

CMTANGE®



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

淮安安洁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



TÜV 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.



统一社会信用代码

91320800734416734C (1/1)

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 (副本)

名称 淮安安洁医疗用品股份有限公司

注册资本 1690万元整

类型 股份有限公司(非上市)

成立日期 2002年01月31日

法定代表人 曹明拓

营业期限 2002年01月31日至*****

经营范围

医疗器械（三类6865医用缝合材料及粘合剂、二类6801基础外科手术器械、6812妇科手术器械、6841医用化学实验和基础设备）、塑料制品、橡胶制品、塑料模具、包装材料、服装生产、加工、销售；本企业生产、加工、销售、经营、设备、或禁止进口业务、但国家所规定的防护用品（非医护人员防护用品、非医用口罩、防护口罩、防护服、防护用品等）的生产、销售、进口、出口业务除外。医用口罩生产、批发、零售、进口、出口业务除外。医疗器械（非医护人员防护用品、非医用口罩、防护用品等）的生产、销售、进口、出口业务除外。依法须经批准的项目，经相关部门批准后方可开展经营活动。

住所 淮安市珠海东路19号




登记机卷1

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:

国家市场监督管理总局监制



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


 Deutsche
 Akkreditierungsstelle
 D-24149-01-02

Date 2018-06-22


 X. Ren


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
 AUSHED BHABAN, MOHAKHALLI, 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, Mitford Road, Dhaka, Bangladesh is Registered with Directorate General of Drug Administration and Licensing Authority (Drugs) under Reg. No. ~~SP-4-5172-017~~ 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 (Drugs) 09 FEB 2017
 Government of the People's Republic of Bangladesh.
 Phone-8880803, email: dgda.gov@gmail.com

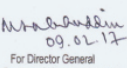
Instructions
 to be displayed only by or
 to the prescription of a
 registered physician.


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, Mitford Road, Dhaka


 09.02.17
 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


 Notified Body
 TÜV Rheinland
 Herbert Ziegler

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.



Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
 Tillystraße 2, 90431 Nürnberg

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

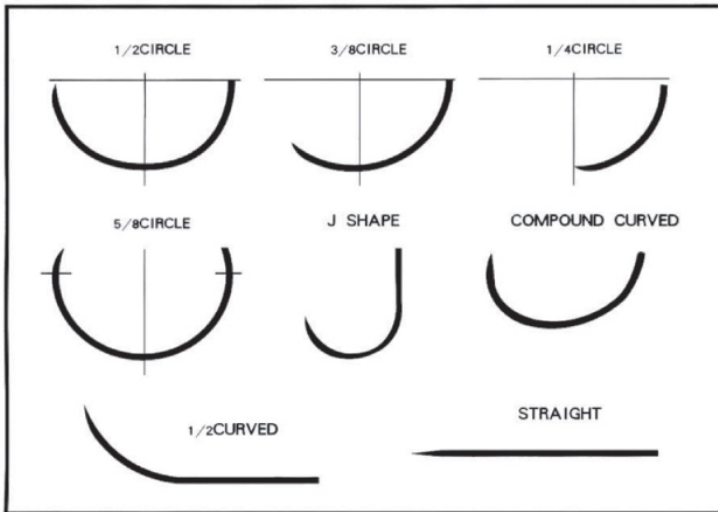


净化车间



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



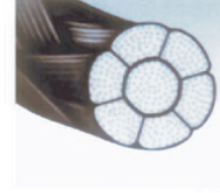
化学合成线
POLYGLYCOLIC ACID



铬制羊肠线
CHROMIC (Catgut)



平制羊肠线
PLAIN (Catgut)



丝编织线
SILK (Braided)



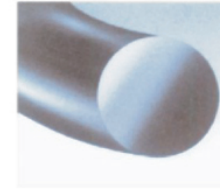
尼龙线
POLYGLACTIN 910
(Synthetic Absorbable Suture)



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。




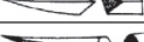
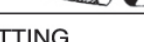

This kind of product is sealed and packed by the compound material of polyester and aluminium foil and polyester packing material. It is sterilized by the gammaradiation and can be used directly without being re-sterilized before use.

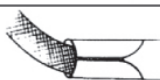
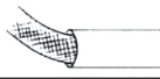

配针 Types of Needle Shape:

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 POINT	
○	BLUNT TAPER POINT	
▲	CUTTING EDGE	
▼	REVERSE CUTTING EDGE	
⊕		
▼	MICRO-POINT 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 Absorbtion: 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 Absorbtion: 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 Absorbtion: 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 Absorbtion: 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 Absorbtion: 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 isopanol 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 Absorbtion: 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 Absorbtion: 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

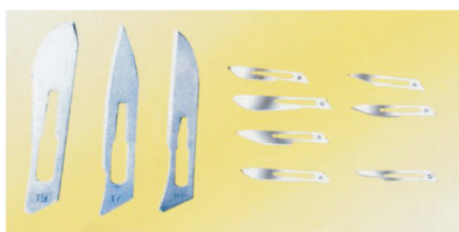
DISPOSABLE STAINLESS STEEL SURGICAL BLADES



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#

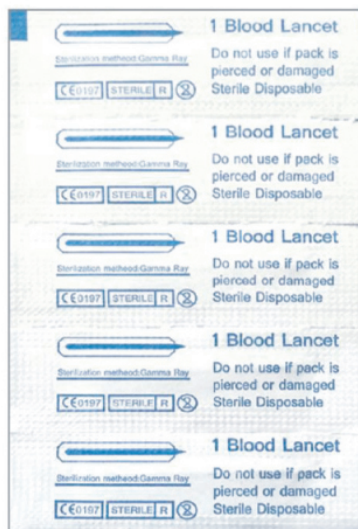


WAY OF STERILIZATION

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.



CMTANGE®

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

Huaian Angel Medical Instruments Co., Ltd.

19 East Zhuhai Road, Huai'an, Jiangsu, China

Tel: +86(517) 83721542, Fax: +86(517) 83717157

E-mail : lisahe528@sina.com, caomingtuo@china.com

www.angel-medical.net