

AKUS[®]

Range for
Locoregional
Anaesthesia



AKUS[®]

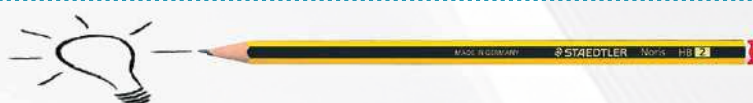
AKUS®

Range for
Locoregional
Anaesthesia

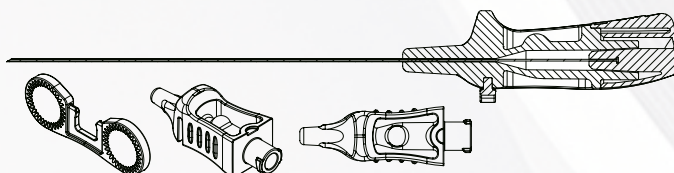
Innovation with an improved design

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.



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.

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.

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.

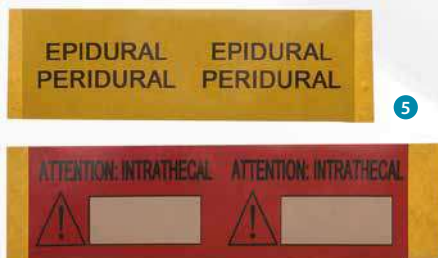


2. Low resistance syringe.

3. Filter 0,2 μ .

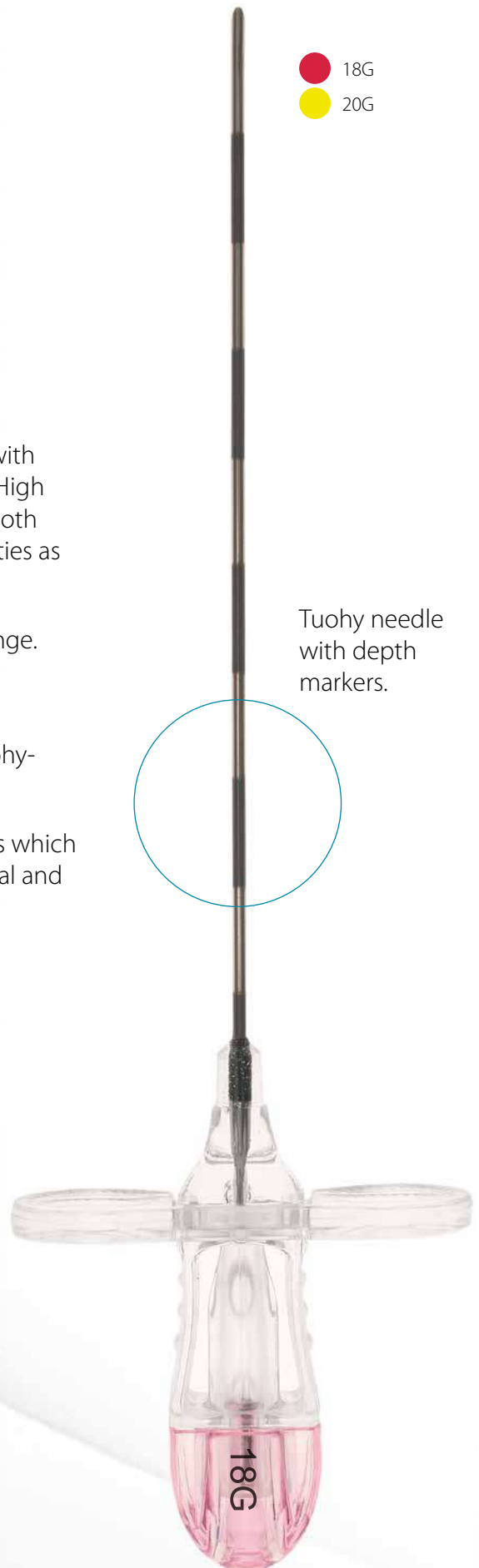
4. High resistance Tuohy-Borst adaptor.

5. INNOVATIVE stickers which differentiate epidural and intrathecal.



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.



