

PROPUESTA DE BARBIJOS KN95

EDUARDO ALBERTO DUPLICH VARGAS

DATOS:

NOMBRE: EDUARDO ALBERTO DUPLICH VARGAS

CANTACTO: 72271095-4476844

CORREO: EDUARDO@DUPLICH.COM

CARACTERÍSTICAS TÉCNICAS OFERTADAS - BARBIJOS KN95

CANTIDAD: 9378

DESCRIPCIÓN: BARBIJOS KN95 CON PINZA NASAL INCORPORADA METÁLICA, 5 CAPAS DE PROTECCIÓN.

CON REGISTRO SANITARIO AGEMED

CON CERTIFICADO FDA

CON CERTIFICADO CE

CON INSPECCIÓN DE CALIDAD INTERNACIONAL SGS

TIPO: BARBIJO SIN FILTRO

PLAZO DE ENTREGA: ENTREGA INMEDIATA

PROCEDENCIA: CHINA

FORMA DE ENTREGA: CAJA SELLADA DE 50 UNIDADES Y CADA BARBIJO EMBOLSADO INDIVIDUALMENTE CON SELLO HERMÉTICO.

PRECIO: 185684 Bs.

PRECIO NUMERAL: CIENTO OCHENTA Y CINCO MIL SEISCIENTOS OCHENTA Y CUATRO BOLIVIANOS/00

EDUARDO ALBERTO DUPLICH VARGAS

DIRECTOR

FOTOS DE RESPALDO



地址：中国广东省广州市经济技术开发区科学城科珠路198号
邮编：510663
电话：(86-20) 8215 5214 传真：(86-20) 8207 5013

INVOICE

Debit

Debit
To(付款人): EDUVAR-BESTEN WERT Py
Attn(收件人): Eduardo Dupleich Vargas
Tel(電話): +591-72271095
ADD:
EMAIL: eduardo@dupleich.com

Invoice No.(發票號碼): COP/JHSL052220

Date (發票日期): MAY 22, 2020

From: Cherry.fan@sgs.com

Terms(支付條款): PRE payment

Contract No. (合同號碼):

EMAIL: eduardo@dupleich.com

ADD: eduardo@dupleich.com Contract No. (合同编号):
 EMAIL: eduardo@dupleich.com
 SERVICE SCOPE: COUNT THE QTY, randomly check 315pcs samples for appearance as sampling plan level II, AQL 0/2.5/4.0

take photos, issue 1 inspection report

Inspection Location		Inspection Date		Supplier	
Taizhou, ZHEJIANG		To be advised		Taizhou Green Valves Co., Ltd	
				Price	Amount

Service or item (Description)	Rate per unit	Quantity	Price	Amount
		1man1days		
FRI				

Total	款号 Item No. *	订单号 PO No. *	货品名称 Goods Description *	数量 Quantity *	单位 Unit	船期 Shipment Date	目的地 Destination
1	KN95	BL200519	口罩 (非医用)	25000	Piece		Bolivia
2	一次性儿童口罩 3D	BL200519		5000	Piece		Bolivia

USD Payment To Be Made To The Following Bank Accounts:

USD Payment To Be Made To The Following Bank Accounts:	
Beneficiary's A/C Name:	SGS-CSTC Standards Technical Services Co., Ltd.

Beneficiary's A/C No.:	411
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Beneficiary's Bank:

SWIFT CODE

SWIFT CODE	2	28
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Bank Address:	-7202, Office Tower, Plaza. an He North Road, Guangzhou 510613 P.R. China
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For and on behalf of
SGS-CSTC Standards
Technical Service Co., Ltd.

Cherry Fan (020)

Authorized Signatory



COPY 1: Findiv

Important Note

CERTIFICATE OF FDA**Facility Registration and Device Listing of Medical Device****Taizhou Yu Xing Shoes Co., Ltd.****Owner/Operator Number: 10065514****Registration/FEI Number: Active, Waiting for Registration Number Assignment****Address: Industrial Park, Hou Wan Center Village, Yu Cheng Street, Yuhuan,
Taizhou, Zhejiang, 317600, CHINA**

has completed the Facility Registration and Device Listing with the US FDA, through
HUMISS INC.

