

# AKUS<sup>®</sup>

Range for  
Locoregional  
Anaesthesia



# AKUS<sup>®</sup>

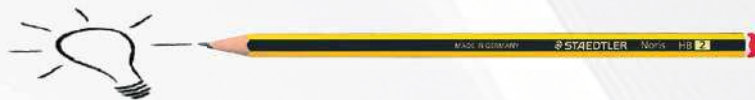
# AKUS®

## Range for Locoregional Anaesthesia

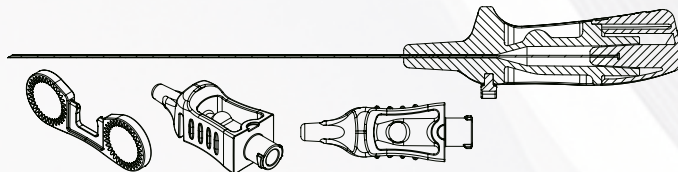
### Innovation with an improved design

After years of collaborative development between doctors and a team of engineers, AKUS® creates a new concept for locoregional anaesthesia. The new design facilitates anaesthesiologists in their day to day work, thanks to improvements and novelties introduced into the new range of AKUS® needles.

2013



2014



2015



2016



The AKUS needles have been developed with careful thought given to all users' profiles



#### Tired Vision

An integrated magnifying glass improves the ability to see the exit of the cerebrospinal fluid.



#### General fatigue

The design allows better handling and stability of all movements. Distinct mandrel colors help to increase the speed of the decision making process at the time of selecting appropriate needle size.



#### Less Force

Ergonomic shape with a pointer which defines the correct needle position and helps to ensure precise introduction.



#### Larger hands

Less problems with grip; larger sized handle and mandrel. Increased roughening with an anti-slip handle surface.

# Spinal Needle

- 22G
- 23G
- 25G
- 26G
- 27G

## Whitacre expan tip

Easy introduction into the dura mater, with a "click" detected on puncture.

## Introducer with tri-beveled tip

The 15° tri- beveled tip enables skin puncture, thus avoiding the risk of creating a subcutaneous wheal with local anaesthetic.



Diameter identification by colours and visible numbers on the mandrel.



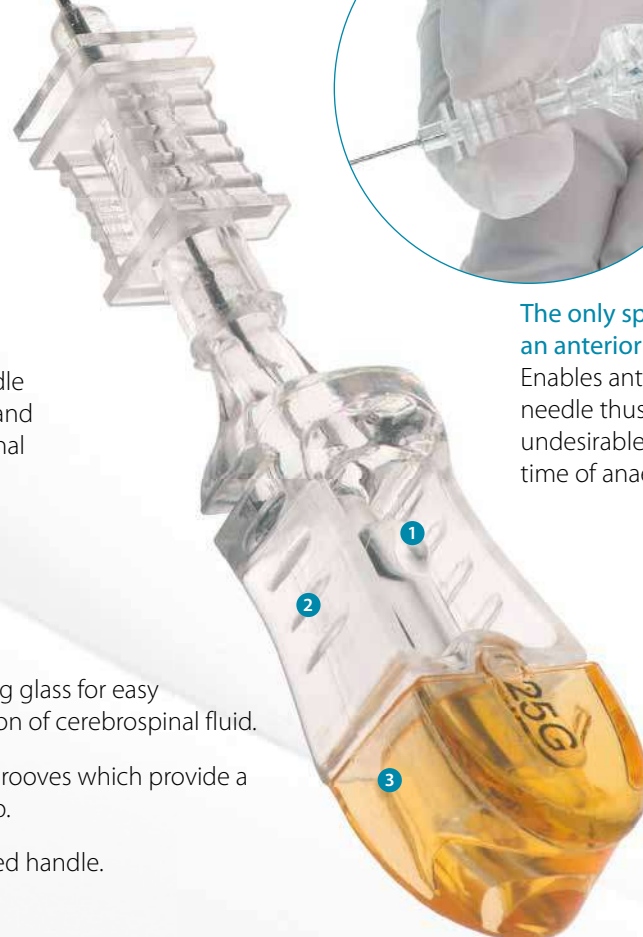
## The only spinal needle with an anterior grip

Enables anterior grip of the needle thus avoiding any undesirable movements at the time of anaesthetic injection.

## Ergonomic

Its ergonomic structure allows the needle to be directed with absolute precision and orientation thus allowing the professional to identify at all times the tissue types through which the needle is crossing.

1. Magnifying glass for easy visualisation of cerebrospinal fluid.
2. Anti-slip grooves which provide a better grip.
3. Larger sized handle.





# Hybrid needle for Plexus Block

## Echogenic and stimulating needle for Plexus Blocks

AKUS® echogenic and stimulating needles. Combine neurostimulation with perfect echogenicity to maximise the technique's results.

### Precision

Centimeter markings which allow checking of the depth of needle insertion.

### Echogenicity

New system of die-cutting in the last cm of the tip making it perfectly visible in ultrasounds. Better precision and safety in anesthetic application without damage to the corresponding nerve.



Syringe coupled directly to the needle.

### Safety

Ergonomic, transparent handle which allows smooth circumferential sliding making the ultrasonic point more effective. This allows the technique to develop in a safe and efficient manner, whilst continually controlling the positions of the tip and the nerve.

### Neurostimulation

Removable cable; bilateral connection.

### Versatility

Includes a removable extension which allows, if deemed necessary, the needle to be coupled directly to the needle.

