Xi'an HaiYe Medical Equipment Co., Ltd

西安海业医疗设备有限公司

Product 1

Video Laryngoscope with reusable blades

Item: HYHJ-KC

HYHJ-KC is Reusable video layrngoscope with 5 blades and 1 display. It can separate the display and replace different size blades.

Reusable Video Laryngoscope: The Tip Blade Size of HYHJ-KC

Tip Blade Size	length (mm)	height (mm)	Width (mm)	Max width of insert part (mm)	Mini width of insert part (mm)	Ref. Picture	Remark
Tip Blade 1 (L Adult)	153	54.5	29.23	22.41	14.37		MAC 4
Tip Blade 2 (M Adult)	140	49	29.23	21.37	14.46		MAC 3
Tip Blade 3 (S Adult or L Child)	122	34	29.23	21.4	13.56		MAC 2
Tip Blade 4 (M Child)	77.4	22.74	18.35	14.5	10.34		Miller 1
Tip Blade 5 (S Child & Infat)	59.9	17.46	18.55	14.7	10.6		Miller 0

Remark: Tolerance: ±5%.

HYHJ-KC
Video Laryngoscope

Miller0

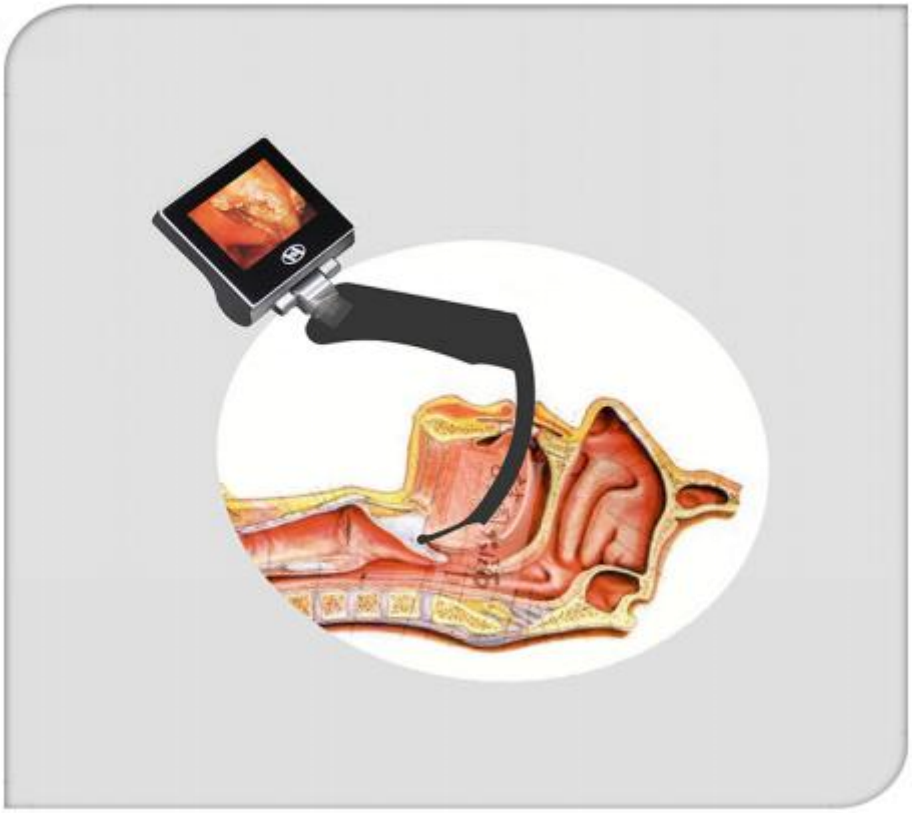
Miller1

Mac 2

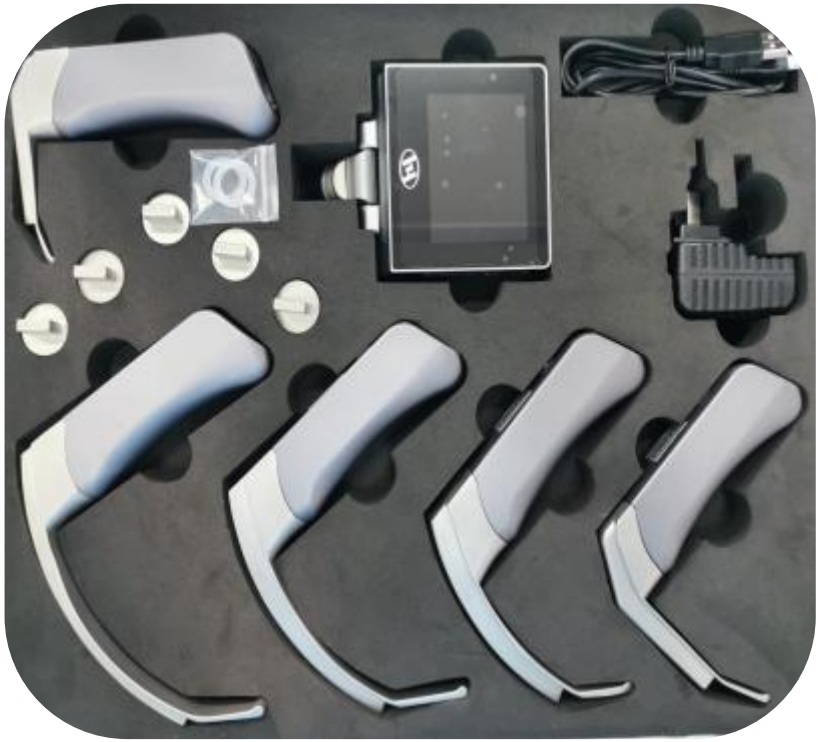
Mac 3

Mac 4

Reusable blades with different size for adults and children.




