



SPECIALIZING IN ANESTHESIA
AND RESPIRATION CARE

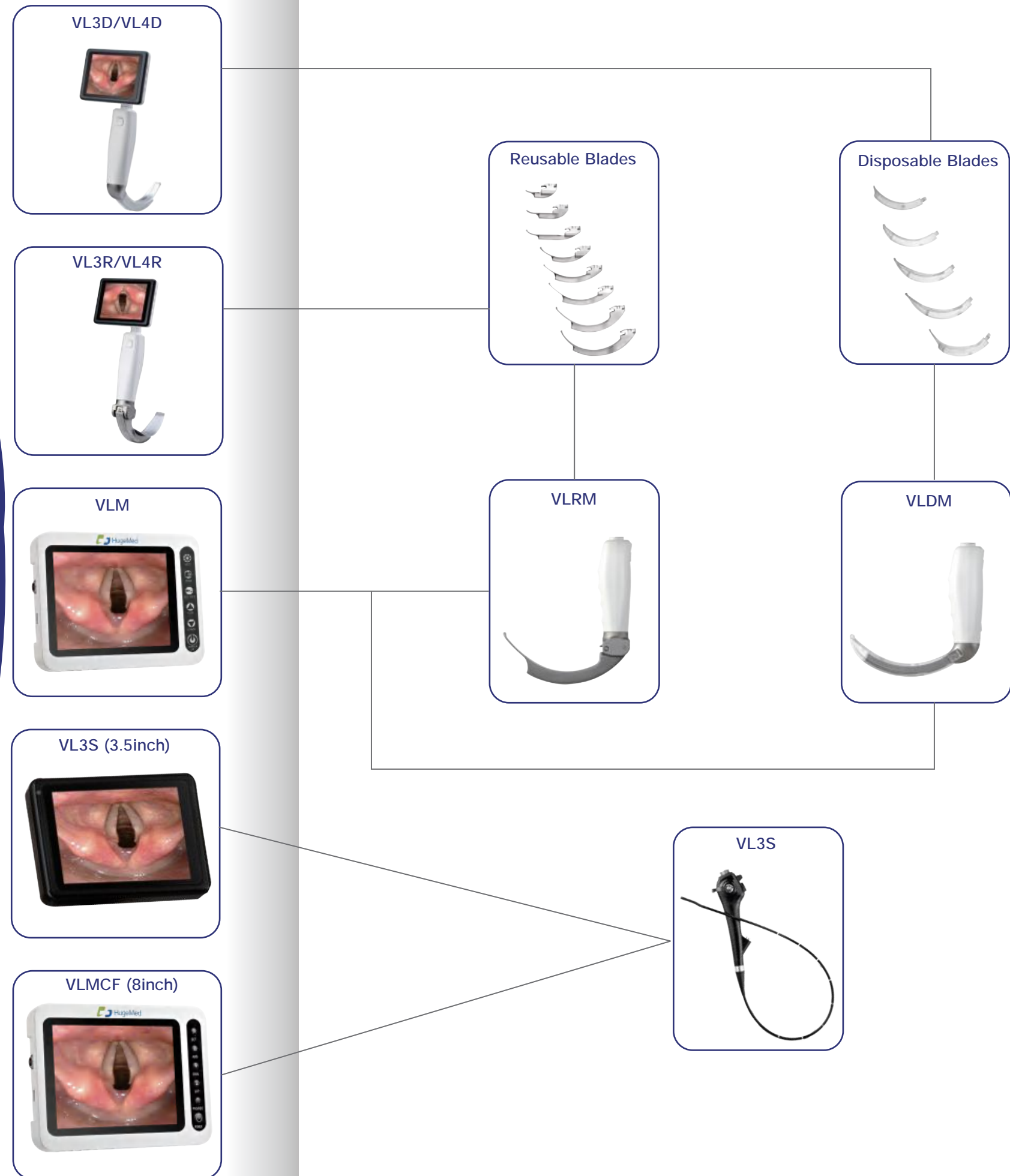


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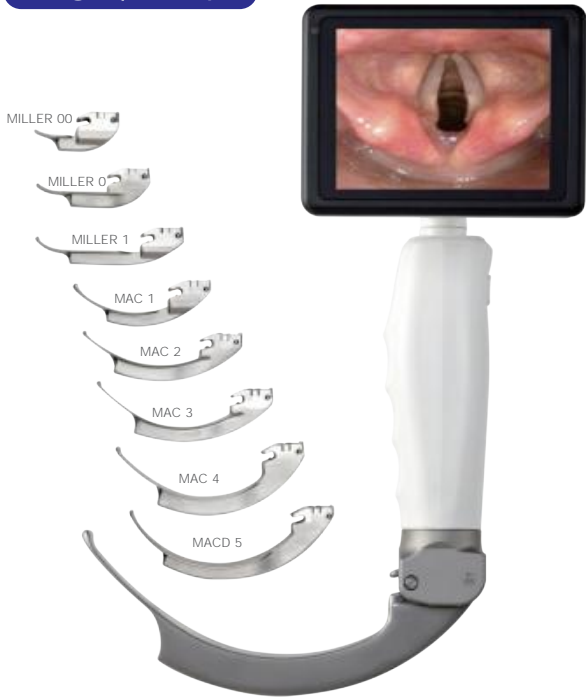
SPECIALIZING IN ANESTHESIA AND RESPIRATION CARE

HugeMed provides the right equipment and supplies to support the vital role of the anesthesia team. With extensive knowledge in both respiratory and anesthesia care, HugeMed bridges the gap in critical care by integrating effective solutions that: Improve patient safety and outcomes. Reduce cross contamination risk. Deliver cost savings on both specialty and everyday products. Support compliance efforts.



HugeMed Resuable Video Laryngoscope

VL3R/VL4R



The image quality

- 3.5/4 inch full-angle LCD high resolution display, Resolution ratio: 640 * 480RGB/800*480RGB
- Rotation: up/down:140° left/right:180°



Functional

- one-click button for photography and video recording
- built-in 8G storage card



Model is complete

- 8 models of blades are designed for various population

HugeMed Disposable Video Laryngoscope

VL3D/VL4D



Convenient for teaching

- Through the USB data interface, charging, video copy the output
- Extensible external HD interface display



High resolution wide-angle

- 2 megapixels camera
- Field angle ≥60 degrees, and the lens angle is between 50°-60°



Model is complete

- 5 models of blades are designed for various population

Safety

- Anti-Fog Lens
- Anti-Microbial Handle
- Disposable blades
- Sterile package
- Single use design avoid Cross Infection

Reusable blades

- Durable 316 Medical stainless steel
- IPX8 waterproof grade design