# Epidural Needle and Epidural Kit

## Composition of complete set



1. Epidural Catheter, with soft silicone point. High rate of flow to aid both elastomeric properties as well as pump.



2. Low resistance syringe.



3. Filter 0,2  $\mu$ .



4. High resistance Tuohy-Borst adaptor.

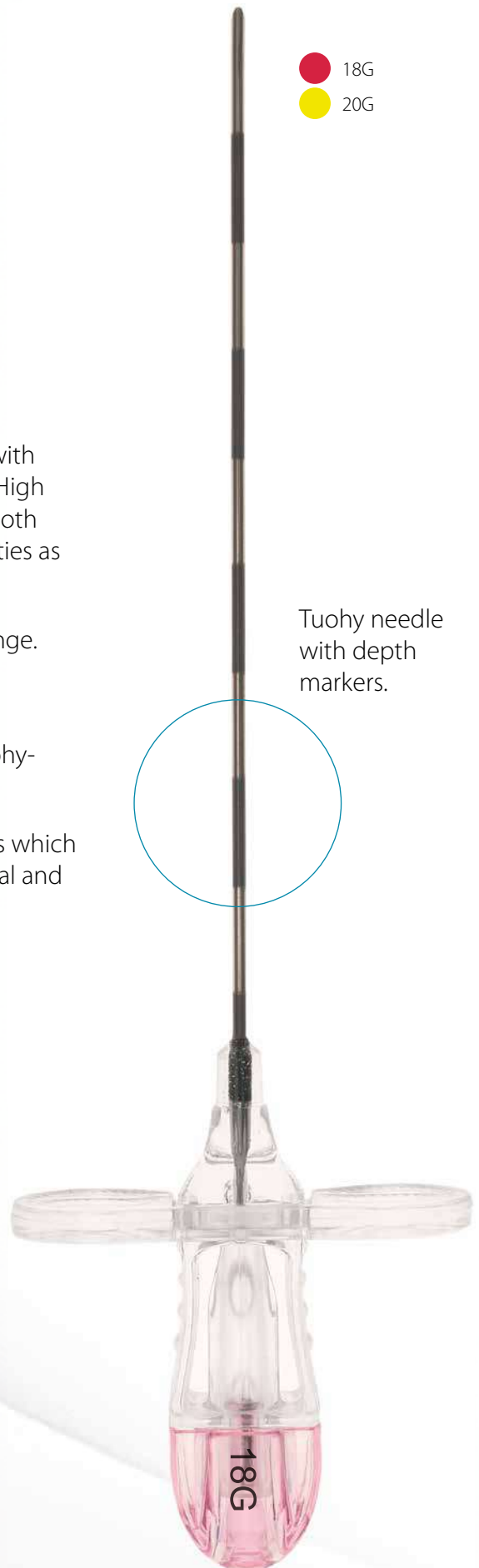


5



18G  
20G

Tuohy needle with depth markers.



# Procedure Kit



## Akus offers you a kit composed of

- A small tray.
- A large tray.
- Three luer-lock syringes of 20ml, 10ml and 5 ml.
- Particulate filter loader.
- Three needles of 25G, 21G and 16G.
- Adhesive drape.
- Two sponges with handles.
- 15 gauzes without sterilisation markers.

---

## Advantages

**Saves time:** Both in the ordering of the material and the preparation for the catheterization, by combining the materials in one single code.

**Saves space:** All the materials occupy a single space.

**Procedure uniformity:** All international guidelines for the prevention of hospital infection recommend maximum standardization of the behaviour protocols to avoid errors in asepsis thus potentially improving your success rate.

**Safety:** Working with disposable metallic instruments always guarantees that you are using a new material and, therefore, always operating in optimal conditions.

**Transparent costs:** The best way of knowing the exact cost of material necessary for every type of anaesthetic.

**Hygienic:** Avoids unnecessary manipulation of the material.



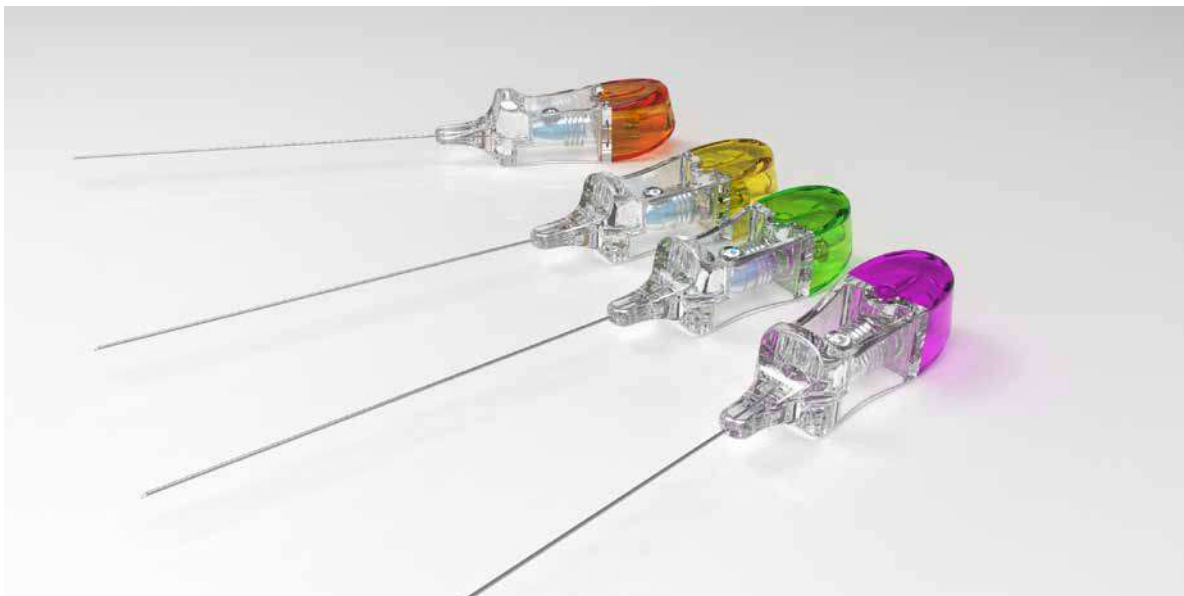
## Reference range Locoregional Anaesthesia

