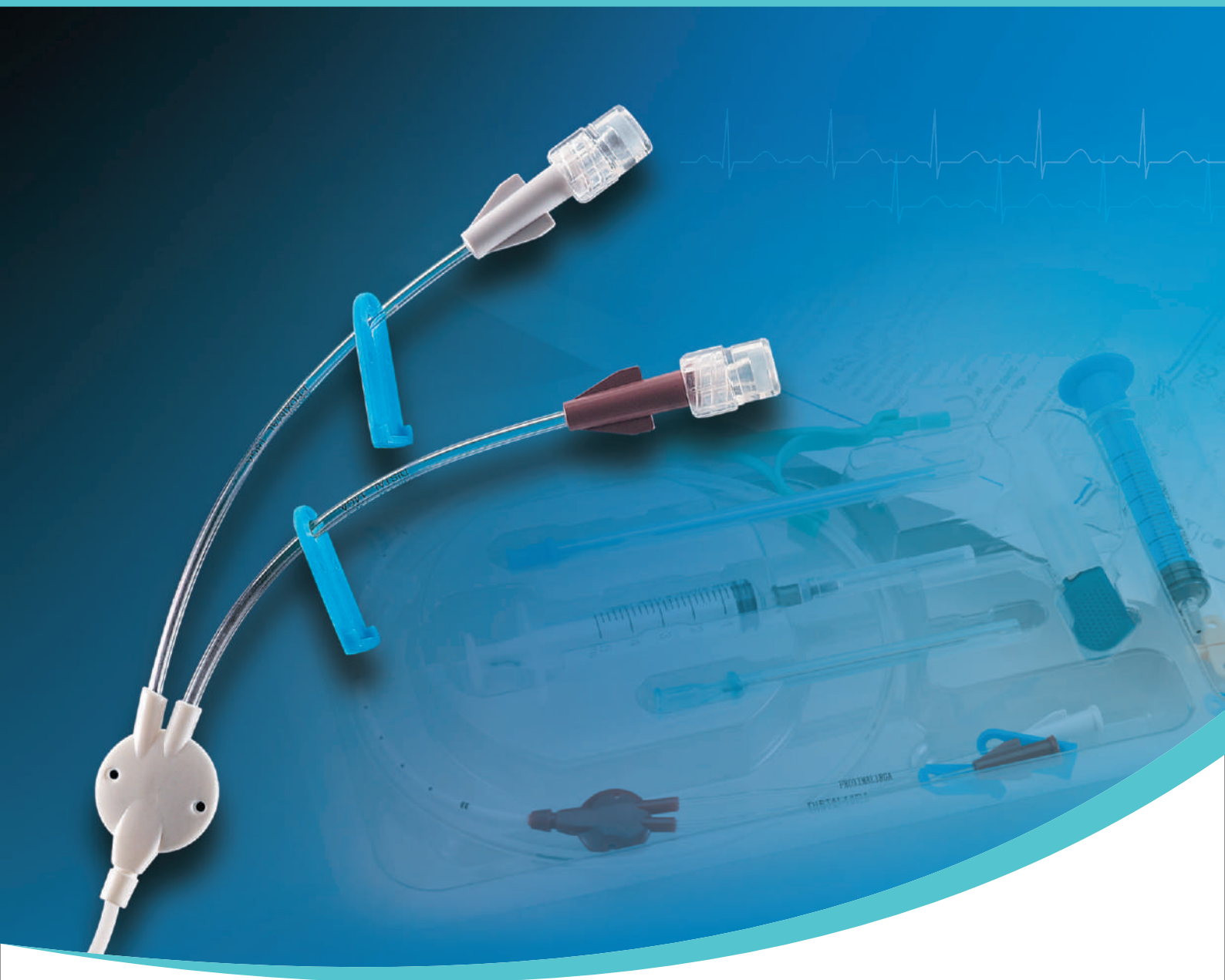




# Disposable Central Venous Catheter Kit

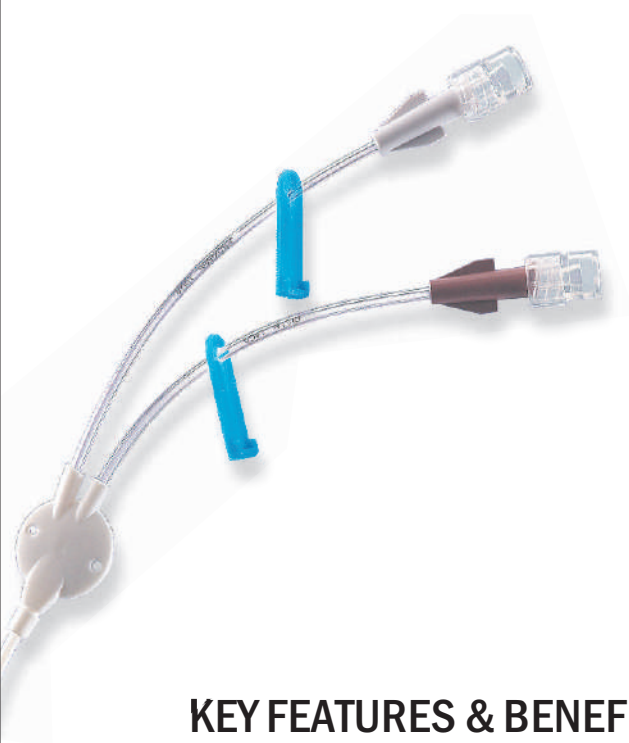


[www.rfornia.com](http://www.rfornia.com)  
Health care for better future



FORNIA® Disposable Central Venous Catheter Kit is for short term use of central venous access.

Safe  
Reliable  
Economical  
Efficient



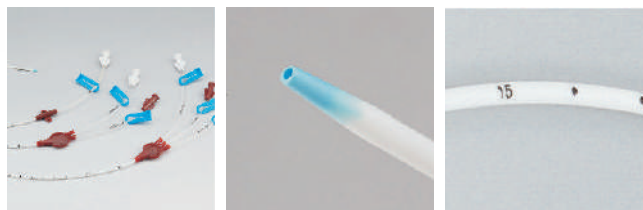
## INTENDED USE

- ◆ Continual or discontinuous intravenous infusions
- ◆ Intravenous infusion of highly permeable or stimulative solutions
- ◆ Blood or blood product transfusion
- ◆ Blood sampling
- ◆ Continual or discontinuous central venous pressure monitoring
- ◆ Intravenous alimentation
- ◆ Unconscious patients unsuitable for venipuncturing
- ◆ Patients with injured limbs or peripheral vein access difficulty

## KEY FEATURES & BENEFITS

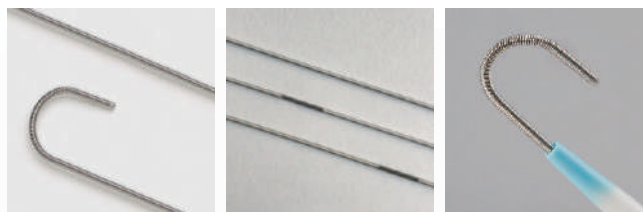
### Catheter

- **Made of polyurethane(PU)**
  - Stiff to be inserted into vein at room temperature
  - Soften with warmth of blood stream
  - Reduce risk of irritating the intima of veins
- **Rounded, smooth and atraumatic catheter tip**
  - Ensure safety during insertion and placement
- **Graduation marking indicated in centimeters**
  - Precisely reveal the depth of insertion
- **Radiopaque**
  - Help check correct placement of catheter



### Guidewire

- **Double-Ended (Straight & J tip) guidewire**
  - Flexible distal tips with dual purpose
- **Depth-indicator markings**
  - Distinct, permanent, 360° ringed bands
  - Facilitate proper placement
- **Superior wire-to-wire consistency**
  - Tight tolerance and special processing of tips
  - Ensure guidewire-to-catheter compatibility



## Blue Introducer Syringe

- **Work in conjunction with introducer needle**
  - Load guidewire through hollow plunger into blood vessel
  - Withdraw blood to help confirm puncture point



## Y Connector

- **Work in conjunction with introducer needle**
  - 5ml syringe attached to one port
  - Load guidewire through the second port into blood vessel



\* Freely combine introducer needle with Blue Syringe or Y connector depending on doctor's preference.

