

CMTANGE®



淮安安洁医疗用品股份有限公司
HUAIAN ANGEL MEDICAL INSTRUMENTS CO., LTD.



公司简介

淮安安吉医疗用品股份有限公司是专业生产一次性医疗器械的股份制企业。我公司不但严格按照国家医疗器械行业标准设计兴建的40000平方米厂房及相应的十万级净化车间，而且拥有专业技术队伍和装备精良的生产检测设备。在专业设备制造，工艺程序设计方面均处于同行领先地位，也是全国最大的一次性医疗器械生产基地之一。公司主要产品有一次性缝合针线、灭菌医用手术刀片、脐带夹、采血针、尿袋等几十个品种和规格。公司始终坚持：“一切对用户负责”的经营宗旨，以高标准，严要求，造就培养出一支适合国际市场要求的职工队伍。我公司产品全部出口，畅销世界六十多个国家和地区，深受客户赞誉。



CE 0197



TUV ISO13485



CE 2292
Surgical Sutures



CE 2292
Surgical Sutures

ISO 13485
Surgical Sutures

Company profile

Huaian Angel Medical Instruments Co., Ltd is specializing in the production of disposable medical devices of joint-stock enterprises. Our company not only in strict accordance with the national standards for medical devices industry design to build 40000 square meters workshop and the corresponding grade purification workshop, and has a professional technical team and well equipped production testing equipment. In the professional equipment manufacturing, process design is a peer leader, is also one of the biggest disposable medical equipment production base. Our main products are absorbable and non absorbable surgical sutures of different classes with needles, sterilizing surgical blade, umbilical cordclamp, blood collection needles, urine bag, and dozens of varieties and specifications. The company always adhere to: all are responsible for the user business purposes, to high standards and strict, make produce a suitable for the international market requirement worker team. Our all company's products are export standard, sell well in more than 60 countries and regions of the world, favored by customers praise.



编号 320800666202004150010

扫描二维码登录“国家企业信用信息公示系统”了解更多登记、备案、许可、监管信息。



营业执照

统一—社会信用代码

91320800734416734C (1/1)

淮安安洁医疗用品股份有限公司

类型 股份有限公司(非上市)

法定代表人

经营范围

[illegible]

注册资本 1690万元整

成立日期 2002年01月31日

营业期限 2002年01月31日至*****

住 所 淮安市珠海东路19号



登记机券₄

<http://www.gsxt.gov.cn>

市场主体应当于每年1月1日至6月30日通过国家企业信用信息公示系统报送公示年度报告。

国家企业信用信息公示系统网址:

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

herby certifies that the organization
**Huaian Angel Medical Instruments
Co., Ltd.**
19 East Zhuhai Road
Huaian
223001 Jiangsu
China

has established and applies a quality management system for medical devices
for the following scope:

**Design and Development, Manufacture and
Distribution of Medical Devices
(see attachment for products included)**

Proof has been furnished that the requirements specified in
EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2018-06-22
Certificate Registration No.: SX 60128392 0001
An audit was performed. Report No.: 15065241 007
This Certificate is valid until: 2021-05-21

Certification Body

Date 2018-06-22

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 906-1271 Fax: +49 221 906-3895 e-mail: cert-enquiry@tue.com http://www.tue.com/cert

GOVERNMENT OF THE PEOPLE'S REPUBLIC OF BANGLADESH
MINISTRY OF HEALTH & FAMILY WELFARE
DIRECTORATE GENERAL OF DRUG ADMINISTRATION
AUSHD BHABAN, MOHAKHALI, DHAKA-1212.

CERTIFICATE OF REGISTRATION

We hereby declare that Surgivicyrl Suture, Violet (Polyglactin 910) Manufactured By M/s. Huaian Angel Medical Instruments Co. Ltd. China and represented by M/s. Medicare Instrument, 34, Milford Road, Dhaka, Bangladesh is Registered with Directorate General of Drug Administration and Licensing Authority (Dugs) under Reg. No. **574-5172-017**. The drug as described below is allowed to be imported into Bangladesh under The Drugs Act 1940 (XXIII of 1940) and The Drugs (Control) Ordinance, 1982 and its Amendment Act 2006 subjected to the provision of import policy published by the Government from time to time.

Name of the Product : Surgivicyrl Suture, Violet (Polyglactin 910)
Generic Name : Absorbable Surgical Suture
Type of Product : Medical Device, Class-C
Size : 1 x 75 cm, 1 x 90cm and 1 x 180cm
Pack Size : 12 Packets in a Box

Major General Md Mustafizur Rahman
Director General
Directorate General of Drug Administration
&
Licensing Authority (Dugs) 09 FEB 2017
Government of the People's Republic of Bangladesh.
Phone-9880803, email: dgda.gov@gmail.com

Instructions
This certificate is valid only by or on the prescription of a registered physician.

