Australian Government

Department of Health

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	333644	DTS INTERNATIONAL GROUP PTY LTD - Mask, surgical, single use
ARTG entry for	Medical Device Included Class 1	
Sponsor	DTS INTERNATIONAL GROUP PTY LTD	
Postal Address	Level 1 414 Victoria Avenue, Chatswood, NSW, 2067 Australia	
ARTG Start Date	7/04/2020	
Product category	Medical Device Class 1	
Status	Active	
Approval area	Medical Devices	

Conditions

- The inclusion of the kind of device in the ARTG is subject to compliance with all conditions placed or imposed on the ARTG entry. Refer Part 4-5, Division 2 (Conditions) of the Therapeutic Goods Act 1989 and Part 5, Division 5.2 (Conditions) of the Therapeutic Goods (Medical Devices) Regulations 2002 for relevant information.
- Breaching conditions of the inclusion related to the device of the kind may lead to suspension or cancellation of the ARTG entry; may be a criminal offence; and civil penalties may apply.

Manufacturers

Name	Address
Sichuan Zhengning Medical Instrument Co Ltd	No 3 Building 2 No 388 Food Avenue Juntun Town Xindu District, Chengdu, China

Products

1. Mask, surgical, single use

Product Type	Single Device Product	Effective date	7/04/2020
GMDN	35177 Mask, surgical, single use		
Intended purpose	Disposable face mask to prevent the transmission of airborne organisms. Intended for single use only.		

Specific Conditions

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ZHENGNING MEDICAL

Public Summary

This is not an ARTG Certificate document.
The onus is on the reader to verify the current accuracy of the information on the document subsequent to the date shown.
Visit www.tga.gov.au for contact information

Certificate Of FDA Registration

2020

This is certified that:
At The Address Stated Below Has Completed U.S. FOOD And DRUG ADMINISTRATION Medical Device Registration Through MANTONG.

SICHUAN ZHENGNING MEDICAL INSTRUMENT CO., LTD.

Address: NO. 3, BUILDING 2, NO. 388, FOOD AVENUE, JUNTUN TOWN, XINDU DISTRICT ,CHENGDU, SICHUAN 610000,CHINA

Proprietary Device Name	Disposable Protective Mask Disposable Mask; Folded Mask Disposable Medical Mask Non-powered air-purifying particle respirator
Product Code	LYU
Device Listing Number	D381546
Proprietary Device Name	Disposable Mask; Disposable Medical Mask; Disposable Protective Mask; Folded Mask; Non-Powered Air-Purifying Particle Respirator
Product Code	QKR
Device Listing Number	D403313
Owner/Operator Number	10065521

The FDA annual establishment registration fee must be paid between Oct. 1 and Dec. 31 of every year.

MTG FDA REGISTER CENTER CORPORATE SEAL CALIFORNIA

Jacky M. Chuang

Executive Director
Date: 05-20-2020

MTG STANDARDS TESTING & CERTIFICATION CENTER www.fdacn.org

This certification affirm that the above device and company was registered with U.S. Food and Drug Administration pursuant to section 305 of the United States Public Health and Bicterrorism Preparedness and response Act of 2002. P.L. 107-188.on the date stated above, and makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder. for whole sole benefit it is issued MTG CO., Inc. assumes no liability to any person or entity in connection with the foregoing. MTG is a private registration agent not affiliated with the U.S. Food and Drug Administration

Allgemeine Anzeigepflicht nach §§ 25 und 30 Abs. 2 MPG
General Obligation to Notify pursuant to §§ 25 and 30 (2) Medical Devices Act, MPG

Formblatt für Medizinprodukte, außer In-vitro-Diagnostika
Form for Medical Devices except In Vitro Diagnostic Medical Devices