Listing Number	Premarket Submission	Product Code(s)	Device Name(s)	Activities	Models
D381530	Exempt	MSH	Respirator, surgical	Manufacturer	Mask 85mm*95mm, 175mm*95mm, 175mm*90mm, 170mm*90mm, 145mm*95mm, 145mm*90mm, 125mm*95mm, KN95, KN99, N95

HUMISS INC. will confirm that such registration remains effective upon request and presentation of this certificate until the end of calendar year stated above, unless said registration is terminated after issuance of this certificate. HUMISS INC. makes no other representations or warranties, nor does this certificate make any representation 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 the certificate-holder's product(s) or establishment by the U.S Food and Drug Administration. HUMISS INC. assumes no liability to any person or entity in connection with foregoing.

The U.S Food and Drug Administration does not issue a certificate of registrations, nor does the U.S Food and Drug Administration recognize a certificate of registration, HUMISS INC. is not affiliated with the U.S Food and Drug Administration.



Certificate No: HU-M-200329024

Issue date: Mar. 29, 2020

Expire date: Dec. 31, 2020

HUMISS INC.

3944 Postal Front Cir Ste 118 Boulder CO 80301 USA

Certificate of Compliance



No. 0P200328E.TYX00076

Technical Construction File no. TPMJ2003173721

Certificate's
Holder:

Taizhou Yu Xing Shoes Co.,Ltd.
Industrial Park, Hou Wan Center Village, Yu Cheng
Street, Yuhuan City, Zhejiang Province, China.

Certification ECM
Mark:



Product:

Mask (Not Sterile)

Model(s):

85mm*95mm, 175mm*95mm,
175mm*90mm, 170mm*90mm,
145mm*95mm, 145mm*90mm,
125mm*95mm, KN90, KN95, KN99, N95

Verification to:

Standard:

EN 149: 2001+A1:2009

related to CE Directive(s):

R 2016/425 (Personal Protective Equipment)

Remark: This document has been issued on a voluntary basis and upon request of the manufacturer. It is our opinion that the technical documentation received from the manufacturer is satisfactory for the requirements of the ECM Certification Mark. The conformity mark above can be affixed on the products accordingly to the ECM regulation about its release and its use.

Additional information and clarification about the Marking:



The manufacturer is responsible for the CE Marking process, and if necessary, must refer to a Notified Body. This document has been issued on the basis of the regulation on ECM Voluntary Mark for the certification of products. RG01_ECM rev.3 available at: www.entecema.it

Issuance date: 28 March 2020

Expiry date: 27 March 2025

Reviewer
Technical expert
Amanda Payne

Approver
ECM Service Director
Luca Bedonni

REGISTRO SANITARIO

VISTOS:

El expediente N° **421887** presentado por el Regente Farmaceutico(a)
FABIOLA MEJIA ROSENDY con Matrícula N° **M-793708** en representación de la firma
LUMEBOL por el que solicita la **INSCRIPCION** del producto
DISPOSITIVO MED - MASCARILLA KN95-1 para su **IMPORTACION**
y comercialización en el país, elaborado por: **GUANGDONG ERMAN LIGHTING CO., LTD.**
de **CHINA** para **CHINA** bajo licencia de

Con aval de la Comisión Farmacológica Nacional: /
Certificado de Control de Calidad: **/ - NO REQUIERE**

CONSIDERANDO:

Qué se han cumplido con todos los requisitos, por tanto:

SE RESUELVE:

Autorizar la **INSCRIPCION** en el Registro Sanitario Nacional del producto
DISPOSITIVO MED - MASCARILLA KN95-1 de laboratorios
GUANGDONG ERMAN LIGHTING CO., LTD. procedente de **CHINA**
para **CHINA** bajo licencia de
bajo el N° **DI-74260/2020.**

que responde a las siguientes especificaciones:

Formula aprobada:

/

PCS 1

Presentación:

Condición de venta:

VENTA LIBRE

Periodo de validez:

36 MESES

Orden de pago N°

5129212/2020

del

8

de

Julio

de

2020

EL presente Registro Sanitario tiene validez de cinco años a partir de la fecha:


La Paz,

17 de

Julio


de

2020


Mra. Maira P. Chicharro Quispe
Dpto. de Autorización
de Comercialización de
Medicamentos y Tecnologías
en Salud
AGEMED

Regístrese, comuníquese y archívese




Dra. Eliana Caballero Vedia
DIRECTORA GENERAL EJECUTIVA
AGENCIA ESTATAL DE MEDICAMENTOS
Y TECNOLOGIAS EN SALUD
AGEMED