



VICART **Med**
Solutions for medical care

INSUFFLATION TUBING



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Insufflation Tubing






The Laparoscopic Filter & Tubing Set contains sterile, single-use product ranges, including insufflation Tubing Set.

The Insufflation Tubing Set is for use to insufflate the abdominal cavity in order to create working space for the endoscopic procedures, and it contains a filter for filtration of the insufflation gas.

The insufflation tubing is available with either a Luer lock or a 15 & 22mm ISO connector for compatibility with a range of insufflators.








- Adaptable to all insufflators for tubing standardization.
- Rotating Luer lock connector prevents twisting or disconnects of CO₂ line.
- Durable, non-collapsing tubing.

Product code	Connector	Description
GC1952B00B0	 Luer Lock	Filtration Efficiency: 99.99% Total length 300cm, OD8.5mm, ID5.9mm
GC1952C00B0	 15mm Connector	Filtration Efficiency: 99.99% Total length 300cm, OD8.5mm, ID5.9mm
GC1952D00B0	 22/15mm Connector	Filtration Efficiency: 99.99% Total length 300cm, OD8.5mm, ID5.9mm
GC1952E00B0	 Push-on Connector	Filtration Efficiency: 99.99% Total length 300cm, OD8.5mm, ID5.9mm
GC1952I00B0	 O Ring Connector	Filtration Efficiency: 99.99% Total length 300cm, OD8.5mm, ID5.9mm






Available with different connectors
Suitable for most machines on the market



Product code	Connector	Description
GC1952B10B0	 Luer Lock	Filtration Efficiency: 99.99% Total length 300cm, OD8.5mm, ID5.9mm
GC1952C10B0	 15mm Connector	Filtration Efficiency: 99.99% Total length 300cm, OD8.5mm, ID5.9mm
GC1952D10B0	 22/15mm Connector	Filtration Efficiency: 99.99% Total length 300cm, OD8.5mm, ID5.9mm
GC1952E10B0	 Push-on Connector	Filtration Efficiency: 99.99% Total length 300cm, OD8.5mm, ID5.9mm
GC1952I10B0	 O Ring Connector	Filtration Efficiency: 99.99% Total length 300cm, OD8.5mm, ID5.9mm



With a wide range of filters for your option

Picture	Product code	Connector	Description
	GC1952D30B0	22/15mm Connector	Filtration Efficiency: 99.99% Total length 300cm OD8.5mm, ID5.9mm
	GC1952E20B0	Push-on Connector	Filtration Efficiency: 99.99% Total length 300cm OD8.5mm, ID5.9mm
	GC1952C21B0	15mm Connector	Filtration Efficiency: 99.99% Total length 300cm OD8.5mm, ID5.9mm



EC Certificate

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

Registration No.: DD 60138811 0001
Report No.: 15065307 008

Manufacturer: GCMEDICA ENTERPRISE LTD.(WUXI)
Loujin Industrial Park, Shuofang
Wuxi
214143 Jiangsu
China

Products: Medical Devices
(see attachment for products included)
Replaces Approval, Registration No.: DD 60138545 0001

Expiry Date: 2024-02-07

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: 2019-05-24
Date: 2019-05-24

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. 1/2, Rev. 0

Attachment to Certificate
Registration No.: DD 60138811 0001
Report No.: 15065307 008

Manufacturer: GCMEDICA ENTERPRISE LTD.(WUXI)
Loujin Industrial Park, Shuofang
Wuxi
214143 Jiangsu
China

Products:
Closed Suction Catheters, Infusion Sets / Infusion Sets with Burette, Transfusion Sets / Transfusion Sets with Burette, Extension Tubes with 3 Way Stopcock, Sepsis Caps, Prester Suction Tubes, Mini Sucker, Suction Connecting Tubes with and without Yankauer, Nasal Oxygen Cannula, Oxygen Masks, Non-Rebreath Masks, Aerosol Masks with Nebulizer, Multi-vent Masks/Venturi Masks, Tracheostomy Masks, Air Cushion Face Masks, Suction Catheters, Stomach Tubes and Feeding Tubes, Endotracheal Tubes / Reinforced Endotracheal Tubes, Tracheostomy Tubes, Oxygen Humidifiers, Breathing Circuits, HMP/Heat and Moisture Exchanger Filters, HMP/Heat and Moisture Exchanger, Bacterial/Viral Filters for Breathing or Anesthesia Circuit, Endoscopic Suction and Irrigation Sets, Veress Needles, Laryngeal Masks, Uterine Aspiration Curettes / Uterine Aspiration Tubes, Insufflator Tubings, Suction Specimen Traps, Yankauer Handles, Poole Yankauer, Capnography Masks, Capnography Nasal Cannulas, Irrigation Pump Tubings;

Date: 2019-05-24

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 2/2, Rev. 0

Attachment to Certificate
Registration No.: DD 60138811 0001
Report No.: 15065307 008

Manufacturer: GCMEDICA ENTERPRISE LTD.(WUXI)
Loujin Industrial Park, Shuofang
Wuxi
214143 Jiangsu
China

