



Rev. No.:2022A

Date of issue: 2022-09-22

EN ISO13485:2016

CE0197

INSTRUMENTS FOR PEDIATRIC LAPAROSCOPIC SURGERY



About us

Changzhou Intl. Trade & Enterprises Cooperative Co., Ltd (CITEC) is established in year 2000. We focus on stapling devices, laparoscopic instruments and endoscopic accessories. We are a solution provider, vertically integrated in R&D, manufacturing, sales and services.

We strictly implement the quality management system according to GMP and ISO13485 and have gained the CE certificates for all of our products. We have exported our products to more than 80 countries in the world.

We are committed to provide cost effective and high quality products and best service to our customers. We are working hard to become one of the reliable suppliers in medical devices field.


We accept OEM & ODM production and can meet your special requirements both on manufacturing and service.

Our Company Culture

Core Value: Quality First, Develop Harmoniously.

To Build: Good Corporate Image, Professional Service, High Efficient Team Work.

To Create: More Fortune for the Group, More High-Quality Products and Services for Customers, More Employment Opportunities and Taxes for the Society.



EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

Registration No.: HD 2057087-1

Manufacturer: Changzhou Intl. Trade & Enterprises Cooperative Co., Ltd
No. 20 Floor
Huang Building
NO. 1 Hejing Garden, Zhonglou District
Changzhou
213000 Jiangsu
P.R. China


Products: Hernia Staplers, Disposable Endoscopic Ligating Loops, Sterile Electrocautery Electrodes for Single Use, Sterile Medical Titanium Clips for Single Use, Hernia Patches, Non-vascular Stents, Implantable Ligating Clips, Sterile Trocars for Single Use, Sterile Suction & Irrigation Tubes for Single Use, Dilators, Biopsy Forceps, Disposable Skin Staplers, Disposable Endoscopic Retrieval Bags, Disposable Clip Applicators, Disposable Venous Needles, Disposable Endoscopic Hemostats, Disposable Polyp Snare, Disposable Cytology Brushes, Gastrointestinal and Biliary Balloon Catheters, Grasping Forceps, Non-vascular Cutwires, Stone Extraction Baskets, Stone Extraction Baskets, Injection needles, Disposable Spray Pipes, 3-stage Dilator Balloon Catheters, Wireguided Balloon Dilator Catheters

Aspects of manufacture concerned with securing and maintaining sterile conditions of Disposable Camera Sheaths, Disposable Bite Blocks, Cleaning Brushes for Endoscopes, Balloon Inflators, Sigmoid Valves, Polyp Traps, Clean Connecting Tubes, Disposable Staple Removers

Registree Approval, Registration No.: HD 02147784 0001

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 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 II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II section 4 is required.

Report No.: 244332082-200
Effective date: 2021-05-21
Expiry date: 2024-05-26
Issue date: 2021-05-21



Fuxu Sheng
TUV Rheinland LGA Products GmbH
Tilleystraße 2 · 90431 Nürnberg · Germany

TUV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0187.

Page 1 of 1



Certificate

Quality Management System
EN ISO 13485:2016

Registration No.: SX 2057087-1

Organization: Changzhou Intl. Trade & Enterprises Cooperative Co., Ltd
No. 20 Floor
Huang Building
NO. 1 Hejing Garden, Zhonglou District
Changzhou
213000 Jiangsu
P.R. China

Scope: Design and Development, Manufacture and Distribution of Endoscopic Instruments, Non-vascular Implantable Devices, Surgical Staplers, Orthopaedic Implantable Devices, Manufacture and Distribution of Clean Connecting Tubes



Fuxu Sheng
TUV Rheinland LGA Products GmbH
Tilleystraße 2 · 90431 Nürnberg · Germany

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices. Proof has been furnished that the requirements specified in the above-mentioned standard are fulfilled. The quality management system is subject to periodic surveillance.

Report No.: 15053240 014
Effective date: 2020-10-19
Expiry date: 2023-10-18
Issue date: 2020-09-30



Dakks
Notified Body
© TÜV Rheinland

1 / 1

Index

Product	Page
Disposable Trocars for Pediatric Laparoscopic Surgery	4
Disposable Mini Monopolar Instruments	5
Suction Irrigation Set, Dual Spike	6
Reusable Pediatric Laparoscopic Surgery Instruments	7 - 8

Disposable Trocars for Pediatric Laparoscopic Surgery



Features:

- + Low profile and less weight, specially designed for pediatric laparoscopic surgery.
- + Stainless steel cannula with thin wall and good rigidity, greatly reduce the incision and the damage to the abdominal wall.
- + Unique silicone fixator design, provide great retention force when instrument goes in and out.
- + Flexible and durable seal maintain abdominal insufflation while accommodating instrument's smooth insertion and extraction.