| Ref. No.   | Description                                   |
|------------|-----------------------------------------------|
| BN21050    | Nervous block quincke 21g 50mm                |
| BN21070    | Nervous block quincke 21g 70mm                |
| BN21090    | Nervous block quincke 21g 90mm                |
| BN21140    | Nervous block quincke 21g 140mm               |
| BN22050    | Nervous block quincke 22g 50mm                |
| BN22070    | Nervous block quincke 22g 70mm                |
| BN22090    | Nervous block quincke 22g 90mm                |
| EK18080    | Complete epidural kit tuohy 18 g 80mm         |
| EK18095    | Complete epidural kit tuohy 18 g 95mm         |
| EP20080    | Tuohy epidural needle 20g 80mm with syringe   |
| EP20095    | Tuohy epidural needle 20g 95mm with syringe   |
| EP22080    | Tuohy epidural needle 22g 80mm with syringe   |
| EP22095    | Tuohy epidural needle 22g 95mm with syringe   |
| PKAN001    | Procedure kit                                 |
| SW22092-19 | Whitacre pencil point spinal needle 22g 92mm  |
| SW22110-19 | Whitacre pencil point spinal needle 22g 110mm |
| SW23092-19 | Whitacre pencil point spinal needle 23g 92mm  |
| SW25092-21 | Whitacre pencil point spinal needle 25g 92mm  |
| SW25110-21 | Whitacre pencil point spinal needle 25g 110mm |
| SW26092-21 | Whitacre pencil point spinal needle 26g 92mm  |
| SW26110-21 | Whitacre pencil point spinal needle 26g 110mm |
| SW27092-25 | Whitacre pencil point spinal needle 27g 92mm  |
| SW27092-25 | Spinal needle pencil point whitacre 27g 92mm  |

## WARNING

The designs of AKUS neuroaxial anaesthesia needles, included in this presentation, images, text and other materials here contained is valuable intellectual property and is proprietary to Dr. Bartolome Lajarin and Dra. Beatriz Castellon. These needles belong to the project AKUS Innovation in Anaesthesia, and have been created and developed by its proprietors, whom have patented and registered them legally. Any attempt to copy of above mentioned needles, will be prosecuted through the legal authorities.

This presentation is produced by the company Group Idea for the project AKUS Innovation in Anaesthesia, any total or partial use of images, text and other materials here contained, for different user than explanation of AKUS project, will be legally persecuted.



