

No: 15012005/QĐ-ISOCERT
Re: Issuing certificates of compliance

Hanoi, on the 15th of January, 2020

DECISION

**Re: Issuing the certificate of quality management system - Medical devices
ISO 13485:2016**

DIRECTOR

OF ISOCERT INTERNATIONAL CERTIFICATION AND INSPECTION JSC.

Pursuant to Decree No. 127/2007/ND-CP of August 01, 2007, detailing the implementation of a number of Articles of the Law on Standards and Technical regulations;

Pursuant to Decree No. 132/2008/ND-CP of December 31, 2008, detailing the implementation of a number of Articles of the Law on Product and Goods Quality.

Pursuant to the Regulations on assessment of quality management system of ISOCERT International Certification and Inspection JSC;

Pursuant to Operation Registration Certificate No. 329/TĐC-HCHQ on 31/01/2019 of Directorate for Standards, Metrology and Quality;

Pursuant to Operation Registration Certificate No. 1162/TĐC-HCHQ on 26/04/2019 of Directorate for Standards, Metrology and Quality;

Pursuant to the Result Report of the Group of Assessors and the Results of Examining the certification files;

DECIDES THAT:

Article 1. Issue the certificate of Quality management system - Medical devices in conformity with ISO 13485:2016 standards on TNG Fashion Branch – TNG Investment and Trading Joint Stock Company, having address at No. 434/1, Floor 6, Bac Kan Street, Hoang Van Thu Ward, Thai Nguyen City, Thai Nguyen Province, Vietnam in the operation field of manufacturing, trading medical devices: Nano antimicrobial face masks, Surgical face masks, Medical protective clothing.

Article 2. This certificate is valid within 3 years from 15/01/2020 to 14/1/2023. During the validity period of this certificate, TNG Fashion Branch – TNG Investment and Trading Joint Stock Company is allowed to use Certificate No. 9199293400386-MED and the certificate seal of ISOCERT for the said operation field.

Article 3. TNG Fashion Branch – TNG Investment and Trading Joint Stock Company is responsible for maintaining and improving the Quality management system - Medical devices in conformity with ISO 13485:2016 standards and it will be periodically assessed by ISOCERT once a year, totaling twice in 3 years.

To:

- *As mentioned above*
 - *Kept on file*
- Fax: EMS: Email:*

**AUTH. DIRECTOR
General Dept. Manager**

Nguyen Thi Ngoc Yen

** This decision is valid for 1 (one) year from the signing date.*



ISOCERT INTERNATIONAL INSPECTION AND CERTIFICATION BODY
"HARMONIZATION AND PROSPERITY"

CERTIFICATE

No. 9199293400386-MED

THIS IS TO CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM FOR
MEDICAL DEVICES OF:

TNG FASHION BRANCH
- TNG INVESTMENT AND TRADING JOINT STOCK COMPANY

Address: No. 434/1, Floor 6, Bac Kan Street, Hoang Van Thu Ward, Thai Nguyen City, Thai Nguyen Province, Vietnam.

Has been assessed and found to conform with the requirements of the following standard:

STANDARD

ISO 13485:2016

SCOPE CERTIFIED:

**Manufacturing and trading Medical equipment: Antimicrobial
Nano facemask, Medical mask, Medical protective clothing.**

Certification	: 15.Jan.2020
Issue date	: 15.Jan.2020
Valid date	: 14.Jan.2023
Details in decision no.	: 15012005/QD-ISOCERT

Approved to bear certification mark



Retrieval Information Code:
9199293400386



ISO 13485:2016



MSc. Vu Van Thao

Check the validity of the certificate: <https://isocert.org.vn>

ISOCERT INTERNATIONAL CERTIFICATION AND INSPECTION JOINT STOCK COMPANY

No.40 A Row, Block 12, Dinh Cong New Urban Area, Dinh Cong Ward, Hoang Mai District, Hanoi City

Hotline: 1900.636.538, Hanoi office: 02473.036.538, HCM office: 02873.056.538, Email: contacts@isocert.org.vn, Website: <https://isocert.org.vn>

CERTIFICATE ISO 13485:2016

NUMBER :VNMT20004886

Intertek Vietnam Ltd.