# ORDERING INFORMATION



## Single Lumen

| REF NO   | Catheter |         | Lumen size |        |          | Lumen Section | Guidewire    | Vessel Dilator | Introducer Needle |
|----------|----------|---------|------------|--------|----------|---------------|--------------|----------------|-------------------|
|          | Size     | Length* | Media      | Distal | Proximal |               |              |                |                   |
| CVC-1111 | 24 G     | 5 cm    | -          | 24 G   | -        |               | 0.018"x50 cm | 4Fx5cm         | 22Gx3cm           |
| CVC-1112 | 24 G     | 8 cm    | -          | 24 G   | -        |               | 0.018"x50 cm | 4Fx5cm         | 22Gx3cm           |
| CVC-1121 | 22 G     | 5 cm    | -          | 22 G   | -        |               | 0.018"x50 cm | 4Fx5cm         | 20Gx4.5cm         |
| CVC-1122 | 22 G     | 8 cm    | -          | 22 G   | -        |               | 0.018"x50 cm | 4Fx5cm         | 20Gx4.5cm         |
| CVC-1123 | 22 G     | 10 cm   | -          | 22 G   | -        |               | 0.018"x50 cm | 4Fx5cm         | 20Gx4.5cm         |
| CVC-1131 | 20 G     | 5 cm    | -          | 20 G   | -        |               | 0.021"x50 cm | 4Fx5cm         | 20Gx4.5cm         |
| CVC-1132 | 20 G     | 8 cm    | -          | 20 G   | -        |               | 0.021"x50 cm | 4Fx5cm         | 20Gx4.5cm         |
| CVC-1134 | 20 G     | 13 cm   | -          | 20 G   | -        |               | 0.021"x50 cm | 4Fx5cm         | 20Gx4.5cm         |
| CVC-1142 | 18 G     | 8 cm    | -          | 18 G   | -        |               | 0.025"x50 cm | 5.5Fx7cm       | 19Gx4.5cm         |
| CVC-1144 | 18 G     | 13 cm   | -          | 18 G   | -        |               | 0.025"x50 cm | 5.5Fx7cm       | 19Gx4.5cm         |
| CVC-1145 | 18 G     | 16 cm   | -          | 18 G   | -        |               | 0.025"x50 cm | 5.5Fx7cm       | 19Gx4.5cm         |
| CVC-1155 | 16 G     | 16 cm   | -          | 16 G   | -        |               | 0.035"x60 cm | 6.5Fx10cm      | 18Gx7cm           |
| CVC-1156 | 16 G     | 20 cm   | -          | 16 G   | -        |               | 0.035"x60 cm | 6.5Fx10cm      | 18Gx7cm           |
| CVC-1157 | 16 G     | 30 cm   | -          | 16 G   | -        |               | 0.035"x70 cm | 6.5Fx10cm      | 18Gx7cm           |
| CVC-1165 | 14 G     | 16 cm   | -          | 14 G   | -        |               | 0.035"x60 cm | 7.5Fx10cm      | 18Gx7cm           |
| CVC-1166 | 14 G     | 20 cm   | -          | 14 G   | -        |               | 0.035"x60 cm | 7.5Fx10cm      | 18Gx7cm           |
| CVC-1167 | 14 G     | 30 cm   | -          | 14 G   | -        |               | 0.035"x70 cm | 7.5Fx10cm      | 18Gx7cm           |