- Support immersion disinfection

Faster

- Lightweight, Portable
- Faster Installation and Intubation
- Faster Removal of blades or Drop blades

High-Definition

The 3.5 inch anti-reflective display with full view has the high performance visualization capabilities for every intubation
Better View: 2.0 Megapixels Cameras

Easier

Rechargeable li-ion battery, One Shot Button for Recording

Cost Effective

Low cost disposable blades
316 medical stainless reusable blades can be used 1000 times

Technical Specifications

Display	Size: 3.5inch/4inch Full view
	Monitor: LCD
	Resolution Ratio: 640X480RGB/800*480RGB
	Aspect Ratio: 4:3
	Video refresh Rata: 30FPS
Data output	Illumination: LED
	Easy to establish and store files
Image output	USB interface
Laryngoscope blade Camera Include	Resolution Ratio 2.0M Pixels
	Field Angle: 66°
	Illuminance ≥800LUX
Handle	Confortable ergonomic short handle design
Battery	Type Rechargeable Lithium Battery
	Long working time ≥120-150 Minutes
	Voltage 3.7V
	Capacity 3200mAh
	Battery life Cycle: More Than 300 times
	Charging times: less than 4-6hrs

HugeMed VLRM/VLDM

When time is critical, make your go-to device the HugeMed VLRM/VLDM. Ideal for demanding OR, ED, and ICU settings, the VLRM/VLDM provides a consistently clear view of the airway, and enhanced maneuverability enabling fast intubations. The VLRM/VLDM system gives you a choice of 8 reusable blades and 5 disposable blades to cover a wide range of patients—from infant to morbidly obese. Add real-time recording and an onboard tutorial, and you'll see why HugeMed VLRM/VLDM is the one you go to for advanced video laryngoscopy.

