

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