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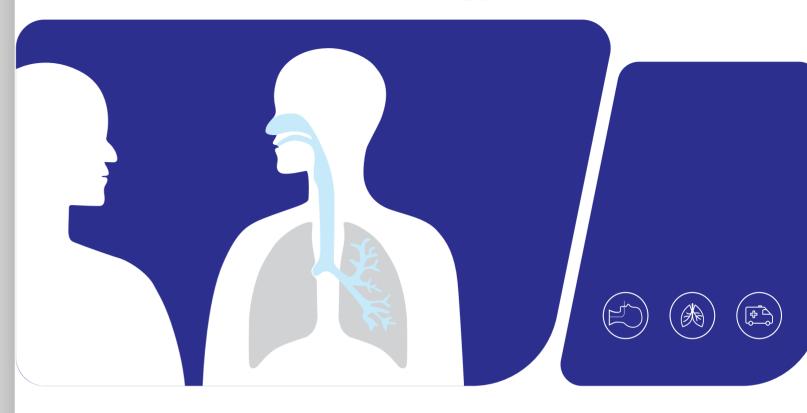












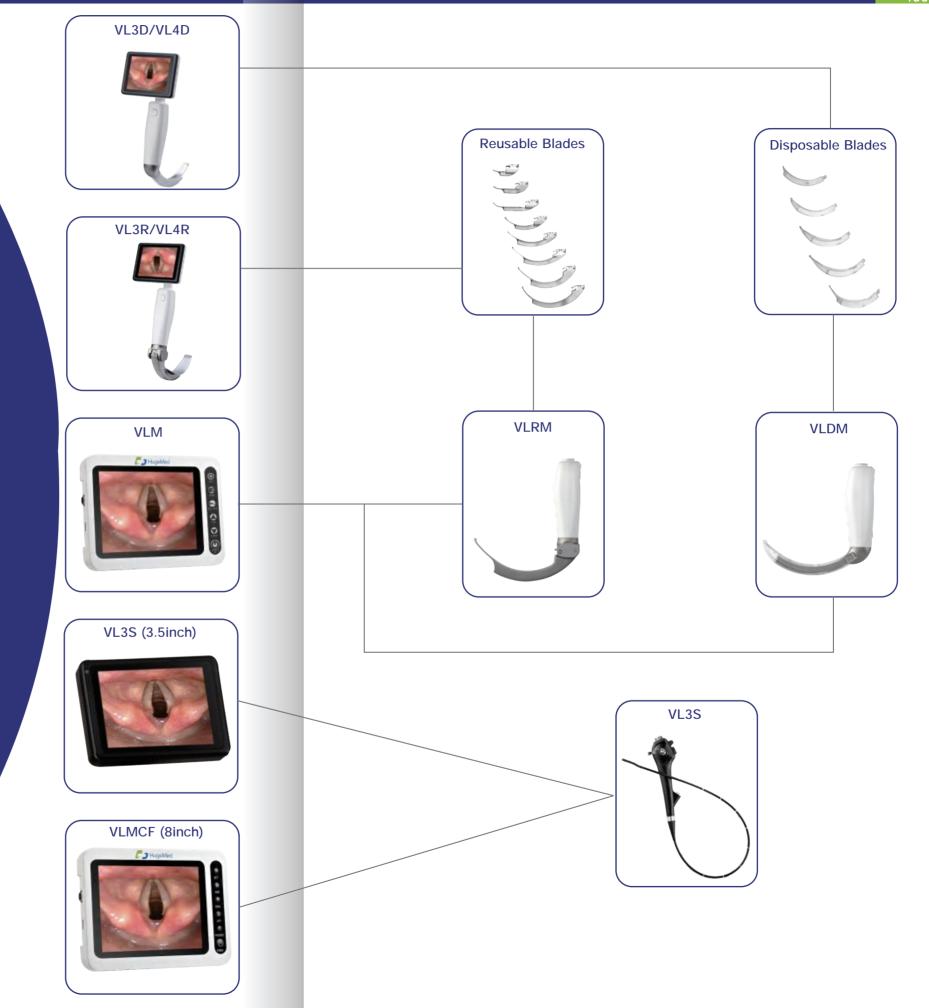


# SPECIALIZING IN ANESTHESIA AND RESPIRATION CARE



# 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 Reusable Video Laryngoscope





# 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 disigned for various population

# HugeMed Disposable Video Laryngoscope







# 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 disigned 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**

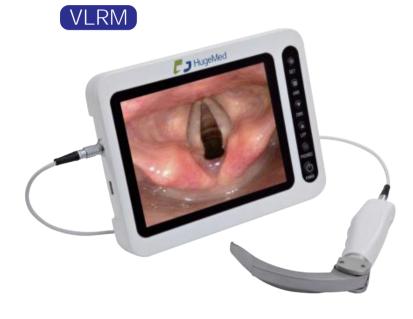
Size: 3.5inch/4inch Full view			
Monitor: LCD			
Resolution Ratio: 640X480RGB/800*480RGB			
Aspect Ratio: 4:3			
Video refresh Rata: 30FPS			
Illumination: LED			
Easy to establish and store files			
USB interface			
Resolution Ratio 2.0M Pixels			
Field Angle: 66°			
Illuminance ≥800LUX			
Confortable ergonomic short handle design			
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.



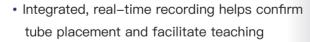


## Reusable Blades

#### VLRM/VLDM=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





- 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



Disposable Blades

# 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

Туре	VLRM	VLDM	
Display	8 Inch LCD monitor HD Display		
Resolution	1024*768RGB		
Data audiovisual output	Support		
Camera Resolution	2M Pixel		
View Angle	66°		
Illumination	≥800	LUX	
Battery Life Time	120–150min		
Battery Capacity	10000mAh		
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 scrren