Code No.	Item	Spec.(mm)
CIT-PT-03	3mm Disposable Trocars for Pediatric Laparoscopic Surgery	3 x 50
CIT-PT-05	5mm Disposable Trocars for Pediatric Laparoscopic Surgery	5 x 80

Disposable Mini Monopolar Instruments



Intended use:

Disposable Mini Monopolar Instruments are designed to cut, grasp, dissect and coagulate selected tissue in laparoscopic surgery. The instrument is connected through a suitable monopolar cable with the monopolar output of the electro-surgical generator.

Features:

- + Compatible with 3mm trocar port, make the trauma to patient as small as possible.
- + Ergonomic handles offer comfort grip.
- + Light weight reduces the doctors' load during the long time surgery.
- + Colorful knobs for easier distinguish.

Rec. Code No.	Item	Spec. (mm)	Color of rotation knob
CIT-XMH-01	Disposable Curved Scissors	3 x 280	Orange
CIT-XMH-03	Disposable Curved Dissector	3 x 280	Blue
CIT-XMH-04	Disposable EndoClinch with Ratchet	3 x 280	Dark Grey
CIT-XMH-05	Disposable Fenestrated Atraumatic Grasper with Ratchet	3 x 280	Dark Grey
CIT-XMH-08	Disposable Blunt with Ratchet	3 x 280	Dark Grey
CIT-XMH-09	Disposable Fenestrated Long Grasper with Ratchet	3 x 280	Dark Grey

Different Jaws:



Curved Scissor



Curved Dissector



Endoclinc



Fenestrated Grasper

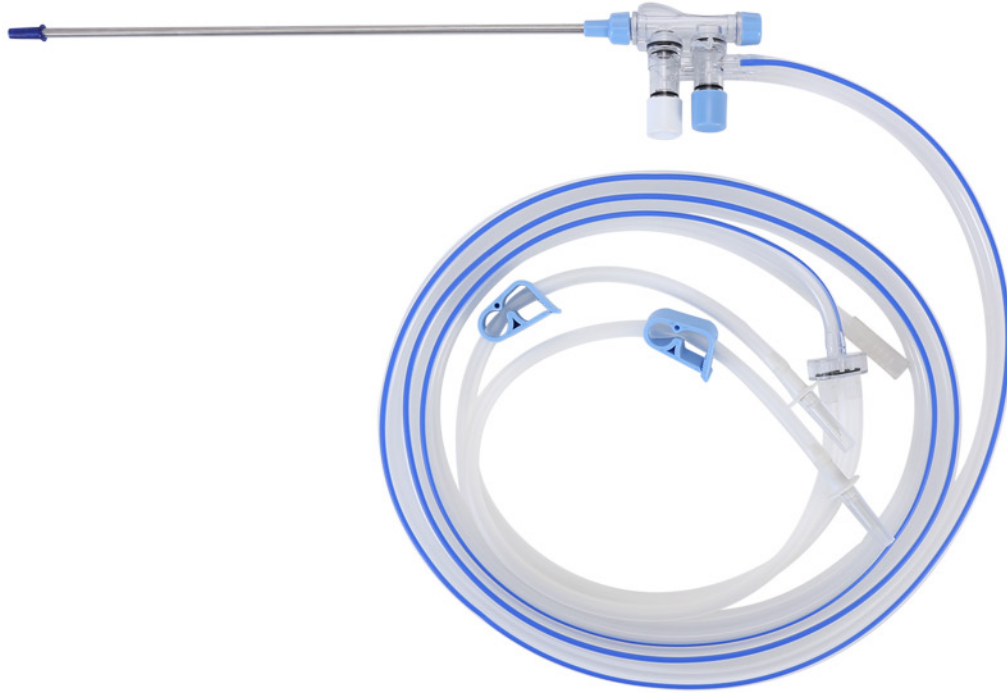


Blunt Grasper



Fenestrated Long Grasper

Suction Irrigation Set, Dual Spike



Features:

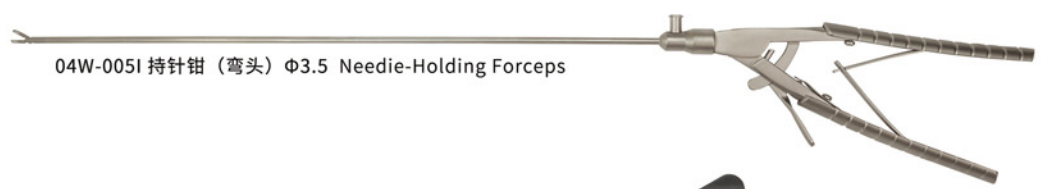
- + Transparent hand-piece for visualization of fluid.
- + Ergonomically designed for both right and left hand.
- + Color-coded buttons and tubings for easy identification.
- + Medical grade material used, DEHP free.