VLRM



Reusable Blades

VLM=ADVANCED AIRWAY VIEWS

- Digital color monitor with LCD-quality resolution
- Reusable video laryngoscope with digital-resolution camera
- Innovative blade sizing, angulation, and camera positioning
- Anti-fog feature, with a rapid heating profile to resist lens clouding and secretions

VLDM



Disposable Blades

VLM=ADVANCED USER FEATURES

- Integrated, real-time recording helps confirm tube placement and facilitate teaching
- Ergonomic design and rugged construction for multiple clinical applications
- Reusable blades in 8 sizes: MILLER 00, 0, 1, MAC 1,2,3,4,5
- Also available in 5 single-use sizes

Advanced Video Laryngoscopy:

Real-time recording. LCD clarity.



Applications

- First-use intubations, replacing direct laryngoscopy
- Normal or restricted oropharyngeal views
- Cormack-Lehane Grades I–IV laryngeal views
- Trauma airways—excellent when dealing with blood and secretions in the airway
- Video-guided tube exchange in the ICU

Specifications

Type	VLRM	VLDM
Display	8 Inch LCD monitor HD Display	
Resolution	1024*768RGB	
Data audiovisual output	Support	
Camera Resolution	2M Pixel	
View Angle	66°	
Illumination	≥800LUX	
Battery Life Time	> 2 hours	
Battery Capacity	3200mAh	
Voltage	3.7V	
Blade type	Reusable Blades	Disposable Blades
Material of Blade	SUS316L	PC
Shot and Record Function	Support	
Anti-fog	Anti-fog when it's on	
Blade Sizing	Miller 00/0/1; Mac 1/2/3/4/5	Mac 1/2/3/4/5
HDMI&USB Port	Include	
Connector for Screen and Handle	Include	
Bracket (with tray)	Include	
Attachments	Adapter, Power cord, Data connection line	
Blades Disinfection	Refer to the reusable laryngoscope instructions	Refer to the Disposable laryngoscope instructions

HugeMed VL3H Rigid Laryngoscope



Main Features

Five Size Diameter Rigid Laryngoscope

The VL3H Series Features

5 Size: 3.0mm、3.9mm、5.0mm

5 models of VL3H hard blades: N3065、N3965、H5055、H5065、H5075

- Specification H5055, H5065, H5075, diameter for disposable
- Specification N3065, N3965, diameter can be reused for more than 5,000 times

- Integrated design, no maintenance
- 3.5-inch full view LCD screen
- resolution ratio: 640X480
- 5 diameter specifications
- support oxygen supply
- The stylet can be arbitrary plastic, rear end high elastic, not easy to damage the airway
- Can take pictures, videos, data output storage files
- The diameter of the pipe can be reused for more than 5,000 times

Specifications

PARTS	PARAMETER		
	Infant(flexible)	Adult(flexible)	Adult(un-bending)
Field Angle	100±10%		60±5%
Depth of Focus	3-50mm		20-50mm
Resolution	640*480		
Display	3.5"		
Pixels	400*400		640*480
Illuminance	≥400LUX		
Weight	330g	340g	350g
Swivel Up and Down	0°~130°		
Swivel Left and Right	0°~270°		
Rigid Tube Diameter	3mm	3.9mm	5.0mm
Rigid Tube Radian	80mm>R>50mm		R=55mm,R=65mm,R=75mm
Rigid Tube Length	L=300	380mm	
Battery Discharging Time	/		
Battery Recharging Time	/		
Recharging Times	>300		
Adapter Input	100-240VAC 50/60Hz		
Adapter Output	5V 2000mA		
Working Temperature	5℃~+40℃		
Working Humidity	20%~80%		
Working AP	860hpa~1060hpa		

HugeMed Series VL3S



Display
Horizontal and vertical rotation angle: $\geq 120^\circ$
HD full view screen, 6 function buttons, USB port, HDMI port for big display.

