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 certificated.

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

GCMEDICA ENTERPRIESE 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

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

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

GCMEDICA ENTERPRIESE 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

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

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.

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

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

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

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.

S**pecial 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.

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

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

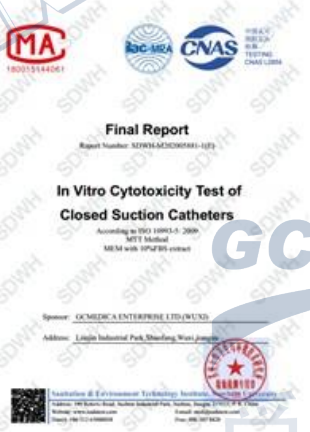
Listing Number D305561
Listing Status Active

Premarket Submission Number

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

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

Biocompatibility Test Report



Final Report

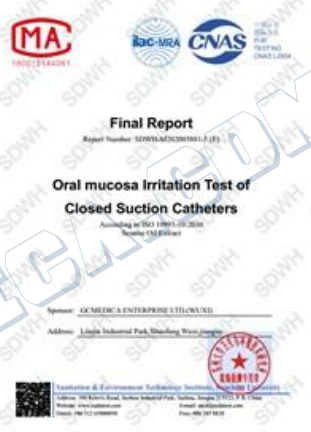
In Vitro Cytotoxicity Test of
Closed Suction Catheters

Final Report

Skin Sensitization Test of
Closed Suction Catheters

Final Report

Oral mucosa Irritation Test of
Closed Suction Catheters



Final Report

Oral mucosa Irritation Test of
Closed Suction Catheters

Final Report

Skin Sensitization Test of
Closed Suction Catheters

Summary

1 Test Article

2 Main Reference

3 Test Method

4 Conclusion

CE 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

Expiry Date:

TÜV Rheinland LGA Products GmbH · Tillystraße 2 · 90431 Nürnberg

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

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

Date: 2019-05-24

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

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

Date: 2019-05-24

Declaration of Conformity

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

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