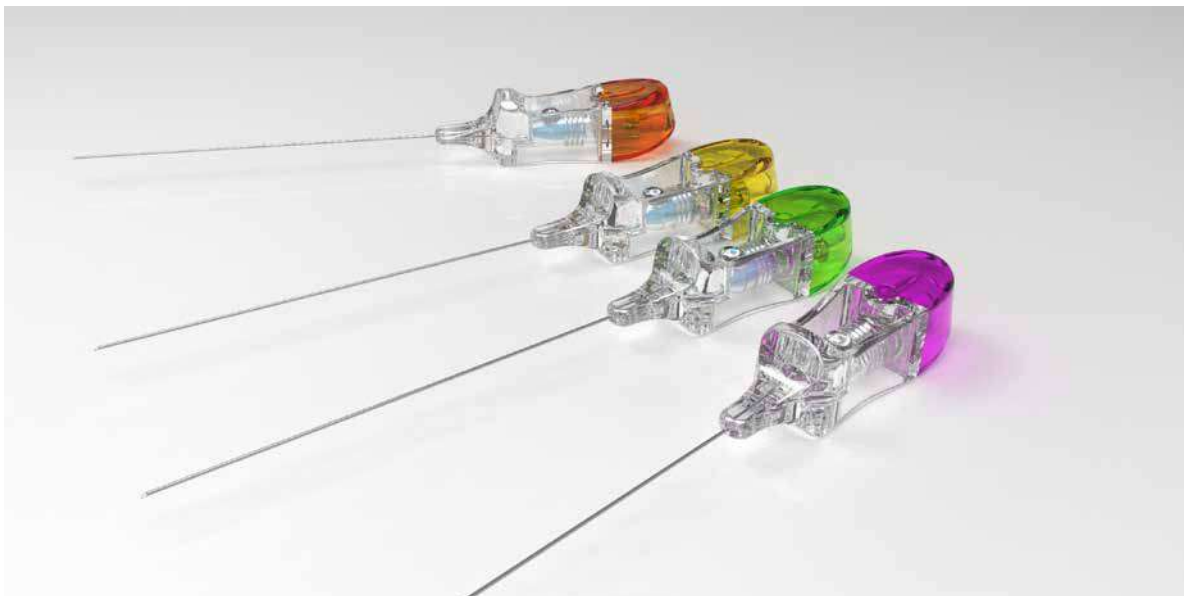
Reference range Locoregional Anaesthesia

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

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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

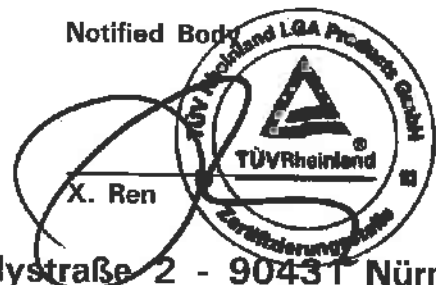
Expiry Date: 2020-04-14

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

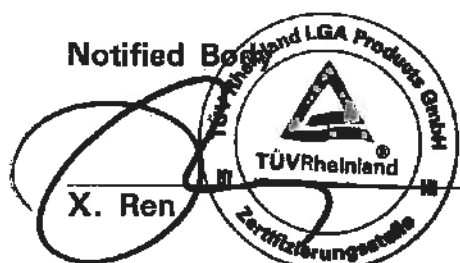
Products:

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:

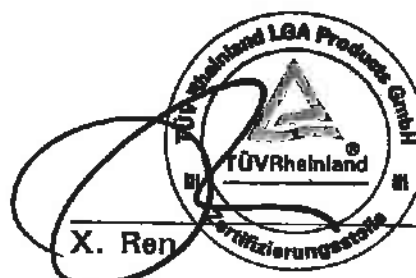
Design and Development, Manufacture and Distribution of
Epidural Kits for Single Use, Anesthesia Needles for Single
Use, Infusion Pumps for Single Use, Silicone Foley Catheters
for Single Use

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

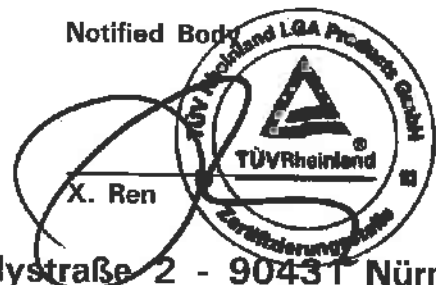
Expiry Date: 2020-04-14

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

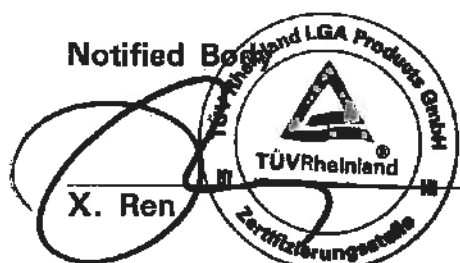
Products:

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

Producator: 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