## Double Lumen

| REF NO   | Catheter |         | Lumen size |        |          | Lumen Section | Guidewire    | Vessel Dilator | Introducer Needle |
|----------|----------|---------|------------|--------|----------|---------------|--------------|----------------|-------------------|
|          | Size     | Length* | Media      | Distal | Proximal |               |              |                |                   |
| CVC-2141 | 4 F      | 5 cm    | -          | 22G    | 22G      |               | 0.018"x50 cm | 6.5Fx7cm       | 20Gx4.5cm         |
| CVC-2142 | 4 F      | 8 cm    | -          | 22G    | 22G      |               | 0.018"x50 cm | 6.5Fx7cm       | 20Gx4.5cm         |
| CVC-2143 | 4 F      | 10 cm   | -          | 22G    | 22G      |               | 0.018"x50 cm | 6.5Fx7cm       | 20Gx4.5cm         |
| CVC-2144 | 4 F      | 13 cm   | -          | 22G    | 22G      |               | 0.018"x50 cm | 6.5Fx7cm       | 20Gx4.5cm         |
| CVC-2145 | 4 F      | 16 cm   | -          | 22G    | 22G      |               | 0.018"x50 cm | 5.5Fx7cm       | 20Gx4.5cm         |
| CVC-2151 | 5 F      | 5 cm    | -          | 18G    | 20G      |               | 0.021"x50 cm | 6.5Fx7cm       | 20Gx4.5cm         |
| CVC-2152 | 5 F      | 8 cm    | -          | 18G    | 20G      |               | 0.021"x50 cm | 6.5Fx7cm       | 20Gx4.5cm         |
| CVC-2153 | 5 F      | 10 cm   | -          | 18G    | 20G      |               | 0.021"x50 cm | 6.5Fx7cm       | 20Gx4.5cm         |
| CVC-2154 | 5 F      | 13 cm   | -          | 18G    | 20G      |               | 0.021"x50 cm | 6.5Fx7cm       | 20Gx4.5cm         |
| CVC-2155 | 5 F      | 16 cm   | -          | 18G    | 20G      |               | 0.021"x50 cm | 6.5Fx7cm       | 20Gx4.5cm         |
| CVC-2156 | 5 F      | 20 cm   | -          | 18G    | 20G      |               | 0.021"x50 cm | 6.5Fx7cm       | 20Gx4.5cm         |
| CVC-2175 | 7 F      | 16 cm   | -          | 14G    | 18G      |               | 0.035"x60 cm | 8.5Fx10cm      | 18Gx7cm           |
| CVC-2176 | 7 F      | 20 cm   | -          | 14G    | 18G      |               | 0.035"x60 cm | 8.5Fx10cm      | 18Gx7cm           |
| CVC-2177 | 7 F      | 30 cm   | -          | 14G    | 18G      |               | 0.035"x70 cm | 8.5Fx10cm      | 18Gx7cm           |
| CVC-2185 | 8 F      | 16 cm   | -          | 14G    | 14G      |               | 0.035"x60 cm | 9Fx10cm        | 18Gx7cm           |
| CVC-2186 | 8 F      | 20 cm   | -          | 14G    | 14G      |               | 0.035"x60 cm | 9Fx10cm        | 18Gx7cm           |