## AKUS Innovation in Anaesthesia

**Antonio S. Migallon**  
email: [a.migallon@forodigital.es](mailto:a.migallon@forodigital.es)  
mobile: +34 636 455 931

**Dr. Bartolome Lajarin**  
email: [cristinolaja@gmail.com](mailto:cristinolaja@gmail.com)  
mobile: +34 607 583 217



# AKUS

| item number | Product       | G  | length | tip                                    | others                               |                                                                                       |
|-------------|---------------|----|--------|----------------------------------------|--------------------------------------|---------------------------------------------------------------------------------------|
| SW22092-19  | Spinal needle | 22 | 92mm   | pencil point whitacre expan            | packing introducer mounted on needle |                                                                                       |
| SS22092-19  | Spinal needle | 22 | 92mm   | pencil point sprotte                   | packing introducer mounted on needle | on demand                                                                             |
| SQ22092-19  | Spinal needle | 22 | 92mm   | bevel quincke 25°                      | packing introducer mounted on needle |    |
| SL22092-19  | Spinal needle | 22 | 92mm   | bevel lancet 25°                       | packing introducer mounted on needle |                                                                                       |
| SW22110-19  | Spinal needle | 22 | 110mm  | pencil point whitacre expan            | packing introducer mounted on needle |                                                                                       |
| SS22110-19  | Spinal needle | 22 | 110mm  | pencil point sprotte                   | packing introducer mounted on needle | on demand                                                                             |
| SQ22110-19  | Spinal needle | 22 | 110mm  | bevel quincke 25°                      | packing introducer mounted on needle |                                                                                       |
| SL22110-19  | Spinal needle | 22 | 110mm  | bevel lancet 25°                       | packing introducer mounted on needle |                                                                                       |
| SW23092-19  | Spinal needle | 23 | 92mm   | pencil point whitacre expan            | packing introducer mounted on needle |                                                                                       |
| SQ23092-19  | Spinal needle | 23 | 92mm   | bevel quincke 25°                      | packing introducer mounted on needle |    |
| SL23092-19  | Spinal needle | 23 | 92mm   | bevel lancet 25°                       | packing introducer mounted on needle |                                                                                       |
| SW25092-21  | Spinal needle | 25 | 92mm   | pencil point whitacre expan            | packing introducer mounted on needle |                                                                                       |
| SS25092-21  | Spinal needle | 25 | 92mm   | pencil point sprotte                   | packing introducer mounted on needle | on demand                                                                             |
| SQ25092-21  | Spinal needle | 25 | 92mm   | bevel quincke 25°                      | packing introducer mounted on needle |                                                                                       |
| SL25092-21  | Spinal needle | 25 | 92mm   | bevel lancet 25°                       | packing introducer mounted on needle |  |
| SW25110-21  | Spinal needle | 25 | 110mm  | pencil point whitacre expan            | packing introducer mounted on needle |                                                                                       |
| SS25110-21  | Spinal needle | 25 | 110mm  | pencil point sprotte                   | packing introducer mounted on needle | on demand                                                                             |
| SQ25110-21  | Spinal needle | 25 | 110mm  | bevel quincke 25°                      | packing introducer mounted on needle |                                                                                       |
| SL25110-21  | Spinal needle | 25 | 110mm  | bevel lancet 25°                       | packing introducer mounted on needle |                                                                                       |
| SW26092-21  | Spinal needle | 26 | 92mm   | pencil point whitacre expan            | packing introducer mounted on needle |                                                                                       |
| SQ26092-21  | Spinal needle | 26 | 92mm   | bevel quincke 25°                      | packing introducer mounted on needle |  |
| SL26092-21  | Spinal needle | 26 | 92mm   | bevel lancet 25°                       | packing introducer mounted on needle |                                                                                       |
| SW26110-21  | Spinal needle | 26 | 110mm  | pencil point whitacre expan            | packing introducer mounted on needle |                                                                                       |
| SS26110-21  | Spinal needle | 26 | 110mm  | pencil point sprotte                   | packing introducer mounted on needle | on demand                                                                             |
| SQ26110-21  | Spinal needle | 26 | 110mm  | bevel quincke 25°                      | packing introducer mounted on needle |                                                                                       |
| SL26110-21  | Spinal needle | 26 | 110mm  | bevel lancet 25°                       | packing introducer mounted on needle |                                                                                       |
| SW27092-21  | Spinal needle | 27 | 92mm   | pencil point whitacre expan outer 0,42 | packing introducer mounted on needle |                                                                                       |
| SQ27092-21  | Spinal needle | 27 | 92mm   | bevel quincke, outer 0,42              | packing introducer mounted on needle |                                                                                       |
| SL27092-21  | Spinal needle | 27 | 92mm   | bevel lancet, outer 0,42               | packing introducer mounted on needle |                                                                                       |
| SS27092-21  | Spinal needle | 27 | 92mm   | pencil point sprotte, outer 0,42       | packing introducer mounted on needle | on demand                                                                             |

| others  |              |    |      |                              |                                                                                                                                                                                      |
|---------|--------------|----|------|------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| EK16080 | epidural kit | 16 | 80mm | tuohy, keep current material | 1) New packing. 2) Containing: a) soft catheter (0,8, no rigid) with adapter -cable in- and the connector in bag with notch on bag to open b) filter with tampon c) lor syringe 10ml |

|           |                 |       |      |                              |                                                                                                                                                                                        |
|-----------|-----------------|-------|------|------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| EK16095   | epidural kit    | 16    | 95mm | tuohy, keep current material | 1) New packing. 2) Containing: a) soft catheter (0,8, no rigid) with adapter -cable in- and the connector in bag with notch on bag to open b) filter with tampon c) lor syringe 10ml   |
| EK16080-R | epidural kit    | 16    | 80mm | tuohy, keep current material | 1) New packing. 2) Containing: a) ringed catheter (0,8, no rigid) with adapter -cable in- and the connector in bag with notch on bag to open b) filter with tampon c) lor syringe 10ml |
| EK16095-R | epidural kit    | 16    | 95mm | tuohy, keep current material | 1) New packing. 2) Containing: a) ringed catheter (0,8, no rigid) with adapter -cable in- and the connector in bag with notch on bag to open b) filter with tampon c) lor syringe 10ml |
| EK18080   | epidural kit    | 18    | 80mm | tuohy, keep current material | 1) New packing. 2) Containing: a) soft catheter (0,8, no rigid) with adapter -cable in- and the connector in bag with notch on bag to open b) filter with tampon c) lor syringe 10ml   |
| EK18095   | epidural kit    | 18    | 95mm | tuohy, keep current material | 1) New packing. 2) Containing: a) soft catheter (0,8, no rigid) with adapter -cable in- and the connector in bag with notch on bag to open b) filter with tampon c) lor syringe 10ml   |
| EP16080   | epidural needle | 16/17 | 80mm | tuohy, keep current material |                                                                                                                                                                                        |
| EP18080   | epidural needle | 18    | 80mm | tuohy, keep current material |                                                                                                                                                                                        |
| EP18095   | epidural needle | 18    | 95mm | tuohy, keep current material |                                                                                                                                                                                        |
| EP20080   | epidural needle | 20    | 80mm | tuohy, keep current material |                                                                                                                                                                                        |
| EP20095   | epidural needle | 20    | 95mm | tuohy, keep current material |                                                                                                                                                                                        |
| EP22080   | epidural needle | 22    | 80mm | tuohy, keep current material |                                                                                                                                                                                        |
| EP22095   | epidural needle | 22    | 95mm | tuohy, keep current material |                                                                                                                                                                                        |
| ES20080   | epidural needle | 20    | 80mm | tuohy, keep current material |                                                                                                                                                                                        |
| ES20095   | epidural needle | 20    | 95mm | tuohy, keep current material |                                                                                                                                                                                        |
| ES22080   | epidural needle | 22    | 80mm | tuohy, keep current material |                                                                                                                                                                                        |
| ES22095   | epidural needle | 22    | 95mm | tuohy, keep current material |                                                                                                                                                                                        |