Zuständige Behörde / Competent authority			
	Code **DE/CA20**		
	Bezeichnung / Name **Bezirksregierung Düsseldorf, Dezernat 24**		
	Staat / State **Deutschland**		Land / Federal state **Nordrhein-Westfalen**
	Ort / City **Düsseldorf**		Postleitzahl / Postal code **40474**
	Straße, Haus-Nr. / Street, house no. **Cecilienallee 2**		
	Telefon / Phone **+49-211-4750**		Telefax / Fax **+49-211-4752671**
	E-Mail / E-mail **dez24.mpg@brd.nrw.de**		

Anzeige / Notification			
	Registrierdatum bei der zuständigen Behörde Registration date at competent authority **18.05.2020**		Registriernummer / Registration number **DE/CA20/01-Luxuslebenswelt-330/20**
	Typ der Anzeige / Notification type S Erstanzeige / Initial notification £ Änderungsanzeige / Notification of change £ Widerrufsanzeige / Notification of withdrawal		
	Frühere Registriernummer bei Änderungs- und Widerrufsanzeige Previous registration number if notification has been changed or withdrawn		
	Anzeigender nach § 25 MPG / Reporter pursuant to § 25 Medical Devices Act, MPG £ Hersteller / Manufacturer S Bevollmächtigter / Authorised Representative £ Einführer / Importer £ Verantwortlicher für das Zusammensetzen von Systemen oder Behandlungseinheiten nach § 10 Abs. 1 und 2 MPG \ Assembler of systems or procedure packs pursuant to § 10 (1) and (2) Medical Devices Act, MPG £ Betrieb oder Einrichtung (aufbereiten) nach § 25 Abs. 1 MPG i. V. m. § 4 Abs. 2 MPBetreibV Institution (processing) pursuant to § 25 (1) Medical Devices Act, MPG in connection with § 4 (2) MPBetreibV £ Betrieb oder Einrichtung (sterilisieren) nach § 25 Abs. 2 i. V. m. § 10 Abs. 3 MPG Institution (sterilizing) pursuant to § 25 (2) in connection with § 10 (3) Medical Devices Act, MPG		

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Anzeigender / Reporting organisation (person)			
	Code **DE/0000047791**		
	Bezeichnung / Name **Luxus Lebenswelt GmbH**		
	Staat / State **Deutschland**		Land / Federal state **Nordrhein-Westfalen**
	Ort / City **Willich**		Postleitzahl / Postal code **47877**
	Straße, Haus-Nr. / Street, house no. **Kochstr. 1**		
	Telefon / Phone **0049-1715605732**		Telefax / Fax
	E-Mail / E-mail **info.m@luxuslw.de**		

Hersteller / Manufacturer			
	Bezeichnung / Name **Sichuan Zhengning Medical Equipment Co., Ltd**		
	Staat / State **CN**		
	Ort / City **Chengdu**		Postleitzahl / Postal code **610509**
	Straße, Haus-Nr. / Street, house no. **No. 3, building 2, No. 388, food Avenue, juntun Town, Xindu District**		
	Telefon / Phone **086-17380633770**		Telefax / Fax
	E-Mail / E-mail **yuanmingxing@smartope.com**		

Sicherheitsbeauftragter für Medizinprodukte nach § 30 Abs. 2 MPG 9) **Safety officer for medical devices pursuant to § 30 (2) Medical Devices Act, MPG**			
	Bezeichnung / Name **Lin Sun**		
	Staat / State **Deutschland**		Land / Federal state **Nordrhein-Westfalen**
	Ort / City **Willich**		Postleitzahl / Postal code **47877**
	Straße, Haus-Nr. / Street, house no. **Kochstr. 1**		
	Telefon / Phone **0049-1715605732**		Telefax / Fax
	E-Mail / E-mail **info.m@luxuslw.de**		

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Vertreter / Deputy (optional)			
	Bezeichnung / Name		
	Telefon / Phone		Telefax / Fax
	E-Mail / E-mail		
	S Erstanzeige / Initial notification £ Änderungsanzeige / Notification of change		

