.**<br>**Boundary Road**<br>**Hythe**<br>**Kent**<br>**CT21 6JL**<br>**United Kingdom** |

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

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

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# EC Certificate - Full Quality Assurance System

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

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

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# EC Certificate - Full Quality Assurance System

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

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

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# EC Certificate - Full Quality Assurance System

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

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

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# EC Certificate - Full Quality Assurance System

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

# List of Significant Subcontractors

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

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

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# EC Certificate - Full Quality Assurance System

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

# List of Significant Subcontractors

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| **Subcontractor:** | **Service(s) supplied** |
|---|---|
| Smiths Medical Italia Srl<br>Via della Stazione, 2<br>Latina Scalo<br>04100<br>Italy | **Packaging** |
| Sterigenics Belgium<br>(Petit-Rechain) SA<br>Zoning Industriel de Petit-Rechain<br>Avenue Andre Ernst 21<br>B-4800 Verviers<br>Belgium | **ETO Sterilization** |
| Sterigenics UK Limited<br>Cotes Park Estate<br>Somercotes<br>Alfreton<br>DE55 4NJ<br>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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| Date: | **2017-06-28** |
| Issued To: | **Smiths Medical International Ltd.**<br>**Boundary Road**<br>**Hythe**<br>**Kent**<br>**CT21 6JL**<br>**United Kingdom** |

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

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# EC Certificate - Full Quality Assurance System

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

# List of Significant Subcontractors

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| Issued To: | **Smiths Medical International Ltd.**<br>**Boundary Road**<br>**Hythe**<br>**Kent**<br>**CT21 6JL**<br>**United Kingdom** |

| **Subcontractor:** | **Service(s) supplied** |
|---|---|
| STERIS ISOMEDIX Services, Inc<br>7685 Saint Andrews Avenue<br>San Diego<br>California 92154<br>USA | **ETO Sterilization** |
| UPG<br>Avenida La Cuspide #1<br>Parque Industrial Tecnomex<br>Del. Playas de Tijuana<br>Tijuana<br>Baja California<br>22700<br>Mexico | **Manufacture** |
| Velcro USA Inc.<br>95 Sundial Avenue<br>Manchester<br>New Hampshire<br>03103-7206<br>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<br>8603169 | First issue. Transferred from another Notified Body.<br>Certificate renewal. |

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# 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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MUSUROIA MIRELA

By Royal Charter

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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# 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 prestatiile aferente produsului certificat prin:

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

| **Subcontractant:** | **Servicii prestate** |
|---|---|
| Brightwake Limited<br>Lowmoor Business Park<br>Kirkby-in-Ashfield<br>Nottinghamshire<br>NG17 7JZ<br>Marea Britanie | **Fabricatie** |
| GaleMed Corporation<br>Nr. 87, Li-Gong 2nd Road<br>Wu-Jia<br>YILAN 268<br>Taiwan | **Fabricatie** |
| GE Medical<br>Pollards Wood<br>Nightingales Lane<br>Chalfont Saint Giles<br>HP8 4SP<br>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

## Lista subcontractantilor majori

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

| **Subcontractant:** | **Servicii prestate** |
|---|---|
| Koo Medical Equipment (Shanghai) Co., Ltd<br>100 Zhongde Road<br>Dakun Industrial Park<br>Songjiang, Shanghai 201614<br>China | **Fabricatie** |
| Pentair Filtration Solutions<br>1350 Hammond Road<br>St. Paul<br>Minnesota<br>55110<br>USA | **Furnizor crucial** |
| Quadrant EPP Belgium N.V.<br>Industriepark Noord<br>Robert Tavernierlaan 2<br>Tielt<br>8700<br>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

## Lista subcontractantilor majori

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| **Subcontractant:** | **Servicii prestate** |
|---|---|
| Smiths Healthcare Manufacturing<br>SA de CV<br>Avenida Calidad Nr.4<br>Parque, Industrial Internacional<br>Tijuana<br>22425<br>Mexic | **Fabricatie** |
| Smiths Healthcare Manufacturing<br>SA de CV<br>Carretera Miguel Alemán Km 21.7<br>Parque Industrial Monterrey<br>Apodaca<br>Nuevo León<br>66603<br>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 prestatiile aferente produsului certificat prin:

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

| **Subcontractant:** | **Servicii prestate** |
|---|---|
| Smiths Medical ASD Inc.<br>10 Bowman Dr.<br>Keene<br>New Hampshire<br>03431<br>USA | **Fabricatie** |
| Smiths Medical ASD Inc.<br>1265 Grey Fox Road<br>St Paul<br>Minnesota<br>55112<br>USA | **Fabricatie** |
| Smiths Medical ASD Inc.<br>201 West Queen St.,<br>Southington<br>Connecticut<br>06489<br>USA | **Fabricatie** |

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| **Subcontractant:** | **Servicii prestate** |
|---|---|
| Smiths Medical ASD Inc.<br>6250 Shier Rings Road<br>Dublin<br>Ohio<br>43016<br>USA | **Fabricatie** |
| Smiths Medical ASD Inc.<br>9124 Polk Lane, Suite 101<br>Olive Branch<br>Mississippi<br>38654<br>USA | **Distributie** |
| Smiths Medical Republica Ceha a.s.<br>Olomoucká 306<br>753 01 Hranice<br>Republica Ceha | **Fabricatie** |

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| **Subcontractant:** | **Servicii prestate** |
|---|---|
| Smiths Medical Gary<br>5700 W 23rd Ave<br>Gary<br>Indiana<br>46406<br>USA | **Fabricatie** |
| Smiths Medical International Ltd<br>52 Grayshill Rd<br>Cumbernauld<br>Glasgow<br>G68 9HQ<br>Marea Britanie | **Fabricatie** |
| Smiths Medical International<br>Nijmegen<br>Bijsterhuizen 22-08<br>6604 LD Wijchen<br>Olanda | **Distributie** |

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| **Subcontractant:** | **Servicii prestate** |
|---|---|
| Smiths Medical Italia Srl<br>Via della Stazione, 2<br>Latina Scalo<br>04100<br>Italia | **Ambalare** |
| Sterigenics Belgium<br>(Petit-Rechain) SA<br>Zoning Industriel de Petit-Rechain<br>Avenue Andre Ernst 21<br>B-4800 Verviers<br>Belgium | **Sterilizare ETO** |
| Sterigenics UK Limited<br>Cotes Park Estate<br>Somercotes<br>Alfreton<br>DE55 4NJ<br>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

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| **Subcontractant:** | **Servicii prestate** |
|---|---|
| Sterigenics US, LLC<br>344 Bonnie Circle<br>Corona<br>California<br>92880<br>USA | **Sterilizare cu raze gamma** |
| Sterigenics, LLC<br>1700 College Blvd.<br>West Memphis<br>Arkansas<br>72301<br>USA | **Sterilizare cu raze gamma** |
| Sterilization Services of Tennessee, Inc<br>2396 Florida Street<br>Memphis<br>Tennessee 38109<br>USA | **Sterilizare ETO** |

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| **Subcontractant:** | **Servicii prestate** |
|---|---|
| STERIS ISOMEDIX Services, Inc<br>7685 Saint Andrews Avenue<br>San Diego<br>California 92154<br>USA | **Sterilizare ETO** |
| UPG<br>Avenida La Cuspide #1<br>Parque Industrial Tecnomex<br>Del. Playas de Tijuana<br>Tijuana<br>Baja California<br>22700<br>Mexic | **Fabricatie** |
| Velcro USA Inc.<br>95 Sundial Avenue<br>Manchester<br>New Hampshire<br>03103-7206<br>USA | **Furnizor crucial** |

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By Royal Charter

# 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<br>8603169 | Prima editie. Transferat de alt organ de certificare.<br>Reinnoirea certificatului. |



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MINISTERUL JUSTITIEI
MUSUROIA MIRELA
Legitimație nr. 2769
TRADUCĂTOR AUTORIZAT

**********

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