Code No.	Specification	Units/Box
CX3301	Shaft diameter: 3mm, length: 330mm, packed in double pouch	10

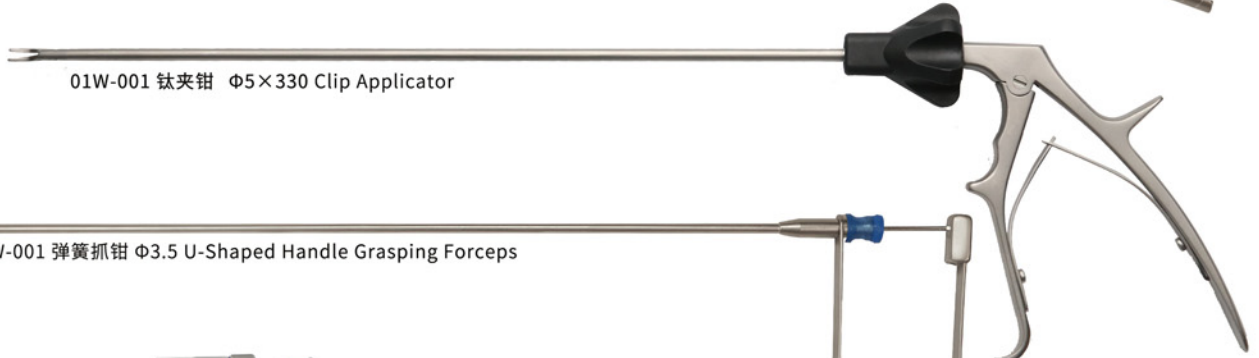
Reusable Pediatric Laparoscopic Surgery Instruments



06W-001 转换器
5MM/3.5MM
REDUCER



04W-005I 持针钳 (弯头) $\Phi 3.5$ Needle-Holding Forceps



01W-001 钛夹钳 $\Phi 5 \times 330$ Clip Applicator



02W-001 弹簧抓钳 $\Phi 3.5$ U-Shaped Handle Grasping Forceps



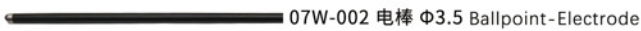
05W-015 穿刺器(磁性) $\Phi 3.5 \times 95$ Magnetic Trocar



05W-002 穿刺器 (十字封帽) $\Phi 3.5 \times 95$ Flap Valve Trocar



07W-001 电钩 $\Phi 3.5$ Hook-Electrode



07W-002 电棒 $\Phi 3.5$ Ballpoint-Electrode



06W-002 冲吸管 $\Phi 3.5$ Suction & Irrigation Tube



02W-002
直分离钳 $\Phi 3.5$
Dissecting Forceps, Straight

02W-003
细齿抓钳 $\Phi 3.5$
Toothed Grasper

02W-004
弯分离钳 $\Phi 3.5$
Dissecting Forceps, Curved

Reusable Pediatric Laparoscopic Surgery Instruments



02W-005
弯剪刀 $\Phi 3.5$
Scissors,Curved



02W-006
直剪刀 $\Phi 3.5$
Scissors,Straight



02W-006I
直剪刀 (单动) $\Phi 3.5$
Scissors,Straight(Single Action)



03W-002
无损伤抓钳 $\Phi 3.5$
Atraumatic Grasper



03W-002I
无损伤抓钳 (无齿) $\Phi 3.5$
Atraumatic (No Tooth)



03W-004
微小型抓钳 $\Phi 3.5$
Claw Grasper Single Action



03W-006
钝头抓钳 $\Phi 3.5$
Alligator



03W-007
弯分离钳(幽门) $\Phi 3.5$
Maryland Grasper



02W-011
弯分离钳(90°) $\Phi 3.5$
Dissecting Forceps, 90°



03W-009
重型抓钳 $\Phi 3.5$
Punch Grasping Forceps



03W-010
重型抓钳 (有孔) $\Phi 3.5$
Punch Grasping Forceps



03W-020
胆囊抓钳 $\Phi 3.5$
Babcock



03W-004
固定抓钳 $\Phi 3.5$
Fundus Grasper



03W-021
加长胆囊抓钳 $\Phi 3.5$
Endocl pinch



04W-001
取石钳 $\Phi 3.5$
Biopsy



03W-018
粗齿抓钳 $\Phi 3.5$
Grasping Forceps With Teeth



03W-013
有齿抓钳 $\Phi 3.5$
Claw Forceps



02W-007
钩剪刀 $\Phi 3.5$
Hook Scissors



03W-012
肠钳 $\Phi 3.5$
Bowel Grasper



03W-008
中孔抓钳 $\Phi 3.5$
Grasper



Changzhou Intl. Trade & Enterprises Cooperative Co., Ltd.

Add: Floor 20,Huajing Building, No. 1 Hejing Garden,Changzhou Jiangsu,P.R.China

Tel: 86-519-86803321

Fax: 86-519-86608539

Website: www.citec-group.com

E-mail: citec@citec-group.com