Conditions:

(1) Labeling should be done in accordance with the provision of the Drugs Act and Rules which require that the name and address of the manufacturer, batch number, Manufacturing date, expiry date, M.R.P. (Maximum Retail Price), DAR No. (Drug Administration Reg. Number) etc. should be displayed on the label of the container and also on the outer cover containing the container.

(2) The registration will be valid for 5(five) years from its date of issue unless it is revoked, suspended or cancelled earlier.

(3) The certificate will be treated as cancelled if any violation of the condition and the name or the formula of this product is changed or modified qualitatively or quantitatively without due approval of the Licensing Authority.

Memo No.DGDA/15-5/17/504y 1860 Date: 09/02/2017

cc: M/s. Medicare Instrument
34, Milford Road, Dhaka

For Director General
Directorate General of Drug Administration

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

Registration No.: DD 60136001 0001
Report No.: 15065241 009

Manufacturer: Huaian Angel Medical Instruments
Co., Ltd.
19 East Zhuhai Road
Huaian
223001 Jiangsu
China

Products: Medical Devices
(see attachment for products included)

Replaces Approval, Registration No.: DD 60101257 0001

Expiry Date: 2024-01-26

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: 2019-01-27
Date: 2019-01-17

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 60136001 0001
Report No.: 15065241 009

Manufacturer: Huaian Angel Medical Instruments
Co., Ltd.
19 East Zhuhai Road
Huaian
223001 Jiangsu
China

Products:

- Disposable Suture Needles
- Disposable Surgical Blades & Scalpels with Plastic Handle
- Sterile Blood Lancets
- Surgical Instruments Kits

For the following medical devices the scope covers only the aspects of manufacture concerned with securing and maintaining sterile conditions:

- Sterile Urinary Drainage Bags
- Disposable Umbilical Cord-Clamps

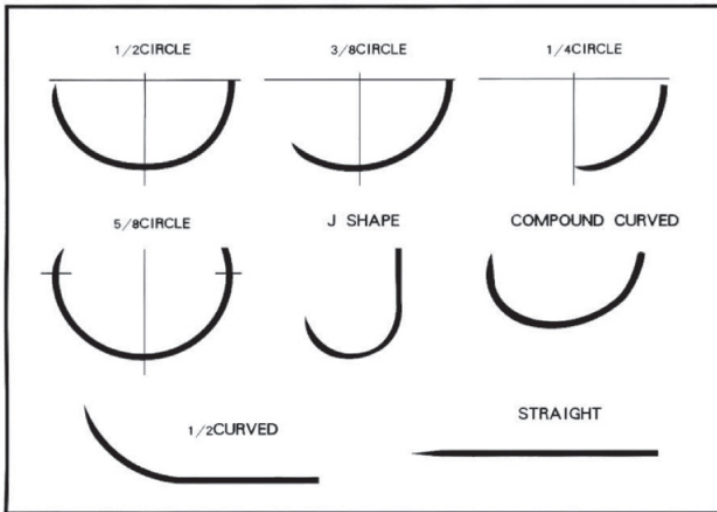
Date: 2019-01-17

Notified Body
TÜV Rheinland
Herbert Ziegler



净化车间





针形状 SHAPES

The choice of needle shape is frequently governed by the accessibility of the tissue to be sutured, and normally the more confined the operative site the greater the curvature required. The basic shapes involved are: straight, 1/4circle, 3/8circle or curved, 1/2circle, 5/8circle, half curved, J Needle and compound curved.

缝线材料

SUTURE MATERIALS



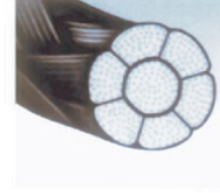
化学合成线
POLYGLYCOLIC ACID



铬制羊肠线
CHROMIC (Catgut)



平制羊肠线
PLAIN (Catgut)



丝编织线
SILK (Braided)



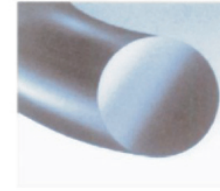
尼龙线
POLYGLACTIN 910
(Synthetic Absorbable Suture)



聚丙烯线
POLYPROPYLENE
(Monofilament)



涤纶编织线
POLYESTER (Braided)



不锈钢丝线
STAINLESS STEEL
WIRE (Monofilament)

无菌医用无损伤缝合针 Sterile Suture Needles with Thread

用途：本产品供显微外科、心、胸、血管外科、眼科及内脏软组织等缝合用。

Use: This kind of product is used in microsurgery, the surgery of the heart and the chest and the blood vessel, ophthalmic surgery and the soft tissues of internal organs.

