

# DISPOSABLE MEDICAL NITRILE GLOVES

INTCO MEDICAL, PROTECT YOUR HEALTH.



## Features

- 100% free from sulfur-based accelerators
- No latex protein to cause allergy
- Excellent softness and wearing fitness
- Undifferentiated shelf life as normal gloves
- Well suitable for high cleanliness industry like electronic, food service, etc.



## Quality standards

- Complies with EN 455 and EN 374
- Complies with ASTM D6319 (USA Related Product)
- Complies with ASTM F1671
- FDA 510(K) Available
- Approved to use with Chemotherapy Drugs

Type	Material	Color	Model	Storage	Size/overall length as per EN455-2	Impermeability as per EN455-1	Durability in original packaging if stored as per din 7716,ISO 2230
Powder-free non-sterile	Nitrile butadiene rubber (NBR)	Blue, White, Violet blue, Black	Ambidextrous with beaded cuff	Protect from heat, humidity, strong light and ozone	S M L XL 240 mm (> 230mm for USA)	AQL1.5 AQL2.5 AQL4.0	Min. 5years



400-050-6868  
[www.intcomedical.com](http://www.intcomedical.com)



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Document Number : INTCO-CE-DC-NBR-001

Version: A/1

## EU DECLARATION OF CONFORMITY

Manufacturer

Authorized Representative

*Name:* Shandong Intco Medical Products Co., Ltd.

*Name:* Lotus NL B.V.

*Address:* Qiwang Road, Naoshan Industrial Park. Qingzhou, Shandong, China

*Address:* Koningin Julianaplein 10, le Verd, 2595AA, The Netherlands

Declares that the MDR described hereafter

*Product name and model:*

**Disposable Nitrile (NBR) Gloves**

**UMDNS code: 11882**

UDI-DI: (XS, S, M, L, XL, XXL)

**Blue Gloves:** 6970245756014 / 6970245756021 / 6970245756038 / 6970245756045 / 6970245756052 / 6970245756069

**White Gloves:** 6970245756410 / 6970245756427 / 6970245756434 / 6970245756441 / 6970245756458 / 6970245756465

**Black Gloves:** 6970245756519 / 6970245756526 / 6970245756533 / 6970245756540 / 6970245756557 / 6970245756564

**Violet Gloves:** 6970245756311 / 6970245756328 / 6970245756335 / 6970245756342 / 6970245756359 / 6970245756366

Meet the provisions of the Council Regulation EU 2017/745 which apply to them.

The medical device has been assigned to class I according to Annex VIII of the Regulation EU 2017/745. It bears the mark



CONFORMITY ASSESSMENT ROUTE: EU 2017/745, Annex I & VII

This Declaration of conformity is valid in connection with the release document for the respective batch of produced devices.

The above mentioned declaration of conformity is exclusively under the responsibility of

**Company:** Shandong Intco Medical Products Co., Ltd.

**Address:** Qiwang Road, Naoshan Industrial Park. Qingzhou, Shandong, China

Shandong 2019-05-06

Chi Yongtao Plant manager

Place, date

Legally binding signature, Function

# Gebrauchsanweisung

Medizinischer Einweghandschuh aus Nitril für medizinische Untersuchungen

**【Produktname】** Medizinischer Einweghandschuh aus Nitril für medizinische Untersuchungen

## 【Spezifikationen】

Modell		XS	S	M	L	XL	XXL
Spezifikationen							
Länge (mm)		≥240	≥240	≥240	≥240	≥240	≥240
Breite (mm)		70±10	80±10	95±10	110±10	120±10	130±10
Stärke (mm)	Finger	≥0.08					
	Handfläche	≥0.07					
Zugfestigkeit (N)		≥6					

Standard: EN455

Klassifikation: Entspricht EN 455 medizinische Einweg-Untersuchungshandschuhe

## 【Die strukturellen Hauptkomponenten】

Einweg-Nitril-Untersuchungshandschuh wird in einem speziellen Verfahren aus Acrylnitril und Butadien hergestellt. Er ist latexfrei, wodurch eine Hautallergie vermieden werden könnte. Er zeichnet sich durch gute Elastizität, Flexibilität, hervorragende Barriereigenschaften und starke physikalische Eigenschaften aus, die bei der Durchführung von medizinischen Untersuchungen einen guten Schutz bieten können.

## 【Produktleistung】

1. Das Aussehen der Handschuhe ist frei von Beschädigungen, Ölflecken und sichtbaren Löchern.
2. Bei diesem Produkt wird nicht zwischen linker und rechter Hand unterschieden, bitte wählen Sie Handschuhe, die Ihren Handspezifikationen entsprechen.
3. Die Lochblende des Handschuhs entspricht AQL1,5, und die physikalische Eigenschaft ist ≥6N.