Aspects of manufacture concerned with securing and maintaining sterile conditions:
Magnetic Drapes for Metal Surgical Device Collection, Suture Retrievers, Decanting Devices/Mixing Cannulas, Spigots Catheters, Stoppers, Flushing Bags for cleaning purpose (Sitz Bath Bags), Sneeze Bags, Urine Beters, Urine Bags, Oropharyngeal Airways, Nasopharyngeal Airways, Surgical Brushes, Vaginal Speculums, Isolation Catheters, Irrigating Syringes, Bar/Ulcer Syringes, Noctual Anesthization Devices, TSP/Bladder Irrigation Sets, Arthroscopy Irrigation Sets, Vessel Cannula, Bowel Irrigation Systems, Disposable Camera Covers/Light Needle Covers, Basin Drapes, Rinsing Devices/Lower Devices, Agon/Drapes, Adaptors/Connectors, Floor Suction Devices, Hole Collector Cords, Rectal Urodynamic Balloon Catheters, External Catheters, Waste Collection Bags, Scleral Maskers, Endoscope Camera Sleeves, Needle Counters, Stylets, Drainage Tubes, Dental Irrigation Sets, ENT-single use suction tubes

Date: 2019-05-24



ISO Certificate



Certificate
Quality Management System
EN ISO 13485:2016

Registration No.: SX 2082448-1

Organization: GCMEDICA ENTERPRISE LTD.(WJX)
Loujin Industrial Park, Shuofang,
Wuxi,
214143 Jiangsu
P.R. China

Scope: Design and Development, Manufacture and Distribution of Yankauer Handles, Poole Yankauer, Rinsing Devices / Blower Devices, Uterine Aspiration Curettes / Uterine Aspiration Tubes, Adaptors / Connectors, Decanting Devices / Mixing Cannulas, Magnetic Drapes for Metal/Surgical Device Collection, Suction Connecting Tubes with and without Yankauer, TUR / Bladder Irrigation Sets, Transfusion Sets / Transfusion Sets with Burette, Extension Tubes with 3-way Stopcocks, Endoscopic Suction and Irrigation Sets, Disposable Camera Covers / Light Handle Covers, Solarai Markers, Vacuum Drainage Bottles, Closed Suction Catheters, Infusion Sets / Infusion Sets with Burette, Hepatic Caps, Frazer Suction Tubes, Mini Sucker, Nasal Oxygen Cannula, Oxygen Masks, Non-Resbreath Masks, Aerosol Masks with Nebulizer, Multi-vent Masks / Venturi Masks, Tracheostomy Masks, Air Cushion Face Masks, Suction Catheter, Stomach Tubes and Feeding Tubes, Endotracheal Tubes / Reinforced Endotracheal Tubes, Tracheostomy Tubes, Oxygen Humidifiers, Breathing Circuits, HMEF (Heat and Moisture Exchanger Filters), HME (Heat and Moisture Exchanger), Bacterial / Viral Filters for Breathing or Anesthesia Circuit, Suture Retrievers, Spigots Catheters, Stoppers, Flushing Bags for Cleaning Purpose (Giz/Bath Bags), Enema Bags, Urine Meters, Urine Bags, Oropharyngeal Airways, Nasopharyngeal Airways, Surgical Brushes,

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
It has been confirmed that the requirements specified in the corresponding standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 244410518-200
Effective date: 2022-04-24
Expiry date: 2025-04-23
Issue date: 2022-04-24


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

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Certificate
Quality Management System
EN ISO 13485:2016

Registration No.: SX 2082448-1

Organization: GCMEDICA ENTERPRISE LTD.(WJX)
Loujin Industrial Park, Shuofang,
Wuxi,
214143 Jiangsu
P.R. China

Scope: Vaginal Speculums, Nelaton Catheters, Irrigating Syringes, Ear / Uter Syringes, Mucosal Atomization Devices, Adrenoscopy Irrigation Sets, Vesical Cannula, Pressure Infusion Bags, Enema Bags and Dispensers, Suction Specimen Drain Bags, Spirometers, Bowel Irrigation Systems, Venous Needles, Laryngeal Masks, Basin Drapes, Apron / Drapes, Floor Suction Devices, Male Catheter Condoms, Rectal Urodynamic Balloon Catheters, External Catheters, Urine Specimen Containers, Medicine Cups, Manual Resuscitators, Insufflator Tubings, Waste Collection Bags, Suction Specimen Traps, Fecal Collection Devices, Endoscope Camera Sleeves, Needle Counters, Capnography Masks, Capnography Nasal Cannulas, Suction liners / Suction Chambers, Dental Irrigation Sets, Irrigation Pump Tubing, ENT-Single Use Suction Tubes, Stylets, Light Handles, Drainage Tubes,
Manufacture and Distribution of Medical Sponges;
Provision of Ethylene Oxide Sterilization Service for Single-use Medical Devices in accordance with EN ISO 11135:2014

Report No.: 244410518-200
Effective date: 2022-04-24
Expiry date: 2025-04-23
Issue date: 2022-04-24


