



**24 Hour
Closed Suction Catheter**

Product Description

Double swivel elbow facilitates the movement of the patient and prevents trauma. Allows 720-degree adjustment.

Thin yet strong sleeve ensures the feeling for introduction of the catheter similar to open catheter insertion.

High quality sleeve material makes little noise upon insertion and retraction of the catheter. The patient is not disturbed.

One-way irrigation port features a retained cap, preventing accidental lose. Easily injected with saline to help clean the catheter tip.

Color-coded suction-pressing and locking valve, follows ISO standard.

FDA, CE certified.

Specification

Product code	Size	Description
8011A12	FR12	Endotracheal intubation, 53cm, with MDI port and irrigation port
8011A14	FR14	Endotracheal intubation, 53cm, with MDI port and irrigation port
8011A16	FR16	Endotracheal intubation, 53cm, with MDI port and irrigation port
8011B12	FR12	Tracheomized intubation, 30.5cm, with MDI port and irrigation port
8011B14	FR14	Tracheomized intubation, 30.5cm, with MDI port and irrigation port
8011B16	FR16	Tracheomized intubation, 30.5cm, with MDI port and irrigation port

GCIVMEDICA ENTERPRISE LTD.(WUXI)
Loujin Industrial Park, Shuofang, Wuxi 214143 P.R.China
Tel: 86-510-88880366

Packing Information

Initial Pack		Secondary Pack		Outer Pack	
PK Method	Size (cm)	PK Method	Size (cm)	PK Method	Size (cm)
Paper pouch	37*16	Shelf box 10 pcs	37*16*15	Shipper case 6 boxes	50*40*32

Product Code	Product Name
BSY	CATHETER, SUCTION, TRACHEOBRONCHIAL

FDA Information

Listing Number D305561

Listing Status Active

Premarket Submission Number

Registration #	Registration Status	Registration Status Reason	Activities
3007681502	Active	Registration number assigned	Contract Manufacturer



Product Description

Thumb Lock system provides convenient adapter switching, closing catheter tip from outer pollution when suction ends, ensuring 72 hours' clean application.

Double swivel elbow facilitates movement of the patient and prevents trauma. Allows 720° adjustment.

Thin yet strong sleeve ensures the feeling for introduction of the catheter similar to open catheter insertion.

High quality sleeve material makes little noise upon insertion and retraction of the catheter.

One-way irrigation port features a retained cap, preventing accidental lose. Easily injected with saline to help clean the catheter tip.

Color-coded suction-pressing and locking valve, follows ISO standard.

FDA, CE certificated.

Specification

Product code	Size	Description
8010A12	FR12	Endotracheal intubation, 53cm, with MDI port and irrigation port
8010A14	FR14	Endotracheal intubation, 53cm, with MDI port and irrigation port
8010A16	FR16	Endotracheal intubation, 53cm, with MDI port and irrigation port
8010B12	FR12	Tracheomized intubation, 30.5cm, with MDI port and irrigation port
8010B14	FR14	Tracheomized intubation, 30.5cm, with MDI port and irrigation port
8010B16	FR16	Tracheomized intubation, 30.5cm, with MDI port and irrigation port

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Product Code	Product Name
BSY	CATHETER, SUCTION, TRACHEOBRONCHIAL

FDA Information

Listing Number D305561

Listing Status Active

Premarket Submission Number

Registration #	Registration Status	Registration Status Reason	Activities
3007681502	Active	Registration number assigned	Contract Manufacturer



72 Hour Closed Suction Catheter

受控文件

Product Description

Hinged shielding valve automatically closes the opening of adapter during suction interval and after suction process ends. The design reduces the opportunity for contamination to occur from outside pathogens, thus reducing bacteria colonization within circuit.

Double swivel elbow facilitates the movement of the patient and prevents trauma. Allows 720-degree adjustment.

Thin yet strong sleeve ensures the feeling for introduction of the catheter similar to open catheter insertion.

High quality sleeve material makes little noise upon insertion and retraction of the catheter. The patient is not disturbed.

One-way irrigation port features a retained cap, preventing accidental lose. Easily injected with saline to help clean the catheter tip.

Color-coded suction-pressing and locking valve, follows ISO standard.

FDA, CE certificated.