## 【Indikation zur Verwendung】

Dieses Produkt unterscheidet nicht zwischen linker und rechter Hand, bitte wählen Sie Handschuhe, die Ihren Handspezifikationen entsprechen;

Wenn Sie Handschuhe tragen, tragen Sie keine Ringe oder andere Accessoires, achten Sie auf die Nägel;

Dieses Produkt ist auf den einmaligen Gebrauch beschränkt; bitte behandeln Sie das gebrauchte Produkt als medizinischen Abfall, um eine Verschmutzung der Umwelt durch Keime zu vermeiden; Direkter Kontakt mit starkem Licht wie Sonnenlicht oder ultravioletten Strahlen kann die Eigenschaften des Produkts verändern

**【Kontraindikationen】**

Keine

**【Warnung】**

1. Das Produkt wird zum Schutz der Hände verwendet, nicht für andere Körperteile.
2. Diese Informationen spiegeln nicht die tatsächliche Dauer des Schutzes am Arbeitsplatz und die Unterscheidung zwischen Mischungen und reinen Chemikalien wider.
3. Die Chemikalienbeständigkeit wurde unter Laborbedingungen anhand von Proben beurteilt, die nur von der Handfläche entnommen wurden (außer in Fällen, in denen der Handschuh gleich oder größer als 400 mm ist - hier wird auch die Stulpe getestet) und bezieht sich nur auf die getestete Chemikalie. Sie kann unterschiedlich sein, wenn die Chemikalie in einer Mischung verwendet wird.
4. Es wird empfohlen, zu überprüfen, ob die Handschuhe für die vorgesehene Verwendung geeignet sind, da die Bedingungen am Arbeitsplatz je nach Temperatur, Abrieb und Abbau von der Typprüfung abweichen können.
5. Bei der Verwendung von Schutzhandschuhen kann die Beständigkeit gegen die gefährliche Chemikalie aufgrund von Änderungen der physikalischen Eigenschaften geringer sein. Bewegungen, Reiben, Abbau durch den Chemikalienkontakt usw. können die tatsächliche Gebrauchsdauer erheblich verkürzen. Bei ätzenden Chemikalien kann die Zersetzung der wichtigste Faktor sein, der bei der Auswahl chemikalienbeständiger Handschuhe zu berücksichtigen ist.
6. Vor dem Gebrauch die Handschuhe auf Mängel oder Unvollkommenheiten untersuchen.
7. Nur für den einmaligen Gebrauch.

**【Verpackung】**

100 Stk./Box

**【Herstellungsdatum】**

Siehe Verpackung












**【Haltbarkeit】**

5 Jahre

**【Lagerbedingungen】**

Das Produkt sollte in einem kühlen und trockenen Lagerhaus (Innentemperatur unter 30 Grad, relative Luftfeuchtigkeit unter 80% ist angemessen) auf Regalen 200 mm über dem Boden gelagert werden.

### 【Erklärung der Symbole】

	Nicht wiederverwenden		Von Sonnenlicht fernhalten
	Nicht steril		Trocken halten
	CE-gekennzeichnetes Gerät		Entspricht der Richtlinie 93/42/EEN für medizinische Geräte
	EU-Bevollmächtigter		Chargencode
	Herstellungsdatum		Verfallsdatum
	Hersteller		

### 【Behandlung nach Gebrauch】

Bitte behandeln Sie das gebrauchte Produkt als medizinischen Abfall, um eine Verschmutzung der Umwelt durch Keime zu vermeiden.

### 【Hersteller/Kundenservice】

Hebei Titans Hongsen Medical Technology Co., Ltd.

### 【Anschrift des Herstellers】

Industriezone Ost, Nangong, Xingtai, Hebei Provinz, China

### 【Kontakt Hersteller/Kundenservice】

Hebei Titans Hongsen Medical Technology Co., Ltd.  
Industriezone Ost, Nangong, Xingtai, Hebei Provinz, China

**EU-Bevollmächtigter**

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Ansprechpartner	Ms. Qian
Dimdi Code	DE/0000048589
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**【Version】** 2020.09

## Test Report

No.: QDHL1809020116SD\_EN

Date: SEP.27,2018

Page: 1 of 6

HEBEI TITANS HONGSEN MEDICAL TECHNOLOGY CO.,LTD  
EASTERN INDUSTRIAL ZONE, NANGONG CITY, XINGTAI CITY, HEBEI, CHINA 051800

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

Sample Description : POWDER FREE BLUE NITRILE EXAMINATION GLOVES  
SGS Ref. No. : TJHL1808004426SD\_EN  
Manufacture : HEBEI TITANS HONGSEN MEDICAL TECHNOLOGY CO.,LTD  
Country of Origin : CHINA  
Country of Destination : EU  
Sample Receiving Date : SEP.07.2018  
Testing Period : SEP.07,2018 TO SEP.27,2018

Test Requested	Result
EN 455-1:2000 medical gloves for single use – part 1: requirements and testing for freedom from holes	Pass
EN 455-2-2015 medical gloves for single use – part 2: requirements and testing for physical properties	Pass
EN 455-3-2015 medical gloves for single use – part 3: requirements and testing for biological evaluation	Pass

Remark: - The test report shall only be used for clients' scientific research, teaching, internal quality control, product research and development, etc... and just for internal reference.

SGS-CSTC Standards Technical Services (Qingdao) Co., Ltd.  
Approved by:



Zhou Xinkuan, SK  
Lab Manager

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**Test Conducted:**

**1. EN 455-1:2000 Medical gloves for single use – part 1: Requirements and testing for freedom from holes**

Number of test sample	:	200 Pieces (L: 100 Pieces S: 100 Pieces)
The type of gloves	:	examination/procedure gloves
Manufacturing batch code	:	/
Batch size	:	/
Sample size	:	/
Number of non-conforming gloves	:	0
Defects observed before testing	:	No defects

Clause	Test Items	Result	Note
5	Watertightness test for detection of holes	---	---
5.1	Referee testing	Pass	# 1

**2. EN 455-2-2015 Medical gloves for single use – part 2: Requirements and testing for physical properties**

Number of test sample	:	78 Pieces
Type	:	examination/procedure gloves b)
Manufacturing batch code	:	/
Size	:	Surgical gloves:/ Examination/procedure gloves: S, M, L, XL
Defects observed before testing	:	No defects

Clause	Test Items	Result	Note
4	Dimensions	Pass	# 2
5	Strength	Pass	# 3

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### 3. 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
Defects observed before testing	:	No defects

Clause	Test Items	Result	Note
4.4	Powder-free gloves	Pass	# 4
4.6	Labeling	---	Not provided

Notes : #1 See result 1  
 #2 See result 2  
 #3 See result 3  
 #4 The average mass of powder per glove was 0.02mg.

#### Test Result:

#### 1. Watertightness test for detection of holes

Sample Quantity: 200 pcs

AQL: 1.5 Accept: 7 Reject: 8 Found: 0

#### 2. Dimensions

Sample Quantity: 13pcs

Size	S												
Length(mm)	295	295	296	296	292	290	297	292	290	291	295	294	293
Width(mm)	86	87	85	86	86	87	87	86	85	86	87	87	87

Median value:

Length (mm): 295  
 Width (mm): 86

Sample Quantity: 13pcs

Size	M												
Length(mm)	290	293	295	295	296	296	295	296	294	293	295	295	296
Width(mm)	96	96	97	97	97	96	96	98	95	96	97	95	96

Median value:

Length (mm): 295  
 Width (mm): 96

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Sample Quantity: 13pcs

Size	L												
Length(mm)	286	290	289	290	288	287	290	291	290	290	290	290	290
Width(mm)	109	108	108	110	109	110	108	109	109	108	108	109	108

Median value:

Length (mm): 290

Width (mm):109

Sample Quantity: 13pcs

Size	XL												
Length(mm)	300	295	300	296	295	298	297	300	300	300	304	300	301
Width(mm)	117	118	118	117	119	118	118	118	119	111	119	115	115

Median value:

Length (mm): 300

Width (mm):118

Requirements: see table 1&2

**Table 1 Dimensions for surgical gloves**

Size	Median length in mm	Median width in mm
5	≥250	67±4
5.5	≥250	72±4
6	≥260	77±5
6.5	≥260	83±5
7	≥270	89±5
7.5	≥270	95±5
8	≥270	102±6
8.5	≥280	108±6
9	≥280	114±6
9.5	≥280	121±6

**Table 2 Dimensions for examination/procedure gloves**

Size	Median length in mm	Median width in mm
Extra small	≥240	≤80
Small		80±10
Medium		95±10
Large		110±10
Extra Large		≥110

### 3. Strength

Sample Quantity: 26pcs

Size	M												
Force at break(N)	6.7	6.6	6.4	5.6	5.5	7.0	5.8	6.7	6.5	7.2	6.5	6.7	6.7
Force at break after challenge testing(N)	7.4	6.6	6.2	7.4	6.2	6.2	5.2	7.2	6.0	6.0	6.5	6.3	6.6

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Median value:

Force at break during shelf life (N): 6.6N

Force at break after challenge testing (N): 6.3N

Requirements: see table 3

**Table 3 — Median values of force at break**

	Force at break in Newton		
	Surgical gloves	Examination/procedure gloves	
	a)	b)	c)
Throughout shelf life tested according to 5.2 and within 12 months of manufacture tested according to 5.3	≥ 9.0	≥ 6.0	≥ 3,6
a) Requirements for all surgical gloves. b) Requirements for all examination gloves, except gloves made from thermoplastic materials (e.g. polyvinylchloride, polyethylene).. c) Requirements for gloves made from thermoplastic materials (e.g. polyvinylchloride, polyethylene).			

Sample Photo:



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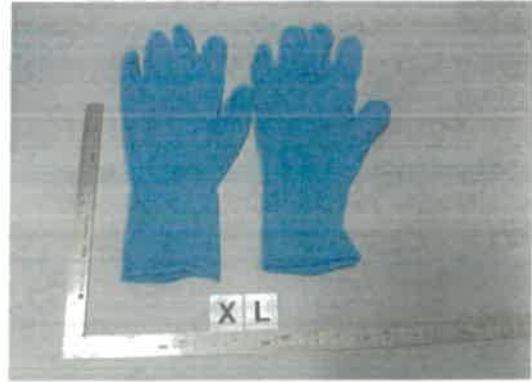
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