on demand



#### Product

|         |                   |  |  |  |                                                                                                                                                                                                                                                                                                                                                                                                                  |
|---------|-------------------|--|--|--|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| PKAN001 | procedure kit     |  |  |  | Containing: 1pc small tray, 1pcs big tray, 3pcs disposable luer lock syringe 20ml, 10ml and 5ml typed STERILE SINGLE USE, charger filter, 3pcs needle 21G, 25G and drill-charger, 1pc cloth without hole (non fenestrated drape) and with 5cm wide adhesive along one longer side, 2pcs cleaning sponge with handle and 15pcs white galuze as sample received                                                    |
| PKAN002 | procedure kit USA |  |  |  | Containing: 1pc small tray, 1pcs big tray, 3pcs disposable luer lock syringe 10ml, 5ml and 3ml typed STERILE SINGLE USE, 18G*80mm epidural needle ,charger filter, 3pcs needle 25G and 18G ,1pc cloth without hole (non fenestrated drape) and with 5cm wide adhesive along one longer side, 2pcs cleaning sponge with handle and 4pcs white gauze.                                                              |
| PKAN003 | Epidural maxi kit |  |  |  | Containing: Tuohy needle 18G x 80mm / epidural catheter 900m x 0,85mm with soft tip / Filter 0,2μ / Filter Kwill 0,5 μ. 1pc small tray, 1pcs big tray, 3pcs disposable luer lock syringe 20ml, 10ml and 3ml typed STERILE SINGLE USE, charger filter, 3pcs needle 25G, 21G, 18G and 16G Trocar, 1pc cloth with hole (fenestrated drape) and with 5cm wide adhesive along one longer side, 1pc clamo, 4pcs cotton |



|         |               |    |       |                 |  |
|---------|---------------|----|-------|-----------------|--|
| BN21050 | block nervous | 21 | 50mm  | quincke 22,177° |  |
| BN21070 | block nervous | 21 | 70mm  | quincke 22,177° |  |
| BN21090 | block nervous | 21 | 90mm  | quincke 22,177° |  |
| BN21140 | block nervous | 21 | 140mm | quincke 22,177° |  |
| BN22050 | block nervous | 22 | 50mm  | quincke 22,177° |  |
| BN22070 | block nervous | 22 | 70mm  | quincke 22,177° |  |
| BN22090 | block nervous | 22 | 90mm  | quincke 22,177° |  |



all products included AKUS SAFETY



**EC Certificate**  
**Directive 93/42/EEC Annex V**  
**Production Quality Assurance**  
**Medical Devices**

**Registration No.:** DD 60108272 0001

**Report No.:** 15079317 002

**Manufacturer:** Jiangsu Province Huaxing Medical  
Apparatus Industry Co., Ltd.  
No. 328 Tongda Road, Touqiao Town  
Yangzhou  
225109 Jiangsu  
China

**Products:** Medical Devices  
(see attachment for products included)  
Replaces Approval, Registration No.: DD 60100458 0001

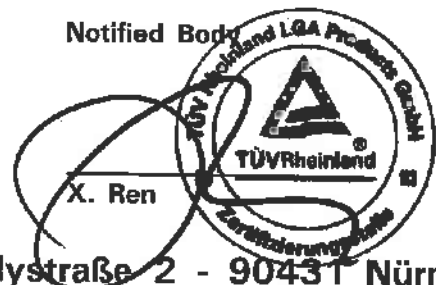
**Expiry Date:** 2020-04-14

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

**Effective Date:** 2016-04-13

**Date:** 2016-04-13

Notified Body



**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**

**TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.**

**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

Doc. 1/1, Rev. 0

**Attachment to  
Certificate**

**Registration No.:** DD 60108272 0001  
**Report No.:** 15079317 002

**Manufacturer:** Jiangsu Province Huaxing Medical  
Apparatus Industry Co., Ltd.  
No. 328 Tongda Road, Touqiao Town  
Yangzhou  
225109 Jiangsu  
China

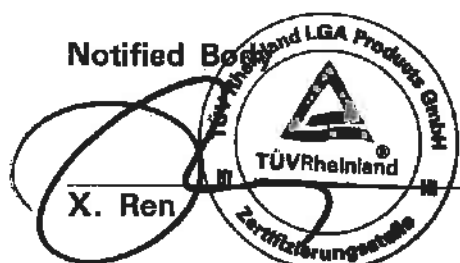
**Products:**

Bone Marrow Needles for Single Use, Biopsy Needles,  
Endotracheal Tubes, Suction Connecting Tubes, Extension  
Tubes, Three-Way Stopcocks, Feeding Tubes, Nelaton  
Catheters, Anaesthesia Procedure Kits for Single Use,  
Anaesthesia Masks for Single Use, Heat and Moisture  
Exchanger Filters for Single Use, Laryngeal Mask Airways for  
Single Use, Tracheostomy Tubes for Single Use, Breathing  
Circuits for Single Use

Aspects of manufacture concerned with securing and  
maintaining sterile conditions:

Forceps for Single Use, Skin Knives, Brushes for Single Use,  
Urine Bags for Single Use, Chest Drainage Bottles

**Date:** 2016-04-13





**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

Doc. 1/1, Rev. 0

**Attachment to  
Certificate**

**Registration No.:** SX 60108273 0001  
**Report No.:** 15079317 002

**Organization:** Jiangsu Province Huaxing Medical  
Apparatus Industry Co., Ltd.  
No. 328 Tongda Road, Tongqiao Town  
Yangzhou  
225109 Jiangsu  
China