- 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		80mm
Battery Discharging Time	/		
Battery Recharging Time	/		
Recharging Times	>300		
Adapter Input	100-240VAC 50/60Hz		
Adapter Output	5V 2000mA		
Working Temperature	5°C~+40°C		
Working Humidity	20%~80%		
Working AP	860hpa~1060hpa		

# HugeMed Series VL3S



# Display

Horizontal and vertical rotation angle: ≥ 120° 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



160 up 130 down

# Reference

Size		M58	M52	M39	M28
	Illumination	LED			
	Joint Outer Diameter	5.8mm	5.2mm	3.9mm	2.8mm
Scope Body	Instrument Chanel Inner Diameter	3.0mm	2.6mm	1.2mm	0mm
	Working Lenth	650mm			
	Anti-Fog	Anti-fog when it's on, no need for preheating.			
Operating syste	m 、Software System upgrades are	free for life			
	Size	3.5inch/8inch			
	Storage	8GB SD Card Support			
	Shoot				
Display	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

Mode	l No.	Size(L*W*H)		Applicable patients
Miller 00		72X14.4X29.5		premature
Miller 0		84X15X29.5		newborn
Miller 1		110X15X29.5		infant
Mac 1	MacD 1	101X18X34	96X18X34	infant
Mac 2	MacD 2	115X21X36.5	115X22X50	children
Mac 3	MacD 3	130X24X40	127X22X34	adult
Mac 4	MacD 4	136X23X43	136X22X57	difficulty (obese)
Mac 5	MacD 5	150X23X51	147X22X59	difficulty



# Disposable Blades

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

#### **EC Declaration of Conformity**

Whose single Authorized Representative Shenzhen HugeMed Medical Technical Shanghai International Holding

Development Co., LTD Corp.GmbH 8F, Block A, Tempus Building, 1st (Europe)

