TEFANESO SERVICE

UNDER THE AUTORITY OF TEFANESO SWITZERLAND S. A.

KN95

Protective Masks

(PARTICULATE RESPIRATOR)

CE and FDA certified

DISPOSABLE Filtering Facepiece

- 4 layers protection ensure a good filtration
- 3D contour fit design to provide maximum confort
- Effective filtering of harmful substance up to >95%

APPLICATIONS

- Civil
- Industrial

Ref. 200 - 010

TEFANESO SERVICES
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IDE: CHE-274.734.952

Certification/ Class (Standard)	N95 (NIOSH-42C FR84)	FFP2 (EN 149-2001)	KN95 (GB2626-2006)	P2 (AS/NZ 1716:2012)	Korea 1st Class (KMOEL - 2017-64)	DS (Japan JMHLW-Notification 214, 2018)
Filter performance – (must be ≥ X% efficient)	≥ 95%	≥ 94%	≥ 95%	≥ 94%	≥ 94%	≥ 95%
Test agent	NaCl	NaCl and paraffin oil	NaCl	NaCl	NaCl and paraffin oil	NaCl
Flow rate	85 L/min	95 L/min	85 L/min	95 L/min	95 L/min	85 L/min
Total inward leakage (TIL)* – tested on human subjects each performing exercises	N/A	≤ 8% leakage (arithmetic mean)	≤ 8% leakage (arithmetic mean)	≤ 8% leakage (individual and arithmetic mean)	≤ 8% leakage (arithmetic mean)	Inward Leakage measured and included in User Instructions
Inhalation resistance – max pressure drop	≤ 343 Pa	≤ 70 Pa (at 30 L/min) ≤ 240 Pa (at 95 L/min) ≤ 500 Pa (clogging)	≤ 350 Pa	≤ 70 Pa (at 30 L/min) ≤ 240 Pa (at 95 L/min)	≤ 70 Pa (at 30 L/min) ≤ 240 Pa (at 95 L/min)	≤ 70 Pa (w/valve) ≤ 50 Pa (no valve)
Flow rate	85 L/min	Varied – see above	85 L/min	Varied – see above	Varied – see above	40 L/min
Exhalation resistance - max pressure drop	≤ 245 Pa	≤ 300 Pa	≤ 250 Pa	≤ 120 Pa	≤ 300 Pa	≤ 70 Pa (w/valve) ≤ 50 Pa (no valve)
Flow rate	85 L/min	160 L/min	85 L/min	85 L/min	160 L/min	40 L/min
Exhalation valve leakage requirement	Leak rate ≤ 30 mL/min	N/A	Depressurization to 0 Pa ≥ 20 sec	Leak rate ≤ 30 mL/min	visual inspection after 300 L /min for 30 sec	Depressurization to 0 Pa ≥ 15 sec
Force applied	-245 Pa	N/A	-1180 Pa	-250 Pa	N/A	-1,470 Pa
CO_2 clearance requirement	N/A	≤ 1%	≤ 1%	≤ 1%	≤ 1%	≤ 1%

*Japan JMHLW-Notification 214 requires an Inward Leakage test rather than a TIL test.

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Fiscal Year 2020
CERTIFICATION OF REGISTRATION

This certifies that:

Shenzhen HUAK Testing Technology Co., Ltd.

Owner/Operator Number: 10067415

Device Listing#: See annex

Shenzhen HUAK 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. Shenzhen HUAK 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. Shenzhen HUAK 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. Shenzhen HUAK is not affiliated with the U.S. Food and Drug Administration.

FDA

Chief Engineer
Issued: April 05, 2020
Expiration Date: December 31, 2020

Fiscal Year 2020
CERTIFICATION OF REGISTRATION

Annex to Device Listing# for Owner/Operator Number: 10067415

Listing No.	Code	Device Name	Activities	Proprietary Name
D385977	LYU	ACCESSORY, SURGICAL APPAREL	Manufacturer	Disposable mask KN95, N95

END OF THE ANNEX

Chief Engineer
Issued: April 05, 2020
Expiration Date: December 31, 2020

Review Report – 审查报告 – 검토 보고서 – Rapport d'Evaluation

Form QAT_10-M06, version 00, effective since March 25th, 2020

CE Documentation Review

No. 4W200401B.GDF0U97

Review goal:	Verification of the presence of Technical Documentation compatible with the Medical Devices Directive 93/42/EEC Annex VII
Product:	KN95 protective mask (Not Sterile)
Model(s):	Disposable mask (KN95)
Classification:	Class I (Not Sterile) (accordingly to the Manufacturer's declaration)
Review output:	This document has been issued on a voluntary basis and upon request of the manufacturer. It is our opinion that the Technical Documentation shared with us by the manufacturer is compatible with the European Standard for Medical Devices. The manufacturer is responsible for the CE Marking process, and not exempted to carry out all necessary compliance activities. 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

Date of issue 01 April 2020
Approver
ECM Service Director
Luca Nadarini

Expiry date 31 March 2025
Technical Expert
Antonio Payne

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CERTIFICATE

- USE OF STANDARD -

Certificate Number UCN	: 802793053159
Job	: J30608
Date of issue	: 2020-03-25
Certificate valid up to	: 2024-03-24
Brand Name	: see label
Type	: Disposable protective mask
Model N	: Ear hanging type

Standard Used : EN 149:2001+A1:2009

Conclusion:
After inspection of the technical documentation issued by the customer, and in his request, we express our opinion that this documentation meets the technical requirement of the above standards.

This opinion is only valid for the equipment and configuration described, in conjunction with the test data detailed above and with compliance with all applicable legal requirement for the product .
The following manufacturer documents was inspected:

Presence of test report using standards as indicated by the manufacturer	✔ OK

Check the authenticity of this certificate and related information before use in the web site www.celab.com introducing the UCN number in the 'Check document authenticity' area. You will see copy of this certificate and regulation on certificate use. This document is released only for scope allowed by laws.

Massimiliano Bertola
General Manager – CELAB
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Doc 125 Voluntary Certificate of Standard rev 2.1

TEFANESO Services provide:

- Product sourcing,
- Quality control according to internal requirements,
- Order tracking,
- Support and assistance with customs and export formalities,
- Active search for solutions.

Our offices in Shanghai and Guangdong are located near the customs offices of these economic hubs. We are therefore able to intervene actively in the progress of customs formalities and procedures and thus help to speed up the finalization, if necessary.

TEFANESO Switzerland SA (hereinafter «Tefaneso») reserves the right to procure the product from supplier(s) different from the company indicated on the certificates mentioned in the appendix if such company cannot deliver the product. Tefaneso shall guarantee that the products from the other supplier(s) will scrupulously correspond to the product in terms of specifications, standards, tests and certifications.

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