Quick Handlings
1 lock design
Fast installation and disassembling
Stay firm and efficient

Angulation Control
Flexible angulation control
Precise location

Scope
True 1:1 Torque Ratio for Easy operation

Camera System
Photo and Video recording function, Easy for clinical teaching and training

Suction Button
Fast Connection; Smooth Suction

Handle
Ergonomic streamline design
Anti-slip and improve hand held comfort

Working Chanel
Inner diameter: 1.2mm/2.2mm/2.6mm available

Insertion part
Outer diameter: 2.5mm/3.9mm/5.2mm/5.8mm
Fracture resistant, smooth, flexible and durable

Distal tip part
Dual diflections
New CMOS Technology
High brightness LED light source
160 up 130 down

Reference

Size		M58	M52	M39	M28
Scope Body	Illumination	LED			
	Joint Outer Diameter	5.8mm	5.2mm	3.9mm	2.8mm
	Instrument Chanel Inner Diameter	2.6mm	2.2mm	1.2mm	0mm
	Working Lenth	650mm			
	Anti-Fog	Anti-fog when it's on, no need for preheating.			
Operating system 、 Software System upgrades are free for life					
Display	Size	3.5inch/8inch			
	Storage	8GB SD Card			
	Shoot	Support			
	Video Record	Support			
	White Balance	Support			
	Freeze/Backwards	Support			
	Video Synchronous Out put	Support			

Note: * M28/M39 is not applicable for endoscopic diagnosis and treatment accessories.
* M28/M39/M52/M58 is not suitable for high-frequency electrotherapy surgery and laser hemostasis.
* Continuous working time in more than two hours, but it depends on ambient temperature and battery condition.

Advantages

Portable

Light weight, Easy to operate, Saving time for EMS, Convenient for transportation and storage

Multifunction

Available for the intubation of difficult airway, Inspection of airway and double chamber,Alveolarlavage, Biopsy, Treatment of pneumothorax, Stent Implantation, Removal of tracheal foreign bodies, Other treatments for the bronchi, Such as Local radiotherapy and chemotherapy, Medication Injection

Economic

One screen for four scopes, Four working channel sizes for option

Durable

Electronic camera system with LED, New technology for the photo processing: CMOS, Higher quality pictures, Last longer than traditional scope

Application

Applied to the departments such as: ICU, NICU, Respiration, Anesthesia, Emergency etc.

Accessories available: Trolley



ACCESSORIES



MOBILE STAND

A stand-alone configuration for use in a variety of hospital settings



RIGID STYLET

For use with endotracheal tubes 6,0 mm and larger.
Recommended to facilitate successful intubations.



EMS BAG

Color: BLUE/RED
Size: 3.5inch/8inch



Full Cover Blades covid-19

Mac1/2/3/4/5
Option: blades with channel (Mac 3/4)



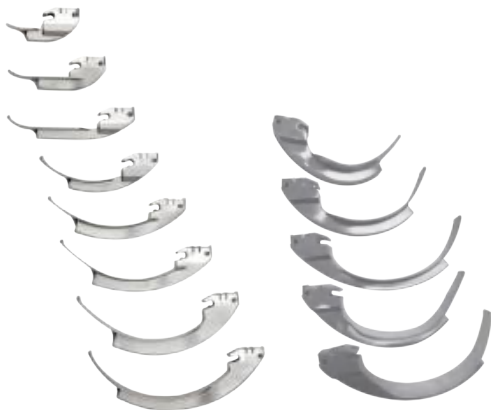
Silicone Cover Blades

Mac 1/2/3/4/5
Option: blades with channel (Mac 3/ 4)



Half Cover Blades

Mac 1/2/3/4/5
Option: blades with channel (Mac 3/ 4)



Reusable Blades

Model No.		Size(L*W*H)		Applicable patients
Miller 00		72X16X30		premature
Miller 0		84X17X30		newborn
Miller 1		110X18X30		infant
Mac 1	MacD 1	101X18X34	96X18X34	infant
Mac 2	MacD 2	117X23X37	115X22X50	children
Mac 3	MacD 3	130X24X39	127X22X34	adult
Mac 4	MacD 4	138X26X49	136X22X57	difficulty (obese)
Mac 5	MacD 5	150X25X52	147X22X59	difficulty