Specification

Product code	Size	Description
8066A12	FR12	Endotracheal intubation, 53cm, with MDI port and irrigation port
8066A14	FR14	Endotracheal intubation, 53cm, with MDI port and irrigation port
8066A16	FR16	Endotracheal intubation, 53cm, with MDI port and irrigation port
8066B12	FR12	Tracheomized intubation, 30.5cm, with MDI port and irrigation port
8066B14	FR14	Tracheomized intubation, 30.5cm, with MDI port and irrigation port
8066B16	FR16	Tracheomized intubation, 30.5cm, with MDI port and irrigation port

Packing Information

Initial Pack		Secondary Pack		Outer Pack	
PK Method	Size (cm)	PK Method	Size (cm)	PK Method	Size (cm)
Paper pouch	37*16	Shelf box 10 pcs	37*16*15	Shipper case 6 boxes	50*40*32

Product Code	Product Name
BSY	CATHETER, SUCTION, TRACHEOBRONCHIAL

FDA Information

Listing Number D305561

Listing Status Active

Premarket Submission Number

Registration #	Registration Status	Registration Status Reason	Activities
3007681502	Active	Registration number assigned	Contract Manufacturer



Primary 72 Hour Closed Suction Catheter

Product Description

Turbo irrigating system cleans the catheter tip in an isolated and vacuum-sealed turbulent cleaning chamber. The turbulent irrigation cleans the catheter tip much clearer comparing to a standard closed suction catheter.

Special shielding system automatically closes the opening of adapter during suction interval and after suction process ends. The system reduces the opportunity for contamination to occur from outside pathogens.

Double layer catheter scratching system cleans catheter twice, effectively reducing bacteria colonization within circuit.

Red plug helps removing tracheal and endotracheal tube from swivel elbow connector safely, avoiding sudden and inadvertent drag.

Ergonomic Thumb control valve, providing comfortable processing.

One-way irrigation port features a retained cap, preventing accidental lose. Easily injected with saline to help clean the catheter tip.

FDA, CE certificated.

Specification

Product code	Size	Description
8061P12	FR12	Endotracheal intubation, 53cm, with MDI port and irrigation port
8061P14	FR14	Endotracheal intubation, 53cm, with MDI port and irrigation port
8061P16	FR16	Endotracheal intubation, 53cm, with MDI port and irrigation port
8061Q12	FR12	Tracheomized intubation, 30.5cm, with MDI port and irrigation port
8061Q14	FR14	Tracheomized intubation, 30.5cm, with MDI port and irrigation port
8061Q16	FR16	Tracheomized intubation, 30.5cm, with MDI port and irrigation port

Packing Information

Initial Pack		Secondary Pack		Outer Pack	
PK Method	Size (cm)	PK Method	Size (cm)	PK Method	Size (cm)
Paper pouch	37*16	Shelf box 10 pcs	37*16*15	Shipper case 6 boxes	50*40*32

Product Code	Product Name
BSY	CATHETER, SUCTION, TRACHEOBRONCHIAL

FDA Information

Listing Number D305561

Listing Status Active

Premarket Submission Number

Registration #	Registration Status	Registration Status Reason	Activities
3007681502	Active	Registration number assigned	Contract Manufacturer

Biocompatibility Test Report



Final Report

Report Number: SDWH1620190811-019

In Vitro Cytotoxicity Test of Closed Suction Catheters

According to ISO 10993-5:2009
MTT Method
MIM with USP2161 extract

Sponsor: GCIVMEDICA ENTERPRISE LTD.(WUXI)
Address: Lianjin Industrial Park, Shuangfeng West, Jiangsu



Institution & Environmental Technology Institute, Suzhou University
Address: 200 East Road, Suzhou Industrial Park, Suzhou, Jiangsu 215122, P. R. China
Website: www.cerchina.com Email: cerchina@163.com
Phone: 0512-82088888 Fax: 0512-82088888



Final Report

Report Number: SDWH1620190811-019

Skin Sensitization Test of Closed Suction Catheters

According to ISO 10993-10:2016
Closed Pig Maculation Test
Extract of Extract

Sponsor: GCIVMEDICA ENTERPRISE LTD.(WUXI)
Address: Lianjin Industrial Park, Shuangfeng West, Jiangsu



Institution & Environmental Technology Institute, Suzhou University
Address: 200 East Road, Suzhou Industrial Park, Suzhou, Jiangsu 215122, P. R. China
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Phone: 0512-82088888 Fax: 0512-82088888



Final Report

Report Number: SDWH1620190811-019

Oral mucosa Irritation Test of Closed Suction Catheters

According to ISO 10993-10:2016
0.1% Sodium Chloride Extract

Sponsor: GCIVMEDICA ENTERPRISE LTD.(WUXI)
Address: Lianjin Industrial Park, Shuangfeng West, Jiangsu



Institution & Environmental Technology Institute, Suzhou University
Address: 200 East Road, Suzhou Industrial Park, Suzhou, Jiangsu 215122, P. R. China
Website: www.cerchina.com Email: cerchina@163.com
Phone: 0512-82088888 Fax: 0512-82088888



Final Report

Report Number: SDWH1620190811-019

Oral mucosa Irritation Test of Closed Suction Catheters

According to ISO 10993-10:2016
Number 150 Extract

Sponsor: GCIVMEDICA ENTERPRISE LTD.(WUXI)
Address: Lianjin Industrial Park, Shuangfeng West, Jiangsu



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Phone: 0512-82088888 Fax: 0512-82088888



Final Report

Report Number: SDWH1620190811-019

Skin Sensitization Test of Closed Suction Catheters

According to ISO 10993-10:2016
Control Pig Maculation Test
0.1% Sodium Chloride Injection Extract

Sponsor: GCIVMEDICA ENTERPRISE LTD.(WUXI)
Address: Lianjin Industrial Park, Shuangfeng West, Jiangsu



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Address: 200 East Road, Suzhou Industrial Park, Suzhou, Jiangsu 215122, P. R. China
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Summary

1 Test Article
2 Test Method
3 Test Results
4 Conclusion

CE Certificate

WWW.GCMEDICA.COM

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)
Reference Approval, Registration No.: **DD 601046 0001**

Expiry Date: **2019-05-24**

The notified body hereby declares, for the purposes of Annex V of the directive 93/42/EEC, that the manufacturer has established and operates a quality management system, which is subject to regular surveillance, according to article 10 of the aforementioned directive. For placing on the market of class II and class IIa devices covered by the certificate in CE, the manufacturer shall comply with the requirements of Annex VI to the directive.

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
certifying medical devices with the identification number 0197.

受控文件


TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Rev.: 013, 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 Venous Catheters, Infusion Sets / Infusion Sets with Burette, Transfusion Sets / Transfusion Sets with Burette, Extension Tubes with 3 way stopcock, Angiostatic Caps, Flexible Suction Tubes, Mini Suction, Suction Clamping Tubes with and without Suction, Drain Drainage Canister, Oxygen Masks, Non-Adhesive Masks, Anaxial Masks with Millimeter, Multi-use Reusable Medical Masks, Disposable Masks, Air Purifier New Masks, Earloop Catheters, Suction Tubes and Feeding Tubes, Endotracheal Tubes / Endotracheal Suction Tubes, Tracheotomy Tubes, Oxygen Humidifiers, Subcutaneous Tubing, SMD/Heat and Moisture Exchangers, Filters for Air and Moisture Exchangers,
Bacterial/Viral Filters for Breathing or Respiration Circuit, Endotracheal Suction and Irrigation Sets, Nasal Cannulae, Laryngeal Masks, Sterile Aspiration Canisters / Aspiration Aspiration Tubes, Incentivator Pumps, Suction Appliances, Sings, Inhaler Mask, Pedia FaceMask, Sphygmomanometer, Oropharyngeal Head, Chinstrap, Sphygmomanometer.

Notified Body

Date: 2019-05-24
Fukui Sheng


TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Rev.: 013, 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

AGENCY ON THE BASIS OF THE AGREEMENT WITH MANUFACTURER AND MANUFACTURING FACILITY CONDITIONS:
Heart/Lung Support for Renal Hemodialysis Circulation, Single Ventricles, Inserting Devices/Inserting Devices, Nitroxa Catheters, Stoppers, Flushing Bags for cleaning pumps (ISO 800 Bag), Suction Bags, Urine Measur, Urine Bag, Ombi-Infusional Airway, Non-Adhesive Airway, Surgical Sutures, Vascular Sponges, Suction Catheters, Irrigating Sponges, Bar/Type Sponges,
Manual Resuscitation Devices, CO2 Scavenger
Triglycine Salt, Anticoagulant Circulation Sets, Venous Catheter, Venous Irrigation Systems, Siphonage Canes (Insert/Light Medical Device, Radio Sponges, Fixing Device/Liver Device, Agon/Stopper, Adaptor/Connector, Fluid Suction Device, Drain Catheter, Drainage, Urinary/Urinary Catheters, Suctional Catheters, Drain Collection Bags, Suction Washers, Suction/Urinary Sponges, Media Insulator, Syringe, Drainage Tubes, Special Irrigation Sets, SPC-socket use suction tubes

Notified Body

Date: 2019-05-24
Fukui Sheng

Declaration of Conformity

GCMEDICA ENTERPRISE LTD., (WUXI) CE Technology Documents for Product	Chapter No.: GC/CE-27-002	
EC Declaration of Conformity	Edition: A.0	Version No.: 2019
The Chapter Page 1 of 1		

EC Declaration of Conformity

Manufacturer:

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

whose single Authorized Representative:

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

Closed Suction Catheters

(Type: Double Swivel closed suction catheter; Trach T-piece closed Suction Catheter; Pedi Y connector closed suction Catheter; Pedi Elbow closed suction)

UMDNS-Code: 17795

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