Hochiminh office: 5th,6th,7th floor, Lobby D, S.O.H.O Biz Office Building, No. 38 Huynh Lan Khanh St., Ward 2, Tan Binh District, Ho Chi Minh City, Vietnam. Tel: (84-28) 62971099
Fax: (84-28) 62971098 Email: consumergoods.vietnam@intertek.com
Hanoi office:3rd floor, Au Viet Building, No.01 Le Duc Tho Street, Mai Dich Ward, Cau Giay District, Hanoi, Vietnam. Tel:(84-24)37337094 Fax:(84-24)37337093
Website:www.intertek.com

TEST REPORT

NUMBER : VNMT20004886

DATE : 18-Feb-2020

APPLICANT : FASHION LINK JOINT STOCK COMPANY.
176 HONG BANG, WARD 12, DISTRICT 5, HO CHI MINH CITY,
VIETNAM, HCM, VIET NAM

ATTN : THANH TUYEN

Sample Description As Declared : Nano Fabric
Color : White
No. of Sample : 1 pc
Order No./PO No. : -
Buyer Name : -
Style No. : -
Fiber Content : -
Article No. :
Date Received/Date Test Started : 14 Feb 2020
Date Confirmation Received : -

TEST CONDUCTED : AS PER THE REQUEST OF THE APPLICANT. FOR FURTHER DETAILS PLEASE REFER TO ENCLOSED PAGE(S)

AUTHORIZED BY
FOR INTERTEK VIETNAM LTD. [HO CHI MINH]



PHUONG LE
SOFTLINES GENERAL MANAGER

(THIS REPORT SHALL NOT BE REPRODUCED WHOLLY OR IN PARTS WITHOUT WRITTEN APPROVAL FROM THE LABORATORY)

Intertek Vietnam Ltd.

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TEST REPORT**NUMBER : VNMT20004886****DATE : 18-Feb-2020**

TEST CONDUCTED (AS REQUESTED BY THE APPLICANT)

1. Antibacterial ActivityAATCC 100 - 2012 Organism *Klebsiella pneumoniae* (ATCC 4352) And Organism *Staphylococcus aureus* (ATCC 6538)Test Organism : *Staphylococcus Aureus* (ATCC 6538)*Klebsiella Pneumoniae* (ATCC 4352)

Sterilization Of Sample Before Test : Autoclave At 121°C, 15 Minutes

Neutralizing Solution : 0.85% Sodium Chloride Solution

Contact Time : 24 Hours

Incubation Temperature : 37°C

Incubation Period : 48 Hours

Agar Medium : Nutrient Agar

Tested Specimen : Submitted Sample (8 Pieces Of Swatches With 4.8 cm In Diameter)

Result :

	<u><i>Staphylococcus Aureus</i> (ATCC 6538)</u>	<u><i>Klebsiella pneumoniae</i> (ATCC 4352)</u>
Initial Count (CFU/ml)	5.5x10 ⁵	4.8x10 ⁵
The number of bacterial recovered from the inoculated tested sample swatches immediately after inoculation ("0" contact time)(b)(CFU/Sample)	4.4x10 ⁵	5.5x10 ⁵
The number of bacterial recovered from the inoculated tested sample swatches incubated over 24 hours contact period (a)(CFU/Sample)	<1.0x10 ²	<1.0x10 ²
Percent reduction of Bacterial	>99.98%	>99.98%

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TEST REPORT

NUMBER : VNMT20004886

DATE : 18-Feb-2020

2. UV Protection

EN 13758-1:2001 As Received

Dry

The Mean Ultraviolet Protection Factor, UPF	24.80
The Mean UVA Transmittance, T (UVA) (%)	6.06
The Mean UVB Transmittance, T (UVB) (%)	3.47
Percent UVA Blocking (%)	93.94
Percent UVB Blocking (%)	96.53
UV Protection Category	Good Protection
UPF Rating For Label	20

Wet

The Mean Ultraviolet Protection Factor, UPF	49.11
The Mean UVA Transmittance, T (UVA) (%)	4.39
The Mean UVB Transmittance, T (UVB) (%)	1.35
Percent UVA Blocking (%)	95.61
Percent UVB Blocking (%)	98.65
UV Protection Category	Good Protection
UPF Rating For Label	20

END OF THE TEST REPORT

This report (including any enclosures and attachments) are prepared for the exclusive use of the Customer(s) named in the report and solely for the purpose for which it is provided and on the basis of instructions and information and/or materials supplied by Intertek's Customer. The test results relate only to the specific items tested and are not intended to be a recommendation for any particular course of action. Customer is responsible for acting as it sees fit on the basis of such results. Unless Intertek provide express prior written consent, no part of this report should be reproduced, distributed or communicated to any third party. Intertek do not accept any liability if this report is used for an alternative purpose from which it is intended, nor do Intertek owe any duty of care to any third party in respect of this report. Except where explicitly agreed in writing, all work and services performed is governed by Intertek Standard Terms and Conditions of Service which is available on request or can be obtained at <http://www.intertek.com/terms>.