**Scope:**

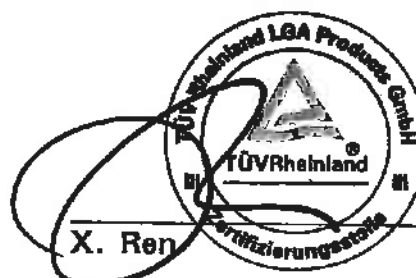
Design and Development, Manufacture and Distribution of  
Epidural Kits for Single Use, Anesthesia Needles for Single  
Use, Infusion Pumps for Single Use, Silicone Foley Catheters  
for Single Use

Manufacture and Distribution of Bone Marrow Needles for  
Single Use, Biopsy Needles, Endotracheal Tubes, Suction  
Connecting Tubes, Extension Tubes, Three-Way Stopcocks,  
Feeding Tubes, Nelaton Catheters, Anaesthesia Procedure  
Kits for Single Use, Anaesthesia Masks for Single Use,  
Heat and Moisture Exchanger Filters for Single Use,  
Laryngeal Mask Airways for Single Use, Tracheostomy Tubes  
for Single Use, Breathing Circuits for Single Use, Forceps  
for Single Use, Skin Knives, Brushes for Single Use, Urine  
Bags for Single Use, Chest Drainage Bottles

**Certification Body**



**Date:** 2016-04-13





**Certificat CE**  
**Directiva 93/42/CEE Anexa V**  
**Asigurarea Calitatii Productiei**  
**Dispozitive Medicale**

**Nr. de inregistrare: DD 60108272 0001**  
**Raport nr.: 15079317 002**

**Prodicator:** Jiangsu Province Huaxing Medical Apparatus Industry Co., Ltd.  
Tongda Road nr. 328, Oras Touqiao  
Yangzou  
225109 Jiangsu  
China

**Produse:** Dispozitive medicale (consultati anexa pentru produsele incluse)  
Inlocuieste Autorizatia cu nr. de inregistrare: DD 60100458 0001  
**Data expirarii:** 2020-04-14

**Organul de certificare declara, prin prezenta, ca produsele enumerate indeplinesc cerintele Anexei V a Directivei 94/42/CEE. Producatorul mentionat mai sus a stabilit si aplica un sistem de asigurare a calitatii, supus supravegherii periodice, definit in Anexa V, sectiunea 4 a sus-mentionatei directive. Pentru lansarea pe piata a dispozitivelor din clasa IIB si din clasa III care constituie obiectul prezentului certificat este necesar un certificat CE de examinare a tipului, conform Anexei III.**

**Data intrarii in vigoare: 2016-04-13**  
**Data: 2016-04-13**

**Organ de certificare:**  
(Stampila TUV si semnatura indescifrabila) **X.Ren**

**TÜV Rheinland LGA Products GmbH – Tillystrasse 2 – 90431 Nürnberg**  
TÜV Rheinland LGA Products GmbH este organ de certificare in acceptiunea Directivei 93/42/CEE privind dispozitivele medicale cu numarul de identificare 0197.





Doc.1/1, Editia 0

**TÜV Rheinland LGA Products GmbH**  
**Tillystrasse 2, 90431 Nürnberg**

**Anexa la Certificat**

**Nr. de inregistrare: DD 60108272 0001**

**Raport nr.: 15079317 002**

**Prodicator: Jiangsu Province Huaxing Medical Apparatus Industry Co., Ltd.**  
**Tongda Road nr. 328, Oras Touqiao**  
**Yangzou**  
**225109 Jiangsu**  
**China**

**Produse:**

Ace de unica folosinta pentru punctie medulara, ace pentru biopsie, tuburi endotraheale, tuburi de conexiune pentru aspiratie, tuburi de extensie, valve de inchidere cu 3 racorduri, tuburi de alimentare, catetere Nelathon, kit-uri procedurale de unica folosinta pentru anestezie, masti de unica folosinta pentru anestezie, filtre de unica folosinta pentru schimbatoare de caldura si umiditate, tuburi de ventilatie de unica folosinta pentru masca laringeala, circuite respiratorii de unica folosinta.

Aspecte de fabricatie pentru asigurarea si mentinerea conditiilor sterile:

Pense de unica folosinta, bisturiuri cutanate, perii de unica folosinta, pungi de urina de unica folosinta, flacoane de drenaj toracic.

**Organ de certificare:**

**Data: 2016-04-13**

(Stampila TUV si semnatura indescifrabila) **X.Ren**





Doc.1/1, Editia 0

**TÜV Rheinland LGA Products GmbH  
Tillystrasse 2, 90431 Nürnberg**

**Anexa la Certificat**

**Nr. de inregistrare: SX 60108273 0001**

**Raport nr.: 15079317 002**

**Organiztia: Jiangsu Province Huaxing Medical Apparatus Industry Co., Ltd.  
Tongda Road nr. 328, Oras Touqiao  
Yangzou  
225109 Jiangsu  
China**

**Obiectul certificatului:**

Proiectarea si dezvoltarea, fabricarea si distributia de kit-uri epidurale de unica folosinta, ace de unica folosinta pentru anestezie, pompe de unica folosinta pentru perfuzie, catetere Foley de unica folosinta, din silicon.

Fabricarea si distributia de ace de unica folosinta pentru punctie medulara, ace pentru biopsie, tuburi endotraheale, tuburi de conexiune pentru aspiratie, tuburi de extensie, valve de inchidere cu 3 racorduri, tuburi de alimentare, catetere Nelathon, kit-uri procedurale de unica folosinta pentru anestezie, masti de unica folosinta pentru anestezie, filtre de unica folosinta pentru schimbatoare de caldura si umiditate, tuburi de ventilatie de unica folosinta pentru masca laringeala, tuburi de traheostomie de unica folosinta, circuite respiratorii de unica folosinta, pense de unica folosinta, bisturiuri cutanate, perii de unica folosinta, pungi de urina de unica folosinta, flacoane de drenaj toracic.