## Triple Lumen

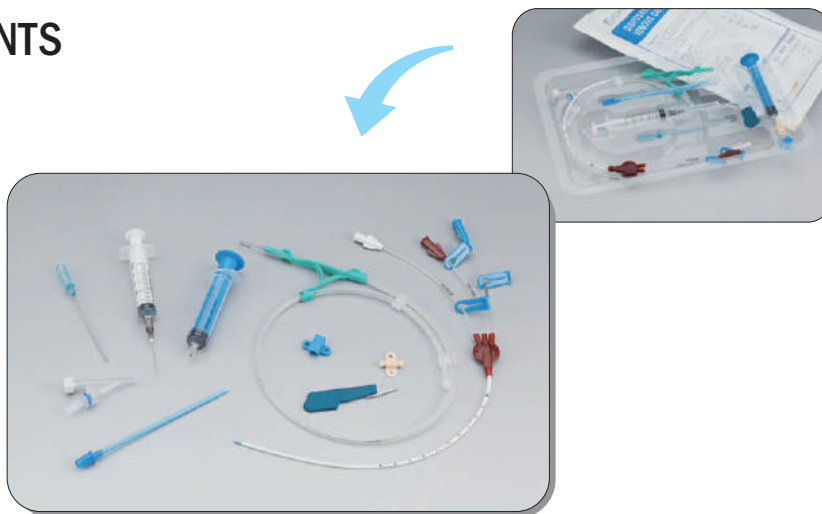
| REF NO   | Catheter |         | Lumen size |        |          | Lumen Section | Guidewire   | Vessel Dilator | Introducer Needle |
|----------|----------|---------|------------|--------|----------|---------------|-------------|----------------|-------------------|
|          | Size     | Length* | Media      | Distal | Proximal |               |             |                |                   |
| CVC-3151 | 5.5 F    | 5 cm    | 22 G       | 18 G   | 22 G     |               | 0.021"x50cm | 6.5Fx7cm       | 20Gx4.5cm         |
| CVC-3152 | 5.5 F    | 8 cm    | 22 G       | 18 G   | 22 G     |               | 0.021"x50cm | 6.5Fx7cm       | 20Gx4.5cm         |
| CVC-3153 | 5.5 F    | 10 cm   | 22 G       | 18 G   | 22 G     |               | 0.021"x50cm | 6.5Fx7cm       | 20Gx4.5cm         |
| CVC-3154 | 5.5 F    | 13 cm   | 22 G       | 18 G   | 22 G     |               | 0.021"x50cm | 6.5Fx7cm       | 20Gx4.5cm         |
| CVC-3155 | 5.5 F    | 16 cm   | 22 G       | 18 G   | 22 G     |               | 0.021"x50cm | 6.5Fx7cm       | 20Gx4.5cm         |
| CVC-3156 | 5.5 F    | 20 cm   | 22 G       | 18 G   | 22 G     |               | 0.021"x50cm | 6.5Fx7cm       | 20Gx4.5cm         |
| CVC-3175 | 7 F      | 16 cm   | 18 G       | 16 G   | 18 G     |               | 0.035"x60cm | 8.5Fx10cm      | 18Gx7cm           |
| CVC-3176 | 7 F      | 20 cm   | 18 G       | 16 G   | 18 G     |               | 0.035"x60cm | 8.5Fx10cm      | 18Gx7cm           |
| CVC-3177 | 7 F      | 30 cm   | 18 G       | 16 G   | 18 G     |               | 0.035"x70cm | 8.5Fx10cm      | 18Gx7cm           |
| CVC-3185 | 8.5 F    | 16 cm   | 14 G       | 16 G   | 16 G     |               | 0.035"x60cm | 9Fx10cm        | 18Gx7cm           |
| CVC-3186 | 8.5 F    | 20 cm   | 14 G       | 16 G   | 16 G     |               | 0.035"x60cm | 9Fx10cm        | 18Gx7cm           |
| CVC-3187 | 8.5 F    | 30 cm   | 14 G       | 16 G   | 16 G     |               | 0.035"x70cm | 9Fx10cm        | 18Gx7cm           |

\* More catheter length from 5cm ~30cm is available upon customer's request.

## STANDARD KIT CONTENTS

Each CVC kit contains:

- ◆ Central venous catheter
- ◆ Guidewire with advancer
- ◆ Vessel dilator
- ◆ Introducer needle
- ◆ Y connector
- ◆ 5ml syringe
- ◆ 22g syringe needle
- ◆ Catheter clamp
- ◆ Surgical scalpel
- ◆ Fastener: catheter clamp
- ◆ Blue introducer syringe



## PACKAGE

| Unit Package                    | Pieces per box | Pieces per carton | Carton dimension(cm) |
|---------------------------------|----------------|-------------------|----------------------|
| Peel-open tray with Tyvek cover | 10             | 120               | 71.5x57.2x48         |

### Royal Fornia Medical Equipment Co., Ltd.

Fornia Tech Park, No.18, Kejiji Road, Hi-tech Innovation Coast,  
Tangjia Bay 519085 Zhuhai, Guangdong Province  
PEOPLE'S REPUBLIC OF CHINA

Tel : 86-756-3399206

Fax : 86-756-3399288

E-mail : fornia@rfornia.com

Web : www.rfornia.com



**ISO13485**

Fornia constantly strives to improve quality and comply with regulatory requirements. Our Quality Management System is certified according to ISO 13485 and product is CE-proved.



Product Service

# EC Certificate

## Full Quality Assurance System

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

No. G1 14 10 54466 017

**Manufacturer:** **Royal Fornia Medical Equipment Co., Ltd.**

Fornia Tech Park, No.18, Kejiyi Road,  
Hi-tech Innovation Coast, Tangjia Bay  
519085 Zhuhai, Guangdong Province  
PEOPLE'S REPUBLIC OF CHINA

**EC-Representative:** **Shanghai International Holding Corp. GmbH (Europe)**

Eiffestraße 80  
20537 Hamburg  
GERMANY

**Product Category(ies):**

Disposable Infusion Pump, Disposable central venous catheter and kit, Disposable laryngeal mask, Endotracheal Tube, Endobronchial Blocker Tube, Reinforced Endotracheal Tube, Double lumen Endobronchial Tube, Disposable Airway Management Intubation Kit, Endoscopy Mask.

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

**Report No.:** BJ1486607

**Valid from:** 2015-01-10

**Valid until:** 2020-01-09



*H.-H.*

**Date,** 2014-11-24

Hans-Heiner Junker

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

Page 1 of 2



Product Service

**EC Certificate****Full Quality Assurance System**

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

**No. G1 14 10 54466 017****Facility(ies):**

Royal Fornia Medical Equipment Co., Ltd.  
Fornia Tech Park, No.18, Kejiyi Road,, Hi-tech Innovation Coast,  
Tangjia Bay, 519085 Zhuhai, Guangdong Province, PEOPLE'S  
REPUBLIC OF CHINA

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## **CERTIFICAT – CE**

### **Sistemul de Asigurare a Calității**

**(Directiva 93/42/CEE cu privire la Dispozitivele Medicale, Anexa II exclusiv (4))**

**(Dispozitive în Clasa IIa, IIb sau III)**

**Nr. G1 14 10 54466 017**

**Producător:** **Royal Fornia Medical Equipment Co., Ltd.**  
Fornia Tech Park, Nr. 18, Kejiyi Road  
Hi-tech Innovation Coast, Tangjia Bay  
519085 Zhuhai, Provincia Guangdong  
REPUBLICA POPULARĂ CHINEZĂ

**Reprezentant – CE** **Shanghai International Holding  
Corp. GmbH (Europa)**  
Eiffestrasse 80  
20537 Hamburg  
GERMANIA

**Categorie(i)** **Pompă infuzare de unică folosință, Cateter venos central de unică**  
**Produs:** **folosință și kit, Mască laringiană de unică folosință, Tub Endotraheal,  
Tub Blocator Endobronhial, Tub Endotraheal Ranforsat, Tub  
Endobronhial cu Lumen Dublu, Kit Intubare pentru Managementul  
Căilor Respiratorii, Mască Endoscopie.**

Organul de Certificare al TÜV SÜD Product Service GmbH declară că producătorul mai sus menționat a implementat un sistem de asigurare a calității pentru proiectarea, producerea și inspecția finală a produselor respective / categorii de produs, în conformitate cu Anexa II MDD. Numitul sistem de asigurare a calității se conformează cerințelor Directivei și se supune unei supravegheri periodice. Pentru comercializarea dispozitivelor din clasa III un Certificat Anexa II.4 este obligatoriu. Vedeți notele de pe pagina următoare.