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Medizinprodukt (Erstmaliges Inverkehrbringen) / Medical device (First placing on the market)	
	Klasse / Class S I £ I - steril / sterile £ I - mit Messfunktion / with measuring function £ I - steril und mit Messfunktion / sterile and with measuring function £ IIa £ IIb £ III £ III - hergestellt unter Verwendung von Gewebe tierischen Ursprungs im Sinne der Verordnung (EU) Nr. 722/2012 manufactured utilising tissues of animal origin in terms of Commission Regulation (EU) No 722/2012 £ Aktives implantierbares Medizinprodukt / Active implantable medical device £ Aktives implantierbares Medizinprodukt - hergestellt unter Verwendung von Gewebe tierischen Ursprungs im Sinne der Verordnung (EU) Nr. 722/2012 Active implantable medical device - manufactured utilising tissues of animal origin in terms of Commission Regulation (EU) No 722/2012
	App (Software auf mobilen Endgeräten) £ ja / yes S nein / no
	Nummer(n) der Bescheinigung(en) / Certificate number(s)
	Handelsname des Produktes / Trade name of the device **Disposable Medical mask (non-sterile)**
	Produktbezeichnung / Name of device **Disposable Medical mask (non-sterile)**
	Nomenklaturcode / Nomenclature code **15-230**
	Nomenklaturbezeichnung / Nomenclature term **Maske, sonstige**
	Kategoriecode / Category code **10**
	Kategorie / Category **Produkte zum Einmalgebrauch**
	Kurzbeschreibung deutsch / German short description **Produktmodell: WS-MED-1, Standard: EN14683: 2019 + AC: 2019 Typ I, Dieses Produkt wird vom klinischen Personal bei nicht-invasiven Eingriffen getragen, die Mund, Nase und Kiefer des Benutzers abdecken und eine bestimmte physische Barriere bilden um die direkte Übertragung von pathogenen Mikroorganismen und Partikeln zu verhindern.**
	Kurzbeschreibung englisch / English short description **Product Model: WS-MED-1,Standard: EN14683:2019+AC:2019 Type I,This product is worn by clinical personnel during non-invasive procedures, covering the user's mouth, nose, and jaw, and provides a certain physical barrier to prevent direct transmission of pathogenic microorganisms and particulate matter.**

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Medizinprodukte (Aufbereiten) / Medical devices (Reprocessing)
£ Semikritische Medizinprodukte / Semicritical medical devices £ Gruppe A / Group A £ Gruppe B / Group B
£ Kritische Medizinprodukte / Critical medical devices £ Gruppe A / Group A £ Gruppe B / Group B £ Gruppe C / Group C Nummer der Bescheinigung / Certificate number
Sterilisationsverfahren / Sterilisation procedures £ Dampfsterilisation / Steam sterilisation £ Gassterilisation / Gas sterilisation £ Strahlensterilisation / Radiation sterilisation £ andere / others Angewandtes Verfahren / Applied procedure

Ich versichere, dass die Angaben nach bestem Wissen und Gewissen gemacht wurden.
I affirm that the information given above is correct to the best of my knowledge.

Ort
City **Willich**

Datum
Date **2020-05-15**

Name
Lin Sun

Unterschrift
Signature

Bearbeitungsvermerke / Processing notes Nur von der zuständigen Behörde auszufüllen / To be filled in only by the competent authority	
Bearbeiter / Person responsible **Frau Nadine Schlingmeier**	Telefon / Phone **0211-475-3853**

ZHENGNING MEDICAL

EC Declaration of Conformity

Manufacturer:

Sichuan Zhengning Medical Equipment Co., Ltd
No. 3, building 2, No. 388, food Avenue, juntun Town, Xindu District, Chengdu, The peoples republic of China

whose single Authorized EU-Representative:

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

We, the manufacturer, herewith declare that the products

Disposable Mask (non-sterile)

Product Model: WS-MED-1

Standard: EN14683:2019

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

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

CE

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

ISO 10993-5: 2009

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

Sichuan Zhengning Medical Equipment Co., Ltd
No. 3, building 2, No. 388, food Avenue, juntun Town, Xindu District, Chengdu, The peoples republic of China

Chengdu Mar 9th, 2020
Place, date

Factory director: Yuan Mingxing
Legally binding signature, Function

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