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

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Final Product Inspection Report

无锡市九龙医疗器械有限公司
GCMEDICA ENTERPRISE LTD., (WUXI)
成品检验报告

Final Product Inspection Report

JL/QR-8.2.4-01

Version A.0 版

Report No.报告编号: JL22050101

产品名称 Product Name	Insufflation Tubing Sets	产品批号 LOT No.	220501	产品编号 Code	All Gcmédica insufflation tube sets
产品数量 Qty	3pcs per size	检验日期 Inspection Date	2022.5.1	报告日期 Report Date	2022.5.1
检测依据 Ref	JL/SOP-06-385				
测试项目 Test Item	要求 Requirements				结果 Result
外观 Appearance	产品上的黑点、晶点或嵌入式异物不应超过 3 个，且尺寸应小于 0.5mm There should be no more than 3 black spots, crystal spots or embedded foreign bodies on the product, and the size should be less than 0.5mm				<input checked="" type="checkbox"/> 符合 Pass <input type="checkbox"/> 不符合 Fail
	产品应无变形、缩水、碰伤现象 Products should be free of deformation, shrinkage, bruising				<input checked="" type="checkbox"/> 符合 Pass <input type="checkbox"/> 不符合 Fail
	组件正确、无脱落、漏装、错装 Correct components, no shedding, missing or wrong assembling				<input checked="" type="checkbox"/> 符合 Pass <input type="checkbox"/> 不符合 Fail
	管体无破洞、扁瘪、折弯、变形 The tube shall has no holes, flat, bending and deformation				<input checked="" type="checkbox"/> 符合 Pass <input type="checkbox"/> 不符合 Fail
	接头完好，无断裂、脱落 The connector shall be in good condition without breaking or falling off				<input checked="" type="checkbox"/> 符合 Pass <input type="checkbox"/> 不符合 Fail
尺寸 Size	应符合图纸要求 Should meet drawing				<input checked="" type="checkbox"/> 符合 Pass <input type="checkbox"/> 不符合 Fail
密封性 Sealing	无气泡冒出 (测试设备: 检漏仪) No bubbles (Test machine: Leak detector)				<input checked="" type="checkbox"/> 符合 Pass <input type="checkbox"/> 不符合 Fail
滤除率 Filtration Efficiency	滤除率: 99.99% (测试设备: 尘埃粒子检测仪) Filtration efficiency: 99.99% (Test machine: Dust particle detector)				<input checked="" type="checkbox"/> 符合 Pass <input type="checkbox"/> 不符合 Fail
气体流量 Gas Flow	流量损耗≤3% (测试设备: 流量计) Flow loss ≤3% (Test machine: Flowmeter)				<input checked="" type="checkbox"/> 符合 Pass <input type="checkbox"/> 不符合 Fail
结论 Conclusion	<input checked="" type="checkbox"/> 合格 Pass <input type="checkbox"/> 不合格 Fail				

检测人/日期: Kris Liu

Inspector / Date: 2022.5.1

复核人/日期:

Review / Date:

批准人/日期:

Approve / Date:



Document of Conformity

GCMEDICA ENTERPRISE LTD., (WUXI) CE Technology Documents for Product	Chapter No.: GC/CE-59-002	
	Edition: A.0	Version No.: 2019
EC Declaration of Conformity	The Chapter Page 1 of 1	

EC Declaration of Conformity

Manufacturer:

whose single Authorized Representative:

GCMEDICA ENTERPRISE LTD., (WUXI)
 Loujin Industrial Park, Shuofang, Wuxi, 214143, CHINA
 Adam Jiang
 Tel: 86 510 85300900
 E-mail: adam@gcmedica.com

Luxus Lebenswelt GmbH
 Kochstr.1, 47877, Willich, Germany
 DIMID: DE/0000047791
 Lin Sun
 Tel: 0049-1715605732
 E-mail: info.m@luxuslw.de

We, the manufacturer, herewith declare that the products

Insufflator Tubings

(Type: Insufflator Tubings)

UMDNS-Code: 15265

meet the provisions of Directive 93/42/EEC which apply to them.

The medical device has been assigned to class IIa according to Annex IX of the Directive 93/42/EEC. It bears the mark

CE 0197

Compliance of the designated product with the Directive 93/42/EEC aspects of manufacture concerned with securing and maintaining sterile conditions has been assured via assessment of the quality management system by the Notified Body

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

Certificate No.: DD 60138811 0001

Issue date: 2019-05-24

Expiry date: 2024-02-07

following the procedure relating to the EC Declaration of Conformity set out in Annex VII and Annex V of Directive 93/42/EEC.

This Declaration of Conformity covers all medical devices as specified in the product list belonging to this declaration.

The above mentioned declaration of conformity is exclusively under the responsibility of

Company: GCMedica Enterprise Ltd.(WUXI)
 Address: Loujin Industrial Park, Shuofang, Wuxi, 214143, CHINA

2019.05.30, Wuxi
 Place, Date

Legally binding signature, Quality Manager



VICART Med

Solutions for medical care

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