DakS – Deutsche Akkreditierungsstelle  
D-ZM-14169-01-02

Organ de certificare

**Data: 2016-04-13**

(Stampila TUV si semnatura indescifrabila) **X.Ren**





**Certificat CE**  
**Directiva 93/42/CEE Anexa V**  
**Asigurarea Calitatii Productiei**  
**Dispozitive Medicale**

**Nr. de inregistrare: DD 60108272 0001**  
**Raport nr.: 15079317 002**

**Prodicator:** Jiangsu Province Huaxing Medical Apparatus Industry Co., Ltd.  
Tongda Road nr. 328, Oras Touqiao  
Yangzou  
225109 Jiangsu  
China

**Produse:** Dispozitive medicale (consultati anexa pentru produsele incluse)  
Inlocuieste Autorizatia cu nr. de inregistrare: DD 60100458 0001  
**Data expirarii:** 2020-04-14

**Organul de certificare declara, prin prezenta, ca produsele enumerate indeplinesc cerintele Anexei V a Directivei 94/42/CEE. Producatorul mentionat mai sus a stabilit si aplica un sistem de asigurare a calitatii, supus supravegherii periodice, definit in Anexa V, sectiunea 4 a sus-mentionatei directive. Pentru lansarea pe piata a dispozitivelor din clasa IIB si din clasa III care constituie obiectul prezentului certificat este necesar un certificat CE de examinare a tipului, conform Anexei III.**

**Data intrarii in vigoare: 2016-04-13**  
**Data: 2016-04-13**

**Organ de certificare:**  
(Stampila TUV si semnatura indescifrabila) **X.Ren**

**TÜV Rheinland LGA Products GmbH – Tillystrasse 2 – 90431 Nürnberg**  
TÜV Rheinland LGA Products GmbH este organ de certificare in acceptiunea Directivei 93/42/CEE privind dispozitivele medicale cu numarul de identificare 0197.







Doc.1/1, Editia 0

**TÜV Rheinland LGA Products GmbH**  
**Tillystrasse 2, 90431 Nürnberg**

**Anexa la Certificat**

**Nr. de inregistrare: DD 60108272 0001**

**Raport nr.: 15079317 002**

**Prodicator: Jiangsu Province Huaxing Medical Apparatus Industry Co., Ltd.**  
**Tongda Road nr. 328, Oras Touqiao**  
**Yangzou**  
**225109 Jiangsu**  
**China**

**Produse:**

Ace de unica folosinta pentru punctie medulara, ace pentru biopsie, tuburi endotraheale, tuburi de conexiune pentru aspiratie, tuburi de extensie, valve de inchidere cu 3 racorduri, tuburi de alimentare, catetere Nelathon, kit-uri procedurale de unica folosinta pentru anestezie, masti de unica folosinta pentru anestezie, filtre de unica folosinta pentru schimbatoare de caldura si umiditate, tuburi de ventilatie de unica folosinta pentru masca laringeala, circuite respiratorii de unica folosinta.

Aspecte de fabricatie pentru asigurarea si mentinerea conditiilor sterile:

Pense de unica folosinta, bisturiuri cutanate, perii de unica folosinta, pungi de urina de unica folosinta, flacoane de drenaj toracic.

**Organ de certificare:**

**Data: 2016-04-13**

(Stampila TUV si semnatura indescifrabila) **X.Ren**





Doc.1/1, Editia 0

**TÜV Rheinland LGA Products GmbH  
Tillystrasse 2, 90431 Nürnberg**

**Anexa la Certificat**

**Nr. de inregistrare: SX 60108273 0001**

**Raport nr.: 15079317 002**

**Organiztia: Jiangsu Province Huaxing Medical Apparatus Industry Co., Ltd.  
Tongda Road nr. 328, Oras Touqiao  
Yangzou  
225109 Jiangsu  
China**

**Obiectul certificatului:**

Proiectarea si dezvoltarea, fabricarea si distributia de kit-uri epidurale de unica folosinta, ace de unica folosinta pentru anestezie, pompe de unica folosinta pentru perfuzie, catetere Foley de unica folosinta, din silicon.

Fabricarea si distributia de ace de unica folosinta pentru punctie medulara, ace pentru biopsie, tuburi endotraheale, tuburi de conexiune pentru aspiratie, tuburi de extensie, valve de inchidere cu 3 racorduri, tuburi de alimentare, catetere Nelathon, kit-uri procedurale de unica folosinta pentru anestezie, masti de unica folosinta pentru anestezie, filtre de unica folosinta pentru schimbatoare de caldura si umiditate, tuburi de ventilatie de unica folosinta pentru masca laringeala, tuburi de traheostomie de unica folosinta, circuite respiratorii de unica folosinta, pense de unica folosinta, bisturiuri cutanate, perii de unica folosinta, pungi de urina de unica folosinta, flacoane de drenaj toracic.