Qingshuihe Road, Luchu District, Shenzhen Eiffestrasse 80,20537 Hamburg, Germany

518023, P.R China

We, the manufacturer, herewith declare that the products

#### Video Laryngoscope

#### Model:vL3R;vL3D;vL3D Plus;vL3S;vL3H;vLRM;vLDM

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

(Including system components and accessores)

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 80601-1:2006/A12:2014 EN ISO 7376-2009 EN 60601-1-2:2015 Software EN 62304:2006/AC:2008

Usahility

EN 82388 2008

Biological Evaluation EN ISO 10993-1:2009/AC:2010

EN ISO 15223-1:2016 EN 1641:2008 Label:

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

EN 60601-1-6 2010

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

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



# CERTIFICATE OF QUALITY MANAGEMENT SYSTEM FOR MEDICAL DEVICES

This is to certify that the quality management system of

Shenzhen HugeMed Medical Technical Development Co.,LTD Registered Address: 6B. Block A, Tempus Building, 1st Qingshulle Road, Luohn District, Shenzhen City, Guangdong, China

Manufacturing Address:516-1, Building 2, No. 1, Mawu Road, Baoun Community, Yuanshan Street, Longgang District, Shenzhen, 518100, P.R China

Has been assessed and conformed to the following standard(s)

YY/T 0287-2017 idt ISO 13485:2016

The certificate is valid for the following scope: The Design, Development and Production of Video Laryngoscope

> Date of issue: September 04,2019 Date of expiry: August 04,2022

General Manager: 25413

BELIONG HUA GUANG CERTIFICATION OF MEDICAL DEVICES CO., LTD.



REGISTRATION NO. 04719Q10870R1M

#### CERTIFICATE

## OF QUALITY MANAGEMENT SYSTEM

This is to certify that the quality management system of

Shenzhen HugeMed Medical Technical Development Co. LTD Registered Address: 6B, Block A, Tempus Building, 1st Qingshuike Road, Luoliu District, Shenzhen City, Guangdong, China

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General Manager: 254

BELLING HUA GUANG CERTIFICATION OF MEDICAL DEVICES CO., LTD.





中国认可 以巨级国 管理体系 MANAGEMENT SYSTEM CNAS C047-M

# **CERTIFICATE OF FDA REGISTRATION**

## HEREBY CERTIFY THAT

**Shenzhen HugeMed Medical Technical** Development Co., LTD

HAS SUCCESSFULLY COMPLETED/UPDATED THE FDA REGISTRATION

## FOR

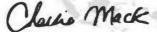
**OWNER/OPERATOR NUMBER: 10052108 ESTABLISHMENT REGISTRATION NUMBER: 3012797688** MEDICAL DEVICE LISTING NUMBER (MDL/LST):

Refer to the Appendix at next page



**FDA US AGENT** 

**IRC USA** www.IRC-US.com



PRINCIPAL ENGINEER

CERTIFICATE NO. IRC-HW-1906/01

## 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

证书稿号: 專金相互輸出 20201299 号 Certificate 80.: 事者商監練出 20201299 号

PARK MRUNNA Product (s): Videe Laryngurupe

District, Shouzhon 518023, China

规格型号: VL3R, VL3D Model: VLSR, VLSD

产品注册或备案凭证号: 粤城注准 20172540103 Registration certificate(s): 事城庄湘 20172540101

生产企业: 原明市宏济医疗技术开发有限公司 Wanufacturer: Shenzhen HugeMed Medical Technical Development Co., Ltd. 在产企业住所: 混划市罗朗区滑水河一路路邦大厦 A 株 45 Address of naturacturer: 6B Block A, Tempus Building, 1st Qingshuike Road, Lunku

生产许可或备案凭证号: 專食商监械生产许 20172951 号 Manufacturing License (s): 專食药量減生产品 20172951 号

在证明上述产品已成价在中国生产和销售。 This is to certify that the above products have been registered to be manufactured and sold in Chias.

证明有兼证期面: 2022年01月21日 This certification valid until: 21/01/2022

Renark:













