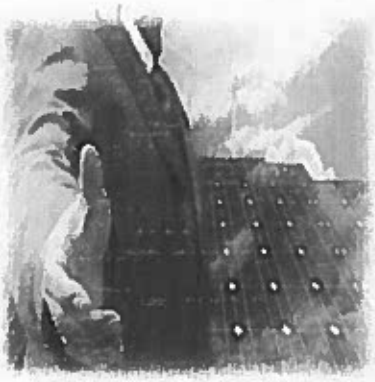
6

María Dolores Luzuriaga Naranjo

De: Raúl Medina <rmedina@veridenergia.com>
Enviado el: miércoles, 1 de julio de 2020 17:30
Para: Adquisiciones
Asunto: OFERTA SUMINISTRO DE MASCARILLAS FACIALES DESECHABLES KN95 CON REGISTRO SANITARIO
Datos adjuntos: MascarillasKN95_Trolebus_Jul2020.pdf; certificate of quality.jpg; FDA.pdf; CE Test Report.pdf; permiso_funcionamiento_ARCSA.pdf; Certificate of Compliance.pdf; MascarillasKN95_Trolebus_Jul2020.pdf; Powerunion-KN95-Technical-Data-Sheet.pdf

Buenas tardes,
Atendiendo a la invitación a ofertar mascarillas faciales desechables KN95, nos complace adjuntar la debida oferta.
Adjuntamos como documentos de soporte:

- Certificados CE, FDA y certificado de calidad
- Ficha técnica
- Reporte de prueba de laboratorio para certificado CE, STD EN149
- Permiso de funcionamiento de nuestra empresa para importación y comercialización de insumos médicos
- Registro sanitario emitido por ARCSA el 17 de Junio del 2020 a favor de nuestra empresa, ENERGY SOLUTIONS ECUADOR RAJEA S.A. Número de registro: 9237 DME 0620







PROPUESTA ECONOMICA

MASCARILLAS FACIALES DESECHABLES KN95

Atención Srs. EMPRESA PUBLICA METROPOLITANA DE TRANSPORTE DE PASAJEROS QUITO

INFORMACIÓN DEL OFERENTE:

ENERGY SOLUTIONS ECUADOR RAJEA S.A.
RUC: 1792718422001
AV. REPUBLICA DEL SALVADOR N36-193 Y AV. NNUU
EDIFICIO MARQUIS PLAZA OF. 22
QUITO, ECUADOR
TELF. 099 288 6281 / 099 800 5341
EMAIL: RMEDINA@VERIDENERGIA.COM

ENERGY SOLUTIONS ECUADOR



Veride Energía
Soluciones Integrales Energéticas

Veride Energía

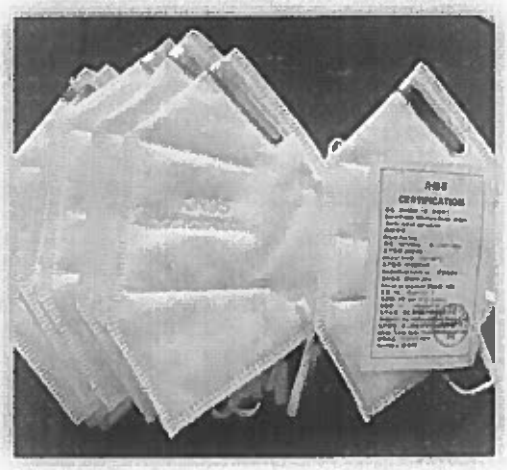
Q20200701-01
Quito, 01 de Julio del 2020

Attn. Srs. EMPRESA PUBLICA METROPOLITANA DE TRANSPORTE DE PASAJEROS QUITO
Asunto: Oferta Económica – MASCARILLAS FACIALES DESECHABLES KN95

Estimados Señores,

En respuesta a su amable invitación, nos complace presentarles la siguiente oferta por la provisión de mascarillas desechables tipo KN95 con todas las certificaciones requeridas.
El mencionado producto estará disponible para **entrega aproximadamente 2-1/2 semanas luego de recibida la orden de compra**.
Nuestra empresa cuenta con el permiso de funcionamiento para importar y comercializar. Adjunto a esta oferta los documentos relevantes.

Item	Característica	Cant.	Unidad	Costo Un.	Costo Total
10	Mascarillas faciales desechables KN95, 10 piezas por caja. REGISTRO SANITARIO, AUTORIZACION DE INEN, MIPRO. CERTIFICACION CE, FDA, REPORTES DE LABORATORIO GB2626	25500	Unid.	$ 1.45	$ 36,975.00
				Subtotal:	**$ 36,975.00**
				12% IVA:	**$ 4,437.00**
				Total:	**$ 41,412.00**



Cuenca, Pichincha
Cell: 099 288 6291, email: mmedina@verideenergia.com



140x120x200mm

ESPECIFICACIONES TÉCNICAS DEL PRODUCTO – MASCARILLA KN95

NOMBRE DEL ITEM	MASCARILLA FACIAL DESECHABLE KN95
CLASIFICACION	FFP2 APROBADO (ADJUNTAMOS REPORTE DE PRUEBAS DE LABORATORIO SEGÚN EN149)
NUMERO DE CAPAS	4
STANDAR DEL REPORTE DE LABORATORIO	GB 2626-2006 / EN149

CERTIFICACION KN95	CERTIFICACION FDA Y CE
BANDA METALICA NASAL	SI DISPONE
ELASTICOS PARA SUJECION AL CONTORNO DE LAS OREJAS	SI DISPONE
RESISTENTE A FLUIDOS	RESISTENTE A FLUIDOS
CUBRE NARIZ Y BOCA	SI
FECHA DE CADUCIDAD	3 AÑOS

REGISTRO SANITARIO EMITIDO POR ARCSA EL 17 DE JUNIO DEL 2020



ECUAPASS

Ventanilla Única Ecuatoriana

1804444725001 VERDEZOTO GUAYANGA ALEX DARIO Cerrar Sesión

ECUAPASS

laboración de Solicitud | Proceso de Solicitud | Soporte al Usuario

Consulta de Estado Actual de Procesamiento

Certificado de Inscripción de Registro Sanitario de Dispositivos Médicos Extranjeros

Datos Básicos

Número de Solicitud	16796803202000000003P	Fecha de Solicitud	12/05/2020
Número de Registro Sanitario	9237-DNE-0620	Fecha de Emisión de Registro Sanitario	17/06/2020
Fecha de Vigencia de Registro Sanitario	17/06/2025	Ciudad de Emisión de Registro Sanitario	QUITO
Tipo de Inscripción	General / Homologación		

Datos de Solicitante

Clasificación de Solicitante	Persona Jurídica / Persona Natural	Número de Identificación de la Empresa Solicitante (RUC)	1792718422001
Tipo de Solicitante	REPRESENTANTE LEGAL	Cargo de Solicitante	
Nombre o Razón Social de Solicitante	ENERGY SOLUTIONS ECUADOR RAJEA S.A		
Representante Legal Solicitante	MEDINA ROSERO HENRRY RAUL		
País de Solicitante	ECUADOR	Provincia de la Empresa Solicitante	PICHINCHA
Cantón/Ciudad de la Empresa Solicitante	QUITO	Parroquia de la Empresa Solicitante	INAQUITO
Dirección de la Empresa Solicitante	LOS EUCALIPTOS Y DE LOS PINOS		
Nombre de Solicitante	MEDINA ROSERO HENRRY RAUL		

ARCSA-MOVIL

9237 DME 0620 Buscar

Fecha de consulta: 1/7/2020
Registro consultado: 9237 DME 0620

INFORMACIÓN DE REGISTRO	
RS/NS:	9237-DME-0620
Titular:	ENERGY SOLUTIONS ECUADOR RAJEA S.A
Producto:	MASCARILLAS
Fecha Emisión:	2020-06-17
Estado:	VIGENTE

Reportar alerta

CARACTERISTICAS DE LA OFERTA:

- Disponibilidad del equipo – **tiempo de entrega: 2-1/2 semanas luego de recibida la orden de compra.**
- Lugar de entrega: QUITO, EN LA UBICACIÓN INDICADA EN LA INVITACION A OFERTAR.
- Validez:
  La validez de la oferta es de 7 días calendario contados a partir de la fecha de la emisión de la proforma.
- Forma de Pago:
  CONTRA ENTREGA DEL PRODUCTO.

Esperamos que esta propuesta sea de su agrado y nos reiteramos a sus órdenes en caso de cualquier pregunta o requerimiento de información adicional.

Atentamente,

Raúl Medina R.
Veride Energía
Celular: 099 288 6281
Email: rmedina@veridenergia.com
www.veridenergia.com; www.facebook.com/veridenergia

CERTIFICATE OF QUALITY
产品合格证

[Product]: KN95 Face Mask (Non Medical)

[品名]: KN95一次性防护口罩（非医用）

[执行标准]: GB 2626-2006

[Inspector]: 01

01
检验专用章

[质检员]: 01

[Material]:33% Polypropylene Melt-blown Fabric,
67% Polypropylene Non-woven Fabric

[主要成分]: 33%聚丙烯熔喷布，67%聚丙烯无纺布

[Validity date]: 24months

[有效期]: 2年

[生产批号]: 20200421

[生产日期]:2020/04/21

[生产地址]: 广东省深圳市龙华区大浪街道
华荣路131号 鹏腾达工业园 三栋三楼西

深圳市珀威尔科技有限公司
SHENZHEN POWERUNION TECHNOLOGY CO.,LTD

Fiscal Year 2020

CERTIFICATION OF REGISTRATION

This certifies that:

SHENZHEN POWERUNION TECHNOLOGY CO.,LTD
3rd Floor West,3rd Building,PengTengda Industrial Park,No.131 Huating Rd,Dalang Street, Longhua District Shenzhen, Guangdong, 518000, CHINA

has completed the FDA Establishment Registration and Device Listing with the US Food & Drug Administration, through

Shenzhen SIT Testing Technology Co., Ltd.

Owner/Operator Number: 10067569

Device Listing#: See annex

SIT 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 after issuance of this certificate. SIT 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 whose sole benefit it is issued. This certificate does not denote endorsement or approval of the certificate-holder's device or establishment by the U.S. Food and Drug Administration. SIT assumes no liability to any person or entity in connection with the foregoing.

Pursuant to 21 CFR 807.39, "Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official 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 and Drug Administration recognize a certificate of registration, SIT is not affiliated with the U.S. Food and Drug Administration.

FDA

Authorized Signer:_____

SHENZHEN SIT TESTING TECHNOLOGY CO.,LTD APPROVED

Department Manager

Date: April 08, 2020

Shenzhen SIT Testing Technology Co., Ltd.
Email:info@sitcert.com Tel: (86)-0755-29173399 Fax: (86)-0755-29179933 Http://www.sit-cert.com

Fiscal Year 2020

CERTIFICATION OF REGISTRATION

Annex to Device Listing# for Owner/Operator Number: 10067569

Listing Number	Premarket Submission Number/Type	Product Code(s)	Device Name(s)	Activities
D386307	Enforcement Discretion	QKR	Face mask (except N95 respirator) for general public/healthcare personnel per IIE guidance	Reprocessor of Single Use Devices Foreign Exporter Manufacturer

END OF THE ANNEX

SHENZHEN SIT TESTING TECHNOLOGY CO., LTD. APPROVED

Authorized Signer: _____
Department Manager

Date: April 08, 2020

Shenzhen SIT Testing Technology Co., Ltd.
Email:info@sitcert.com Tel: (86)-0755-29173399 Fax: (86)-0755-29179933 Http://www.sit-cert.com

CE

Technical Construction File

File No.: VELMA20200316007-PPE-

According to the

Regulation on Personal Protective Equipment: R 2016/425

Related to the

Product: Protective Mask

Model: KN95-V1, KN95-V2, KN95-V3, KN95-V4, KN95-V5, KN95-V6, KN95-V7, KN95-V8

Presented by

Shenzhen Powerunion Technology Co., LTD
3rd Floor West, 3rd Building, PengTengDa Industrial Park, No. 131 Huating Rd,
Dalang Street, Longhua District, Shenzhen, China

Content

Part I: General

1.1 General description of product

1.2 Variations of the series products

1.3 List of applicable regulations and standards

1.4 Quality control system

Part II: Assessment report

2.1 EN 149:2001+A1:2009 Assessment report

Annex: Technical Information

Annex 1 Photos

Part I: General

1.1 General description of product

Indications
This product is suitable for one-time use by medical units, one-time health care in general environment, or barrier or protection of particles such as flower powder considered by pathogenic microorganisms.

Following products were produced in Mar, 2020. And they were selected as samples for test.

Model Name: KN95-V1

1.2 Variations of the series products

Regarding the whole family of the series, they can be divided into various different groups according to their main features, they are:

KN95-V1, KN95-V2, KN95-V3, KN95-V4, KN95-V5, KN95-V6, KN95-V7, KN95-V8

All models are with the same product structure but with some small differences as described as the following:

-

To present the conformity of this series products with R 2016/425 (Regulation on Personal Protective Equipment), we discuss the conformity systematically with the relative Directive and standards for KN95-V1 as a basic evaluation in clause.

1.3 List of applicable regulations and standards

Regulations

Regulation on Personal Protective Equipment: R 2016/425

Standards

EN 149:2001+A1:2009
Respiratory protective devices - Filtering half masks to protect against particles - Requirements, testing, marking

1.4 Quality control system

In order to ensure the conformity of the series production, the SHENZHEN POWERUNION TECHNOLOGY CO., LTD has taken the related procedures mentioned below:

1) Apply for the consultant form the qualified body.
The SHENZHEN POWERUNION TECHNOLOGY CO., LTD has applied for the consultant from Technical Inspection Certification. The complete technical construction file (TCF) have been established before applying for the CE marking certificate.

2) Carry out the inspection for parts and components according to the TCF.
Before the assemblies of the series production, the QC engineers of SHENZHEN POWERUNION TECHNOLOGY CO., LTD has to check and inspect the technical specifications and intended functions of parts and components to ensure the correct use of them according to the contents of TCF and principle described in the related technical information.

3) Carry out the inspection & testing for the products before packing.
Before packing the products, the QC engineers of SHENZHEN POWERUNION TECHNOLOGY CO., LTD have to do the necessary inspection and testing to ensure the conformity of related requirements. In particular, they should do the testing and inspection of electrical characteristics and outer feature.

4) Carry out the inspection for the package.
After finishing the necessary inspection and testing for the products, an inspection for the packing has to be done to ensure the necessary elements being included in this packing before shipment.

5) Provision for the change of design.
Any change of the products described in this TCF must be checked in detail and written down again in the TCF by the designer of SHENZHEN POWERUNION TECHNOLOGY CO., LTD if the change may effects the related electrical or mechanical characteristics.

6) Provision for the Quality Assurance.
For the provisions of internal control measures to ensure the conformity of series production of the machines, SHENZHEN POWERUNION TECHNOLOGY CO., LTD has built an internal quality control system in accordance with the international standard of ISO 9001.

Part II: Assessment report

2.1 EN 149:2001+A1:2009 Assessment report

Assessment Report EN 149 Respiratory protective devices. Filtering half masks to protect against particles. Requirements, testing, marking		
Customer information	Client	Shenzhen Powerunion Technology Co., LTD
	Address	3rd Floor West, 3rd Building, PengTengDa Industrial Park, No. 131 Huating Rd, Dalang Street, Longhua District, Shenzhen, China
Sample information	Name of sample	Protective Mask
	Test Model No.	KN95-V1
	Model May Cover	KN95-V2, KN95-V3, KN95-V4, KN95-V5, KN95-V6, KN95-V7, KN95-V8
	Trade mark	Velma
	Manufacturer	Shenzhen Powerunion Technology Co., LTD
	Address	3rd Floor West, 3rd Building, PengTengDa Industrial Park, No. 131 Huating Rd, Dalang Street, Longhua District, Shenzhen, China
Test information	Sample received	Mar.7 2020
	Testing date	Mar.7 2020 to Mar.21 2020
	Standard/ Foundation	EN 149:2001+A1:2009
Remark		

Possible test case verdicts:

- test case does not apply to the test object ... N(Not apply)

- test object does meet the requirement ..... P (Pass)

- test object does not meet the requirement... F (Fail)

Testing .....

Date of receipt of test item Mar.7 2020

Date(s) of performance of tests ..... Mar.7 2020 to Mar.21 2020

General remarks:

The test results presented in this report relate only to the object tested.

This report shall not be reproduced, except in full, without the written approval of the Issuing testing laboratory.

"(See Enclosure #)" refers to additional information appended to the report.

"(See appended table)" refers to a table appended to the report.

General product information:

Copy of marking plate:

Protective Mask
Model: KN95-V1



Shenzhen Powerunion Technology Co., LTD
Made in China

EN 149			
Clause	**Requirement – Test**	**Result - Remark**	**Verdict**
5	Classification		--
	Particle filtering half masks are classified according to their filtering efficiency and their maximum total inward leakage. There are three classes of devices:		P
	- FFP1		N
	- FFP2		P
	- FFP3		N
6	Designation		--
	Particle filtering half masks meeting the requirements of this European Standard. Year of publication, classification, option	Particle filtering half mask EN 149:2001+A1:2009 FFP2	P
7	**Requirements**		--
7.1	General		P
	All test all test samples shall meet the requirements.	Compled the requirement. see bellow	P
7.2	Nominal values and tolerances		P
	Unless otherwise specified,the values stated in this European Standard are experature limits.		P
7.3	Visual inspection		P
	The visual inspection shall also include the marking and the information supplied by the manufacturer.	Clear marking is provided. see sample body	P
7.4	Packaging		P
	Particle filtering half masks shall be offered for sale packaged in such a way that they are protected against mechanical damage and contamination before use.		P
7.5	Material		P
	Materials used shall be suitable to withstand handling and wear over the period for which the particle filtering half mask is designed to be used. Any material from the filter media released by the air flow through the filter shall not constitute a hazard or nuisance for the wearer.	Comfortable wearing. when releasing no hazards is produced.	P
7.6	Cleaning and disinfecting		N
	If the particle filtering half mask is designed to be re- usable. the materials used shall withstand the cleaning and disinfecting agents and procedures to be specified by the manufacturer.	It's is not re-usable.	N
7.7	Practical performance		P
	The particle filtering half mask shall undergo practical performance tests under realistic conditions.	Complied. see append test.	P
7.8	Finish of parts		P
	come into contact with the wearer shall have no sharp edges or burrs		P
7.9	Leakage	See append table 8.5	P
7.9.1	Total inward leakage		P
	The laboratory tests shall wearer to protect with high probability against the potential hazard to be expected.	Enough safe condition is Provide.	P

EN 149			
Clause	**Requirement – Test**	**Result - Remark**	**Verdict**
	Exercise results for total inward leakage shall be not greater than		P
	25% for FFP1 11% for FFP2 5 % for FFP3	FFP2. Not exceed 11%	P
	And, in addition, at least 8 out of the 10 individual wearer arithmetic means for the total inward leakage shall be not greater than.		P
	22 % for FFP1 8 % for FFP2 2 % for FFP3.	FFP2. Not exceed 8%	P
7.9.2	Penetration of filter material		P
	The penetration of the filter of the particle filtering half mask shall meet the requirements of Table 1.	see append table 7.92	P
7.10	Compatibility with shin		P
	Materials that may come into contact with the wearer's skin shall not be known to be likely tocause irritation or any other adverse effect to health.		P
7.11	Flammability		P
	The material used shall not present a danger for the wearer and shall not be of highly flammable nature.		P
7.12	Carbon dioxide content of the inhalation air		P
	The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1.0% (by volume).	<1.0%	P
7.13	Head harness		P
	Head harness shall be designed can be donned and removed easily and adjustable or selfadjusting and sufficiently robust to hold the particle.	Head harness is donned and removed easily	P
7.14	Field of vision		P
	Field of vision is acceptable in practical performance tests.	Clear field of vsion when wearing	P
7.15	Exhalation valve(s)		P
	A particle filtering half mask may have one or more exhalation valve(s) and shall function correctly in all orientations.	One valve provided	P
	Exhalation valve is provided it shall be protected against or be resistant to dirt and mechanical damage and may be shrouded or may include any other device.	Clearly function	P
	Exhalation valve(s) shall continue to operate correctly after a continuous exhalation flow of 300 l/min over a period of 30 s.		P
	Exhalation valve housing is attached to the faceblank, and withstand axially a tensile force of 10 N applied for 10 s.		P
7.16	Breathing resistance		P
	Breathing resistances apply to valved and valveless and shall meet the requirements.		P
7.17	Clogging		N
	General		N
	For single-use devices clogging test is an optional test.		N
	Devices designed to be resistant to clogging, shown by a slow increase		N

EN 149			
Clause	**Requirement – Test**	**Result - Remark**	**Verdict**
	The specified breathing resistances shall not be exceeded before the required dust load of 833 mg·h/m³.		N
7.17.2	Breathing resistance		N
7.17.2.1	Valved particle filtering half masks		N
7.17.2.2	Valveless particle filtering half masks		N
7.17.3	Penetration of filter materia		N
	All types claimed to meet the clogging requirement shall also meet the penetration requirements given in 7.9.2 after the treatment.		N
7.18	Demountable parts		N
	All demountable parts (if fitted) shall be readily connected and secured, where possible by hand.	No such demountable part	N
8	Testing		-
8.1	General		P
	No special measuring devices and methods are specified, commonly used devices and methods shall be used.		P
8.2	Visual inspection		P
	The visual inspection is carried out appropriate by the test house prior to laboratory or practical performance tests.		P
8.3	Conditioning		P
8.3.1	Simulated wearing treatment		P
	A breathing machine is adjusted to 25 cycles/min and 2.0 l/stroke.	25 cycles/min 2.0 l/stroke.	P
	For testing, a saturator is incorporated in the exhalation line between the breathing machine and the dummy head.	A saturator incorporated by breathing machine and the dummy head.	P
	The spilling out of the dummy's mouth and contaminating the particle filtering half mask the head shall be incline	Incline considered	P
8.3.2	Temperature conditioning		P
	Exposet masks to the following thermal cycle:		P
	a) for 24 h to a dry atmosphere of (70 ± 3) ℃:	71.4℃	P
	b) for 24 h to a temperature of (-30 ± 3) ℃:	-30.5℃	P
	Allow to return to room temperature for at least 4 h between exposures and prior to subsequent testing.	5h to paid for	P
8.3.4	Flow conditioning		P
	A total of 3 valved particle filtering half masks shall be tested, one as received and two temperature conditioned in accordance with 8.3.2.		P
9	Marking		-
9.1	Packaging		P
	The following information shall be clearly and durably marked on the smallest commercially available packaging or legible through it if the packaging is transparent.	Complied, clearly marked	P
9.1.1	The name, trademark or other means of identification of the manufacturer or supplier.		P

EN 149			
Clause	**Requirement – Test**	**Result - Remark**	**Verdict**
9.1.2	Type-identifying marking.		P
9.1.3	Classification: FFP1, FFP2, FFP3.		P
9.1.4	The number and year of publication of this European Standard.		P
9.1.5	At least the year of end of shelf life.		P
9.1.6	The sentence 'see information supplied by the manufacturer', at least in the official language(s) of the country of destination, or by using the pictogram as shown in Figure 12b.		P
9.1.7	The manufacturer's recommended conditions of storage (at least the temperature and humidity) or equivalent pictogram, as shown in Figures 12c and 12d.	See product manual	P
9.1.8	The packaging of those particle filtering half masks passing the dolomite clogging test shall beadditionally marked with the letter "D".		N
9.2	Particle filtering half mask		P
	Particle filtering half masks complying with this European Standard shall be clearly and durably marked with the following:	See product manual	P
9.2.1	The name, trademark or other means of identification of the manufacturer or supplier.	See product manual	P
9.2.2	Type-identifying marking.	See product manual	P
9.2.3	The number and year of publication of this European Standard.	See product manual	P
9.2.4	The symbols FFP1, FFP2 or FFP3 according to class.	See product manual	P
9.2.5	If appropriate the letter D (dolomite) in accordance with clogging performance. This letter shall follow the class designation (see 9.2.4).		N
9.2.6	Sub-assemblies and components with considerable bearing on safety shall be marked so that they can be identified.		N

Attachments: Test table

Table 7.9.2	Penetration of test aerosol test					P
Item \ Models	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Sample 6
Sodium chloride test 95 l/min	18.6	18.3	18.4	18.3	18.1	18.2
Paraffin oil test 95 l/min	18.2	18.3	18.1	18.5	18.3	18.3

Table 8.5	Leakage test				P
Item \ Models	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5
NaCl flow rate (L/min)	90	100	120	110	120
NaCl aerosol (um)	0.3	0.3	0.3	0.3	0.3
0.3Pumping flow rate (L/min)	30	30	30	30	30
NaCl concentration before mask (Mg/m^3)	2	2	2	2	2
NaCl concentration after mask (Mg/m^3)	0.05	0.06	0.07	0.08	0.06
Note: Test ark volume is $2m^3$ Average Leakage ratio is 8%<11% Calculation formula as below :					

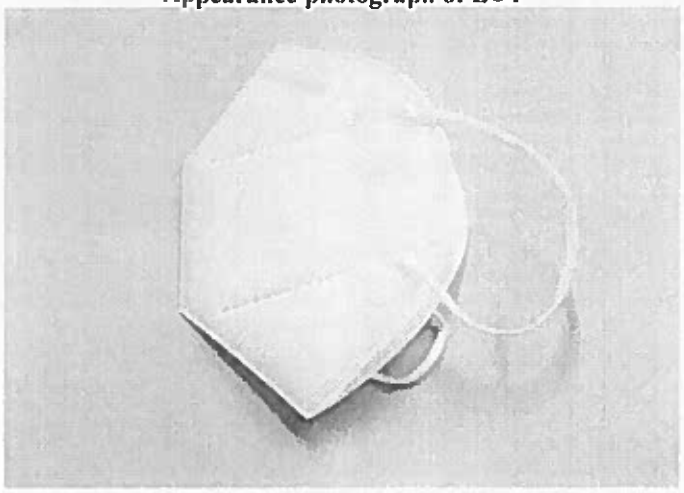
Table 8.9.2	Exhalation resistance test				P
Item \ Models	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5
Inhalation gas velocity (L/min)	160	160	160	160	160
Maximum resistance (mbar)	2.53	2.45	2.46	2.45	2.44
Conclusion: Maximum permitted resistance < 3.0 mbar					

Table 8.9.3	Inhalation resistance test				P
Item \ Models	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5
Inhalation gas velocity (L/min)	30	30	30	30	30
Maximum resistance (mbar)	0.36	0.41	0.38	0.40	0.41
Conclusion: Maximum Inhalation resistance < 0.6 mbar					

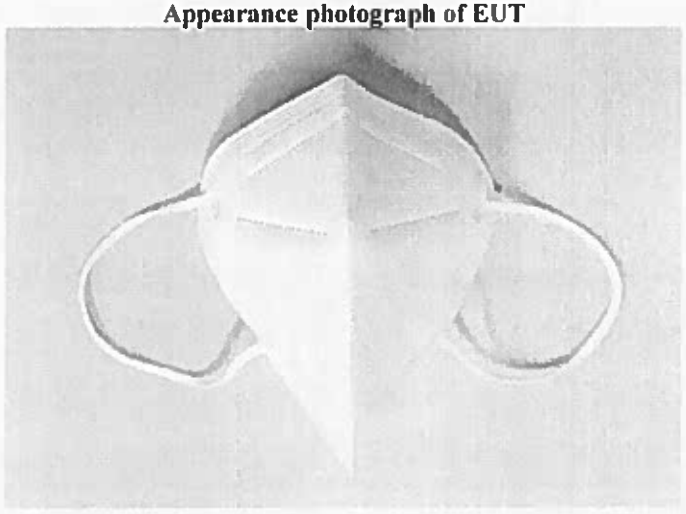
Table 8.9.3.2	Inhalation resistance test				P
Item \ Models	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5
Inhalation (L/min)	95	95	95	95	95
Maximum resistance (mbar)	1.98	1.97	1.96	1.97	1.94
Conclusion: Maximum Inhalation resistance < 2.1mbar					

Annex 1 Photos

Appearance photograph of EUT



Appearance photograph of EUT



AGENCIA NACIONAL DE
REGULACIÓN, CONTROL
Y VIGILANCIA SANITARIA
DR. LEOPOLDO IZQUIETA PÉREZ

PERMISO DE FUNCIONAMIENTO: ARCSA-2020-3.3-0000754

Nombre o Razón Social del establecimiento: ENERGY SOLUTIONS ECUADOR RAJEA S.A

Nombre del Propietario o Representante Legal: MEDINA ROSERO HENRRY RAUL

Número del RUC del establecimiento: 1792718422001 Establecimiento N°: 1

Provincia: PICHINCHA

Cantón: QUITO

Parroquia: IÑAQUITO

Sector/Referencia: IÑAQUITO

Dirección: BARRIO: IÑAQUITO CIUDADELA: IÑAQUITO CALLE: AV REPUBLICA DEL SALVADOR NUMERO: N36-193 INTERSECCION:AV NACIONES UNIDAS

Actividades / Tipo(s) de establecimiento(s):

* 3.3 ESTABLECIMIENTOS DE DISPOSITIVOS MEDICOS Y REACTIVOS BIOQUIMICOS DE DIAGNOSTICO IN VITRO PARA USO HUMANO CASAS DE REPRESENTACION Y DISTRIBUIDORAS DE DISPOSITIVOS MEDICOS Y/O REACTIVOS BIOQUIMICOS DE DIAGNOSTICO IN VITRO PARA USO HUMANO. Riesgo: Medio

Fecha de Emisión: 22-04-2020

Fecha de Vigencia: 22-04-2021

Total pago: 144.00

Estado: VIGENTE

Fecha de Impresión del Documento: 22-04-2020

Ing. Leonardo Da Silva Saralegui
Coordinador General Técnico de Certificaciones - Agencia Nacional De Regulación, Control Y Vigilancia Sanitaria - ARCSA "Dr. Leopoldo Izquieta Pérez"

Ministerio de Salud Pública

Nota:
Las condiciones en la cual se emitió el Permiso de Funcionamiento, son verificables en cualquier momento por la Agencia

Nacional de Regulación, Control y Vigilancia Sanitaria "Dr. Leopoldo Izquieta Pérez" y este se emite en el formato a la fecha de impresión del documento.

Certificate – Сертификат – 證明書 – Certificat – 증명서 – شهادة

Certificate of Compliance

No. 3Q200405B.SPT0Q46

Certificate's Holder: Shenzhen Powerunion Technology Co., LTD
3rd Floor West, 3rd Building, PengTengDa Industrial Park, No. 131 Huating Rd, Dalang Street, Longhua District, Shenzhen, China

Certification ECM Mark: Type Approved

Product: Protective Mask

Model(s): KN95, KN95-V1, KN95-V2, KN95-V3, KN95-V4, KN95-V5, KN95-V6

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:

CE

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.entecerma.it

Issuance date: 05 April 2020

Expiry date: 04 April 2025

Reviewer
Technical expert
Amanda Payne

Approver
ECM Service Director
Luca Berlonni

深圳市珀威尔科技有限公司
POWERUNION TECHNOLOGY CO.,LTD

KN95 Masks (Non-Medical)

TECHNICAL DATA SHEET
KN95 Face Mask (Non-Medical)

Intended use forNK95 Masks: For occupational or home use. Excluding medical use. Reduces wearer's exposure to particles including small particle aerosols and large droplets (all non-oil aerosols), protects from exposure to airborne particles. Use in a non-surgical setting protects from exposure to biological aerosols including viruses and bacteria when fit correctly.

Characteristic	Specification		
Material Composition	**Mask body**	Outer Layer	Breathable protective layer
		Layer 2	Large particle non-woven filter
		Layer 3	Fine particle non-woven filter
		Inner Layer	Comfort layer
	Nose clip	Aluminum	
	Elastic ear loop	100% Cotton	
Description	Folded non-medical KN95 face mask with nosepiece, nose foam band inside, and stretchable dual ear loops.		
Color	**Mask**	White	
	Elastic ear loop	White	
Nose Clip Style	Flat Aluminum Nose Clip		
Dimension	**Body Size**	Length	153 mm
		Width	100 mm
		Height	50 mm
	Nose Clip	Length	96 mm
	Elastic ear loop	Left Length	220 mm
		Right Length	220 mm

Additional Information

Storage Condition	Country of Origin
Store under cool, clean, and dry conditions. Avoid excessive heat (over 40°C or 104°F)	China

Manufactured By	QC Managed By Powerunion
Shenzhen Powerunion Technology Co., Ltd	Your packaging, shipping and quality paperwork will all managed by Shenzhen Powerunion Technology Co., Ltd

Powerunion KN95 non-medical masks meet China's GB2626-2006 standard.

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DISCLAIMER: Shenzhen Powerunion Technology Co., Ltd believes that the information in this Technical Data Sheet is accurate and represents the best and most current information available to us. Shenzhen Powerunion Technology Co., Ltd makes no representations or warranties either express or implied for our KN95 non-medical masks. Shenzhen Powerunion Technology Co., Ltd will not be responsible for damages resulting from use of or reliance upon the information in this Technical Data Sheet.

深圳市珀威尔科技有限公司
POWERUNION TECHNOLOGY CO.,LTD

KN95 Masks

TECHNICAL DATA SHEET
KN95 Face Mask (Non-Medical)

KN95 ADDITIONAL SPECIFICATIONS

Product Name: KN95 Face Mask Aerosol
Type: Non-Oil
Color: White
Size: Universal
Dimension: 15.3*10cm
Exhalation Valve: No
Nose Clips: Yes
Material: 33% Polypropylene Melt-blown Fabric, 67% Polypropylene Non-woven Fabric
Nose Clip Material: Aluminum
Earloop Material: 100% Cotton
Standard: GB2626-2006
Classification: KN95

KN95 Packing Details

PCS/PP Bag: 5pcs/10pcs (optional)
PP Bag/Color Box: 5 PP bags
Color Box/Cardboard Box: 20 Color boxes
PCS/CTN: 1000pcs
Carton Size: 650*350*420mm
PCS/CTN: 1000pcs
Net Weight: 7.39kg
Gross Weight: 8.2kg
Packing: PP bag to color box, color box to cardboard box

KN95 IMPORTANT NOTES

*This is a non-medical mask.
*Not suitable for harmful gases and steam.
*Not suitable for hypoxic environments, underwater operations or fire fighting.
*Not for children. Adult use only.
*Design and packaging may vary but will meet QC standards.

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