Disposable Blades

Model No.	Size(L*W*H)	Applicable patients
Mac 1	95X28X12.5	nfant
Mac 2	110X29X13	children
Mac 3	120X27X13	adult
Mac 4	135X22X14	difficulty (obese)
Mac 5	120X29X16	difficulty

EC Declaration of Conformity

Manufacturer: **Shenzhen HugeMed Medical Technical Development Co., LTD**
8F, Block A, Tempus Building, 1st Qingshuihe Road, Luohu District, Shenzhen 518023, P.R China

Whose single Authorized Representative: **Shanghai International Holding Corp.GmbH**
(Europe)
Eiffelstrasse 80, 20537 Hamburg, Germany

We, the manufacturer, herewith declare that the products

Video Laryngoscope

Model: VL3R; VL3D; VL3D Plus; VL3S; VL3H; VL3M; VLDM

VL3M-01; VL3M-02; VL3M-03; VL3M-04; VL3M-05; VL3M-06; VL3M-07; VL3M-08; VL3M-09;
VLDM-01; VLDM-02; VLDM-03; VLDM-04; VLDM-05; VLDM-06; VLDM-07; VLDM-08; VLDM-09;

(Including system components and accessories)

UMDNS-Code: 12293

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 Rule 5 of the Directive 93/42/EEC. It bears the mark

Applicable Standard(s):

Risk Management:	EN ISO 14971:2012		
Safety:	EN 60601-1:2006/A12:2014	EN ISO 7376-2009	EN 60601-1-2:2015
Software:	EN 62304:2006/AC:2008		
Usability:	EN 62366:2008	EN 60601-1-6:2010	
Biological Evaluation:	EN ISO 10993-1:2009/ AC:2010		
Label:	EN ISO 15223-1:2016	EN 1041:2008	

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

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

Shenzhen HugeMed Medical Technical Development Co., Ltd
8F, Block A, Tempus Building, 1st Qingshuihe Road, Luohu District, Shenzhen 518023, P.R China

Shenzhen 4/1/2019
Place, date

TAN YONG HONG
Legally binding signature, Function

Document No.: HJ-VL-CTF-010-D

Version: A1

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CERTIFICATE OF FDA REGISTRATION

HEREBY CERTIFY THAT

Shenzhen HugeMed Medical Technical Development Co., LTD

HAS SUCCESSFULLY COMPLETED/UPDATED THE FDA REGISTRATION

FOR

OWNER/OPERATOR NUMBER: 10052108
ESTABLISHMENT REGISTRATION NUMBER: 3012797688
MEDICAL DEVICE LISTING NUMBER (MDL/LST):

Refer to the Appendix at next page



FDA US AGENT

IRC USA
www.IRC-US.com

Charlie Mack

PRINCIPAL ENGINEER

CERTIFICATE NO.: IRC-HM-1906/01



Your Partner in Achieving FDA Compliance

IRC
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中华人民共和国 PEOPLE'S REPUBLIC OF CHINA 医疗器械产品出口销售证明 CERTIFICATE FOR EXPORTATION OF MEDICAL PRODUCTS

证书编号: 粤食药监械出 20201299 号

Certificate NO.: 粤食药监械出 20201299 号

产品名称: 麻酔视频喉镜

Product (s): Video Laryngoscope

规格型号: VL3R, VL3D

Model: VL3R, VL3D

产品注册或备案凭证号: 粤械注准 20172540103

Registration certificate (s): 粤械注准 20172540103

生产企业: 深圳市宏济医疗技术开发有限公司

Manufacturer: Shenzhen HugeMed Medical Technical Development Co., Ltd

生产企业住所: 深圳市罗湖区清水河一路腾邦大厦 A 栋 6B

Address of manufacturer: 6B Block A, Tempus Building, 1st Qingshuihe Road, Luohu District, Shenzhen 518023, China

生产许可或备案凭证号: 粤食药监械生产许 20172951 号

Manufacturing License (s): 粤食药监械生产许 20172951 号

兹证明上述产品已准许在中国生产和销售。

This is to certify that the above products have been registered to be manufactured and sold in China.

证明有效日期至: 2022 年 01 月 21 日

This certification valid until: 21/01/2022

备注: /

Remark: /



ISO 13485



NO.:10052108