**Raport Nr.:** 7BJ1486607

**Valabil de la:** 10-01-2015

**Valabil până la:** 09-01-2020

**TÜV  
572844**

Data, 24-11-2014

Hans-Heiner Junker  
Semnătura – indescifrabil

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



## **CERTIFICAT – CE**

**Sistemul de Asigurare a Calității**

**(Directiva 93/42/CEE cu privire la Dispozitivele Medicale, Anexa II exclusiv (4))**

**(Dispozitive în Clasa IIa, IIb sau III)**

**Nr. G1 14 10 54466 017**

**Unități Producție:** Royal Fornia Medical Equipment Co., Ltd.  
Fornia Tech Park, Nr. 18, Kejiyi Road, Hi-tech Innovation Coast, Tangjia  
Bay, 519085 Zhuhai, Provincia Guangdong  
REPUBLICA POPULARĂ CHINEZĂ

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





Product Service

# EC Certificate

## Full Quality Assurance System

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

No. G1 14 10 54466 017

**Manufacturer:** **Royal Fornia Medical Equipment Co., Ltd.**

Fornia Tech Park, No.18, Kejiyi Road,  
Hi-tech Innovation Coast, Tangjia Bay  
519085 Zhuhai, Guangdong Province  
PEOPLE'S REPUBLIC OF CHINA

**EC-Representative:** **Shanghai International Holding Corp. GmbH (Europe)**

Eiffestraße 80  
20537 Hamburg  
GERMANY

**Product Category(ies):**

Disposable Infusion Pump, Disposable central venous catheter and kit, Disposable laryngeal mask, Endotracheal Tube, Endobronchial Blocker Tube, Reinforced Endotracheal Tube, Double lumen Endobronchial Tube, Disposable Airway Management Intubation Kit, Endoscopy Mask.

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

**Report No.:** BJ1486607

**Valid from:** 2015-01-10

**Valid until:** 2020-01-09



*H.-H.*

**Date,** 2014-11-24

Hans-Heiner Junker

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

Page 1 of 2



Product Service

**EC Certificate****Full Quality Assurance System**

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

**No. G1 14 10 54466 017****Facility(ies):**

Royal Fornia Medical Equipment Co., Ltd.  
Fornia Tech Park, No.18, Kejiyi Road,, Hi-tech Innovation Coast,  
Tangjia Bay, 519085 Zhuhai, Guangdong Province, PEOPLE'S  
REPUBLIC OF CHINA

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Product Service

# C E R T I F I C A T E

No. Q1N 16 10 54466 018

**Holder of Certificate:** Royal Fornia Medical Equipment Co., Ltd.

Fornia Tech Park, No.18, Kejiyi Road  
Hi-tech Innovation Coast, Tangjia Bay  
519085 Zhuhai, Guangdong Province  
PEOPLE'S REPUBLIC OF CHINA

**Facility(ies):**

Royal Fornia Medical Equipment Co., Ltd.  
Fornia Tech Park, No.18, Kejiyi Road, Hi-tech  
Innovation Coast, Tangjia Bay, 519085 Zhuhai,  
Guangdong Province, PEOPLE'S REPUBLIC OF  
CHINA

**Certification Mark:****Scope of Certificate:**

Design, Development, Production and Distribution  
of Disposable Infusion Pump, Disposable Electronic  
Infusion Pump, Disposable Central Venous Catheter  
Kit, Insulin Pump, Disposable Infusion Set(only used  
for insulin pump), Disposable Anaesthesia Kit  
(epidural, spinal), Disposable laryngeal mask,  
Endotracheal Tube, Endobronchial Blocker Tube,  
Reinforced Endotracheal Tube, Double  
lumen Endobronchial Tube, Disposable Airway  
Management Intubation Kit, Endoscopy Mask.

**Applied  
Standard(s):**

EN ISO 13485:2012 + AC:2012  
Medical devices - Quality management systems -  
Requirements for regulatory purposes  
(ISO 13485:2003 + Cor. 1:2009)  
DIN EN ISO 13485:2012

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned  
above has established and is maintaining a quality management system, which meets the  
requirements of the listed standard(s). See also notes overleaf.

**Report No.:**

BJ1686604

**Valid from:**

2017-01-01

**Valid until:**

2019-12-31

**Date,** 2016-12-20

Stefan Preiß



Page 1 of 1

**DAKKS**  
Deutsche  
Akkreditierungsstelle  
D-27M-11321-01-00