本品由涤铝复合、涤纶等包装材料密封包装，经伽玛射线辐照灭菌，使用前不再消毒，可直接使用。

This kind of product is sealed and packed by the compound material of polyester and aluminium foil and polyester packing material. It is sterilized by the gammaradiation and can be used directly without being re-sterilized before use.

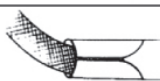
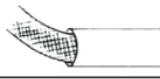
配针 Types of Needle Shape:

1/2 弧	1/2 circle	● ○ ▲ ▼ ⊕ ▼	(8mm-60mm)
3/8 弧	3/8 circle	● ○ ▲ ▼ ⊕ ▼	(8mm-60mm)
5/8 弧	5/8 circle	● ○ ▲ ▼ ⊕ ▼	(8mm-60mm)
直接	straight cutting	● ○ ▲ ▼ ⊕ ▼	(308mm-90mm)

针类型说明

Description of Needle Type

SYMBOL	PONT TYPE
●	TAPER PONG 
○	BLUNT TAPERPOINT 
▲	CUTTING EDGE 
▼	REVERSE CUTTING EDGE 
⊕	
▼	MICRO-POING REVERSE CUTTING
	MICRO-POINT SPATULA CURVED 

针尾型式	
	尾部包卷型
	尾部钻孔型
	普通孔



真丝编织缝线 **Silk (Braided) Suture**

成分 Component part: 天然蚕丝 Natural Silk

结构 Structure: 多股编织, Braided

吸收 Absorbion: 不可吸收 Non-absorbable

颜色 Colour: 黑色或象牙色 Black or Ivory

线径规格 Diameters of sutures: USP 6/0-4

线长 Thread Length: 45cm, 75cm, 90cm and 150cm

灭菌 Sterilization: 伽玛射线灭菌 By Gamma Radiation



平制羊肠线(可吸收缝合线) **Plain Catgut (Absorbable) Suture**

成分组成 Component parts: 由源于牛肠浆膜或羊肠亚粘膜纤维层的洁净肌肉结缔组织(大部分为胶原蛋白)组成。Produced from purified animal intestines (cow or sheep)

结构 Structure: 单股, 线体平滑 Monofilament, Smooth Surface

吸收 Absorbion: 由蛋白酶分解吸收, 90 天后完全吸收 By enzymatic digestion. Complete from 90 days.

颜色 Colour: 麦色 Straw

线径规格 Diameters of sutures: USP 6/0-4

线长 Thread Length: 70cm, 75cm, 90cm and 150cm

包装 Packaging: 异丙醇 In a conditioning fluid containing isopanol water

灭菌 Sterilization: 伽玛射线灭菌 By Gamma Radiation



尼龙线 不可吸收 Nylon (Non-absorbable) Suture

成分 Component part: 聚酰胺(尼龙) Polyamide (Nylon)

结构 Structure: 单股, 线体平滑 Monofilament, Smooth Surface

吸收 Absorption: 不可吸收 Non-absorbable

颜色 Colour: 黑色或蓝色 Black or Blue

线径规格 Diameters of sutures: USP 11/0-3

线长 Thread Length: 45cm, 75cm, 90cm and 150cm

灭菌 Sterilization: 伽玛射线灭菌 Sterilization: By Gamma Radiation

聚丙烯缝线 Polypropylene Suture

成分 Component part: 聚丙烯 Polypropylene

结构 Structure: 单股, 线体平滑 Monofilament, Smooth Surface

吸收 Absorption: 不可吸收 Non-absorbable

颜色 Colour: 蓝色 Blue

线径规格 Diameters of sutures: USP 6/0-3

线长 Thread Length: 45cm, 75cm, 90cm and 150cm

灭菌 Sterilization: 伽玛射线灭菌 By Gamma Radiation



铬制羊肠线(可吸收缝合线) Chromic Catgut (Absorbable) Suture

成分组成 Component parts: 由源于牛肠浆膜或羊肠亚粘膜纤维层的洁净肌肉结缔组织(大部分为胶原蛋白)组成。Produced from purified animal intestines (cow or sheep)

结构 Structure: 单股, 线体平滑 Monofilament, Smooth Surface

吸收 Absorption: 由蛋白酶分解吸收, 90 天后完全吸收 By enzymatic digestion
Complete from 90 days.