DakS – Deutsche Akkreditierungsstelle  
D-ZM-14169-01-02

Organ de certificare

**Data: 2016-04-13**

(Stampila TUV si semnatura indescifrabila) **X.Ren**



**EC Certificate**  
**Directive 93/42/EEC Annex V**  
**Production Quality Assurance**  
**Medical Devices**

**Registration No.:** DD 60108272 0001

**Report No.:** 15079317 002

**Manufacturer:** Jiangsu Province Huaxing Medical  
Apparatus Industry Co., Ltd.  
No. 328 Tongda Road, Touqiao Town  
Yangzhou  
225109 Jiangsu  
China

**Products:** Medical Devices  
  
(see attachment for products included)  
  
Replaces Approval, Registration No.: DD 60100458 0001

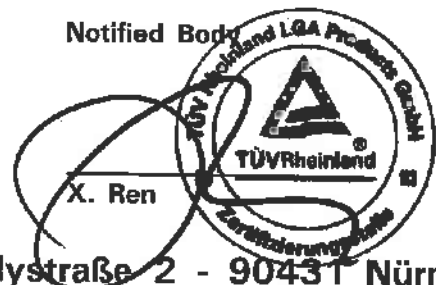
**Expiry Date:** 2020-04-14

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

**Effective Date:** 2016-04-13

**Date:** 2016-04-13

Notified Body



**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**

**TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.**

**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

Doc. 1/1, Rev. 0

**Attachment to  
Certificate**

**Registration No.:** DD 60108272 0001  
**Report No.:** 15079317 002

**Manufacturer:** Jiangsu Province Huaxing Medical  
Apparatus Industry Co., Ltd.  
No. 328 Tongda Road, Touqiao Town  
Yangzhou  
225109 Jiangsu  
China

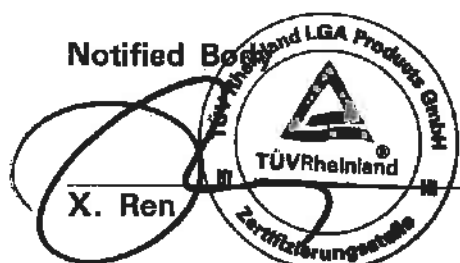
**Products:**

Bone Marrow Needles for Single Use, Biopsy Needles,  
Endotracheal Tubes, Suction Connecting Tubes, Extension  
Tubes, Three-Way Stopcocks, Feeding Tubes, Nelaton  
Catheters, Anaesthesia Procedure Kits for Single Use,  
Anaesthesia Masks for Single Use, Heat and Moisture  
Exchanger Filters for Single Use, Laryngeal Mask Airways for  
Single Use, Tracheostomy Tubes for Single Use, Breathing  
Circuits for Single Use

Aspects of manufacture concerned with securing and  
maintaining sterile conditions:

Forceps for Single Use, Skin Knives, Brushes for Single Use,  
Urine Bags for Single Use, Chest Drainage Bottles

**Date:** 2016-04-13





**Certificat CE**  
**Directiva 93/42/CEE Anexa V**  
**Asigurarea Calitatii Productiei**  
**Dispozitive Medicale**

**Nr. de inregistrare: DD 60108272 0001**  
**Raport nr.: 15079317 002**

**Prodicator: Jiangsu Province Huaxing Medical Apparatus Industry Co., Ltd.**  
**Tongda Road nr. 328, Oras Touqiao**  
**Yangzou**  
**225109 Jiangsu**  
**China**

**Produse:** Dispozitive medicale (consultati anexa pentru produsele incluse)  
Inlocuieste Autorizatia cu nr. de inregistrare: DD 60100458 0001

**Data expirarii:** 2020-04-14

**Organul de certificare declara, prin prezenta, ca produsele enumerate indeplinesc cerintele Anexei V a Directivei 94/42/CEE. Producatorul mentionat mai sus a stabilit si aplica un sistem de asigurare a calitatii, supus supravegherii periodice, definit in Anexa V, sectiunea 4 a sus-mentionatei directive. Pentru lansarea pe piata a dispozitivelor din clasa IIb si din clasa III care constituie obiectul prezentului certificat este necesar un certificat CE de examinare a tipului, conform Anexei III.**

**Data intrarii in vigoare: 2016-04-13**

**Data: 2016-04-13**

**X.Ren**

**Organ de certificare:**

(Stampila TUV si semnatura indescifrabila)

**TÜV Rheinland LGA Products GmbH – Tillystrasse 2 – 90431 Nürnberg**  
**TÜV Rheinland LGA Products GmbH este organ de certificare in acceptiunea Directivei 93/42/CEE privind dispozitivele medicale cu numarul de identificare 0197.**





Doc.1/1, Editia 0

**TÜV Rheinland LGA Products GmbH**  
**Tillystrasse 2, 90431 Nürnberg**

**Anexa la Certificat**

**Nr. de inregistrare: DD 60108272 0001**

**Raport nr.: 15079317 002**

**Prodicator: Jiangsu Province Huaxing Medical Apparatus Industry Co., Ltd.**

**Tongda Road nr. 328, Oras Touqiao**

**Yangzou**

**225109 Jiangsu**

**China**

**Produse:**

Ace de unica folosinta pentru punctie medulara, ace pentru biopsie, tuburi endotraheale, tuburi de conexiune pentru aspiratie, tuburi de extensie, valve de inchidere cu 3 racorduri, tuburi de alimentare, catetere Nelathon, kit-uri procedurale de unica folosinta pentru anestezie, masti de unica folosinta pentru anestezie, filtre de unica folosinta pentru schimbatoare de caldura si umiditate, tuburi de ventilatie de unica folosinta pentru masca laringeala, circuite respiratorii de unica folosinta.

Aspecte de fabricatie pentru asigurarea si mentinerea conditiilor sterile:

Pense de unica folosinta, bisturiuri cutanate, perii de unica folosinta, pungi de urina de unica folosinta, flacoane de drenaj toracic.

**Organ de certificare:**

(Stampila TUV si semnatura indescifrabila)

**Data: 2016-04-13**

**X.Ren**

\*\*\*\*\*

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