HAIYE



HYHJ-KC
complete spare parts

Suitable for you
Adapter and Plug

HYHJ-KC
Packing Case

TÜVRheinland

EC Certificate

Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

Registration No.: DD 60132095 0001

Report No.: 50170533 002

Manufacturer: Xi'an Haiye Medical Equipment
Co., Ltd.
Feng Jing Industrial Park
Xi'an city
710300 Shaanxi
P.R. China

Products: Video Laryngoscopes;
Aspects of manufacture concerned with securing and maintaining sterile conditions:
Disposable Video Laryngoscopes Blades

Expiry Date: 2023-11-09

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Effective Date: 2019-08-29

Date: 2019-08-29

Notified Body

Wenxiang Zhang

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

FDA

Fiscal Year 2020
CERTIFICATE OF FDA REGISTRATION

This certifies that:

Xi'an Haiye Medical Equipment co,.Ltd.

Feng Jing Industrial Park, Xi'an city, 710300 Shaanxi, China

has completed the FDA Establishment Registration and Device Listing with the US Food &Drug Administration, through UCL-REG SERVICE INC.

Owner/Operator Number: 10058939

Registered Establishment Number: 3015139770

No	Device Name	Product Code	Activities
1	Video Laryngoscopes	CCW	Manufacturer
2	Disposable Video Laryngoscopes Blades		

UCL-REG SERVICE INC. will confirm that such registration remains effective upon request and presentation of this certificate until the end of the calendar year stated above, unless said registration is terminated afterissuance of this certificate. UCL-REG SERVICE INC. makes no other representations or warranties, nor does thiscertificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. This certificate does not denote endorsement or approval of thecertificate-holder's device or establishment by the U.S. Food and Drug Administration. UCL UCL-REG SERVICE INC. assumes no liability to any person or entity in connection with the foregoing.

Pursuant to21 CFR 807.39, "Registration of a device establishment or assignment of a registration number doesnot in any way denote approval of the establishment or its products. Any representation that creates animpression of fficial approval because of registration or possession of a registration number is misleading and constitutes misbranding."

The U.S.Food and Drug Administration does not issue a certificate of registration, nor does the U.S Food andDrug Administration recognize a certificate of registration. UCL-REG SERVICE INC. is not affiliated with the U.S. Food and Drug Administration.

MICROKN 微可

UCL-REGSERVICE INC.
3907 PRINCE STREET SUITE 6F Flushing , NY US 11354
Phone: 347 7030850
Email: Gbstandard@163.Com

MICROKN CERTIFIED USA

Issued Date: April 06, 2020

TÜVRheinland

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Xi'an Haiye Medical Equipment Co., Ltd.
Feng Jing Industrial Park
Xi'an city
710300 Shaanxi
China

has established and applies a quality management system for medical devices for the following scope:

Manufacture and Distribution of Video Laryngoscopes and Disposable Video Laryngoscopes Blades

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date:	2019-08-29
Certificate Registration No.:	SX 60132096 0001
An audit was performed. Report No.:	50170533 002
This Certificate is valid until:	2021-11-09

Certification Body

DAkkS
Deutsche Akkreditierungsstelle
D-ZM-14169-01-02

Date: 2019-08-29

Wenalang Zhang

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail:cert-validity@de.tuv.com http://www.tuv.com/safety

REGISTRATION NO. 04718Q10355R0S

CERTIFICATE
OF QUALITY MANAGEMENT SYSTEM

This is to certify that the quality management system of
Xi'an Haiye Medical Equipment.Co.,Ltd
Registered Address:Fengjing Industrial Park, Xian City, Shaanxi Province, China
Postcode: 710300
Manufacturing Address: Fengjing Industrial Park, Xian City, Shaanxi Province, China
Has been assessed and conformed to the following standard(s)
GB/T 19001-2016 idt ISO 9001:2015
The certificate is valid for the following scope:
The Design,Research and development,Production and Service of Medical Video laryngoscope,Disposable video larygoscope blades.

Date of issue: August 17,2018
Date of expiry: August 16,2021

General Manager:

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

IAF MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT

CNAS
中国认可
国际互认
管理体系
MANAGEMENT SYSTEM
CNAS C047-M

Note: This certificate will not be valid until the organization has been approved in the annual audits. The certificate information are available on the website of the certification and accreditation administration of the People's Republic of China (www.cnca.gov.cn) or the website of CMD (www.cmdc.com.cn). Address: 8th floor of Zhong Liao building, No.jia86, An Ding Men Wai street, Dongcheng district, Beijing,100011, P.R. China Telephone: 010-62381993

Best Partner !
Thank You Very much