颜色 Colour: 绿色或棕色 Green or Brown

线径规格 Diameters of sutures: USP 6/0-4

线长 Thread Length: 70cm, 75cm, 90cm and 150cm

包装 Packaging: 异丙醇 In a conditioning fluid containing isopropanol water

灭菌 Sterilization: 伽玛射线灭菌 By Gamma Radiation





合成线 Absorbable Surgical Suture (Synthetic)

成分 Component part: Poly (glycolide-co-L-lactide) (Polyglactin 910), Antibacterial by Chlorhexidine.

类型 Type: 编织 Braided

吸收 Absorption: 可吸收 By Hydrolysis in 45-70 days

颜色 Colour: 紫色和未染色 Violet or Undyed

线径规格 Diameters of Thread: USP 0 (3.5 Metric)

线长 Thread Length: 75cm, 90cm and 180cm

涂层 Coating: Calcium Stearate

伤口支持 Wound Support: 30 days

灭菌 Sterilization: 环氧乙烷灭菌 By Ethylene Oxide



可吸收合成缝合线 Synthetic Absorbable Suture (PGA, PGLA, PDO, PGCL)

成分 Component part: 乙醇酸、乳酸 Ethanoic Acid, Lactic Acid

结构 Structure: 多股紧密编织 Stranded Tight Braided

吸收 Absorption: 简单的水解过程, 60-90 天内完全吸收 By hydrolysis Complete between 60 & 90 days

颜色 Colour: 紫色或未染色 Violet or Undyed

线径规格 Specification: USP 8/0-2

线长 Thread Length: 75cm, 90cm and 150cm

灭菌 Sterilization: 环氧乙烷灭菌 By Ethylene Oxide

一次性塑柄碳钢手术刀
一次性塑柄不锈钢手术刀



SPECIFICATIONS

10#, 11#, 12#, 13#,
14#, 15#, 18#, 19#,
20#, 21#, 22#, 23#,
24#, 25#, 36#,

DISPOSABLE CARBON
STEEL SURGICAL
SCALPELS

WAY OF STERILIZATION

STERILIZED BY GAMMA
RADIATION

DISPOSABLE STAINLESS
STEEL SURGICAL
SCALPELS

规格

10#, 11#, 12#, 13#,
14#, 15#, 18#, 19#,
20#, 21#, 22#, 23#,
24#, 25#, 36#,

DISPOSABLE CARBON STEEL SURGICAL BLADES



一次性碳钢手术刀片
一次性不锈钢手术刀片

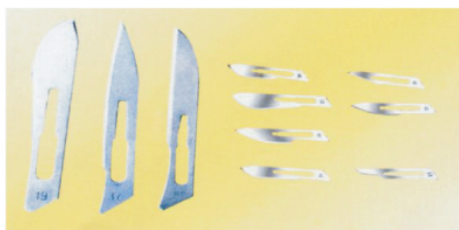
DISPOSABLE STAINLESS STEEL SURGICAL BLADES



灭菌方式
伽玛射线灭菌

SPECIFICATIONS

10#, 11#, 12#, 13#,
14#, 15#, 18#, 19#,
20#, 21#, 22#, 23#,
24#, 25#, 36#



规格

10#, 11#, 12#, 13#,
14#, 15#, 18#, 19#,
20#, 21#, 22#, 23#,
24#, 25#, 36#

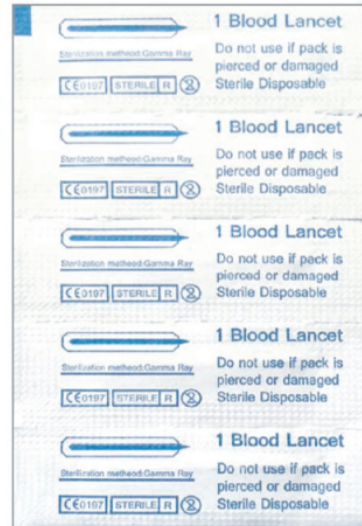


WAY OF STERILIZATION

STERILIZED BY GAMMA
RADIATION

一次性使用采血针

Disposable Blood Lancets



We manufacture with the greatest degree of precision to ensure a consistent blood sample for glucose monitoring. Featuring the highest quality needle, a tri-bevel tip dramatically reduces trauma when skin is punctured. These lancets also offer universal style compatible with nearly all lancing devices. The plastic shield ensures sterility until the lancet is used.



硬铝包装正面



通过优质硬铝由全自动机器一次成型制作出外观更加精美的包装，具有良好的延展性和抗挤压能力。

Through high-quality duralumin produced a forming the appearance more elegant packingby fully automatic machine. It as good ductility and compression resistance.

硬铝包装反面





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