

CONG TY TNHH TM DV VA DL S&M

02-04 DUONG SO 9, KHU DO THI MOI HIM LAM, P.TAN HUNG, Q.7, TP. HO CHI MINH, VIET NAM

The following sample(s) was/were submitted and identified by the client as:

SGS Job No. : VNHL20060 [REDACTED]

Sample Description : "GANG TAY Y TE NHAN TAO KHONG BOT NITRILE"

Color : "TRANG"

Characteristic : "CAO SU NHAN TAO"

Style / Item No. : "GANG TAY Y TE NHAN TAO KHONG BOT NITRILE"

Date of Production : 03/2020

Manufacturer : CONG TY CP VRG KHAI HOAN

Buyer : [REDACTED]

Country of Origin : VIETNAM

Country of Destination : ITALIA

Sample Receiving Date : JUNE 04, 2020

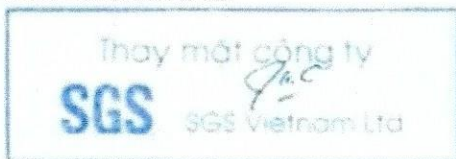
Final Confirmed Date : JUNE 04, 2020

Testing Period : JUNE 04, 2020 TO JULY 10, 2020

Test Requested : SELECTED TEST(S) AS REQUESTED BY APPLICANT

Test Results : PLEASE REFER TO NEXT PAGE(S)

Signed for and on behalf of

SGS Vietnam LTD**Ung Thanh Van**
Hardline Lab Manager

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Test result:
Sample Description:

No.	Component	Material	Color
1	"GANG TAY Y TE NHAN TAO KHONG BOT NITRILE"	"CAO SU NHAN TAO"	WHITE

BS EN 455-1:2000 Medical gloves for single use – Part 1: Requirements and testing for freedom from holes

Number of test sample	:	200 Pieces
Sample size	:	S
Number of non-conforming gloves	:	4 Pieces

Clause	Test Items	Result
5	Watertightness test for detection of holes	---
5.1	Referee testing	Pass (See note 1)

Note	:	1	Sample quantity: 200pcs, AQL:1.5, Ac:7, Re:8, Found:4. The sample selecting amount for this clause is deviated to 200 pcs as assessed by SGS.
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BS EN 455-2:2015 Medical gloves for single use – Part 2: Requirements and testing for physical properties

Number of test sample	:	26 Pieces
Type	:	Examination/procedure gloves: b)
Size	:	Examination/procedure gloves: S

Clause	Test Items	Result
4	Dimensions	---
4.2	Length	Pass (See result 1)
4.3	Width	Pass (See result 1)
5	Strength	---
5.2	Force at break	Pass (See result 2)
5.3	Force at break after challenge testing	Fail (See result 2)
7	Labelling	Fail (See note 1 & See BS EN 455-3 Clause 4.6)

Note	:	1	Date of manufacture: 04.2020
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Result 1: Dimensions

Size	S	
No.	Length (mm)	Width (mm)
1	248	84
2	244	83
3	244	85
4	246	85
5	247	83
6	243	84
7	242	83
8	242	83
9	240	82
10	243	83
11	247	83
12	245	84
13	250	85
Standard requirement	≥240	80±10
Median value	244	83

Result 2: Strength

Size: S			
Force at break (N)			
Before aging		After aging	
No.	/	No.	/
1	5.4	1	5.2
2	5.9	2	5.7
3	6.2	3	6.1
4	6.8	4	5.9
5	6.4	5	4.9
6	6.3	6	5.9
7	5.3	7	4.8
8	6.2	8	5.4
9	6.7	9	6.3
10	6.7	10	6.5
11	4.8	11	4.1
12	5.9	12	5.3
13	6.6	13	6.2
Standard requirement	≥6.0	Standard requirement	≥6.0
Median value	6.2	Median value	5.7

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BS EN 455-3:2015 Medical gloves for single use – Part 3: Requirements and testing for biological evaluation

Number of test sample	:	5 Pieces
Finishes of gloves	:	Powdered-free gloves other than surgeon's gloves
Size	:	S

Clause	Test Items	Result
4.4	Powder-free gloves	Pass (See note 1)
4.5	Proteins, leachable	See result 1
4.6	Labelling	Fail (See note 2)

Note	:	1	Test according to EN ISO 21171:2006, the average mass of powder per glove is 0.88mg. (Requirement: ≤2mg per powder-free glove)
		2	-The "Keep away from sunlight" "Batch code" and "Use-by date" symbols don't satisfy the requirements of the standard. -The dates format don't satisfy the requirements of the standard.

Result 1: Proteins, leachable

Test Item	Test Result
Determination of aqueous extractable protein (µg/g)	372

- Remark** :
- 1 µg/g = microgram per gram.
 - 2 Detection limit of aqueous extractable protein is 10 µg/g

Remark

- 1. The declaration of conformity is only based on the actual value of laboratory activity, measurement uncertainty of the results not take into account.
- 2. Labelling assessment was based on the information provided by the customer, excluding the verification of the authenticity of the content. SGS is not responsible for verifying the accuracy of the information provided by customers.

Remark: This / these test(s) was / were performed by SGS China Lab.

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