

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

*Hanoi, on the 15<sup>th</sup> 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](mailto: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](mailto: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](http://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 : -

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

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**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 Activity**

AATCC 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 <sup>5</sup>	4.8x10 <sup>5</sup>
The number of bacterial recovered from the inoculated tested sample swatches immediately after inoculation ("0" contact time)(b)(CFU/Sample)	4.4x10 <sup>5</sup>	5.5x10 <sup>5</sup>
The number of bacterial recovered from the inoculated tested sample swatches incubated over 24 hours contact period (a)(CFU/Sample)	<1.0x10 <sup>2</sup>	<1.0x10 <sup>2</sup>
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

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**## END OF THE TEST REPORT ##**

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**Test Report**

Number: TWNT01792363

Applicant: FASHION LINK JOINT STOCK COMPANY  
176 Hong Bang, Ward 12,  
District 5, Ho Chi Minh City,  
Vietnam

Date Issued: Feb 13, 2020

**Sample Description :**

One (1) piece of submitted sample said to be 100% Polyester Nano , plain fabric , 160 grams/square meter weight, in Blue/White.

Applicant's Provided Care Instruction/Label : -

Date Received/Date Test Started : Feb 10, 2020  
Standard : -  
Style/Article No. : FL01116274  
Order No. : -  
Mill : -  
Buyer's Name : -  
Agent's Name : -  
Brand Name : -  
Ref. : -

Authorized By:  
On behalf of Intertek Testing Services  
Taiwan Limited

Carol Peng  
General Manager



**Test Report**

Number: TWNT01792363

Tests Conducted (As Requested By The Applicant)

- 1 Determination Of Anti-odor Property - Acetic Acid (ISO 17299-2, By Detector Tube Method):

	Result (µl/l)	
	Testing Gas With A Specimen	Testing Gas Without A Specimen
1	5	20
2	5	20
3	5	20
	Average (A) = 5	Average (B) = 20
ORR(%)	75	

Remark : ORR is the odour reduction rate, expressed as a percentage =  $(B-A) / B \times 100\%$   
 B is the average concentration of testing gas without a specimen, expressed in µl/l  
 A is the average concentration of testing gas with a specimen, expressed in µl/l

End of Report

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