

## **Gdem** Nitrile gloves

**Product: Disposable nitrile gloves** 

EN 455: Medical gloves against hazardous chemicals and microorganisms

EN ISO 374: Gloves provide effective protection against the viruses

Specification: 24 cm x 9,5 cm Shelf life: 5 years Color: Blue Size: S, M, L, XL

Packaging box: Quantity: 100 pcs/box Size: 23 x 12,5 x 6 cm

Packaging carton: Quantity: 10 box/carton Size: 31.5 x 25.8 x 24.5 cm

BETTER AG General-Guisan-Str.8 6300 Zug, Switzerland

100

M

www.OdemShop.com info@OdemShop.com

€€2777

IRL: +353 1 513 75 11 CH: +41 71 58 80 248

# **SYNGUARD**<sup>®</sup> NITRILE EXAM GLOVES FEATURES

- Excellent softness and wearing fitness
- Finger textured for a reliable, consistent grip
- Beaded cuff ensures easy donning and prevents roll down
- Compliant with food handling requirements
- Latex-free, powder-free and odor-free



#### **PRODUCT INFORMATION**

SKU     White     SNBE10023     SNBE10024     SNBE10025     SNBE10026     SNBE10027       Violet     SNBE10033     SNBE10034     SNBE10035     SNBE10036     SNBE10037										
Glove Length   ≥240mm   Freedom from Holes (Inspection level II)   AQL 1.5     Powder Content   Powder-Free   Sterile   No     Finger Thickness(mm)   ≥0.05   Palm Thickness (mm)   ≥0.05     Force at break   ≥6N befor= and after aging   Tensile strength   ≥0.05     Protection against Bacteria and Fungi   Pass   Protection against 40% Sodium Hydroxide (K) 30% Hydrogen peroxide (P) 37% Formaldehyde (T)   >30min   >30min     Dimensions(±10m)   XS/70;S/80;M/95; L/110;XL/120   Surface   Micro-texture on fingers     ORDERING INFORMATION   XS/70;S/80;M/95; L/110;XL/120   Surface   Micro-texture on fingers     SkU   XS/70;S/80;M/95; L/110;XL/120   Surface   Micro-texture on fingers     ORDERING INFORMATION   XS/70;S/80;M/95; L/110;XL/120   Surface   Micro-texture on fingers     SkU   Size   XS   M   L   XL     SkU   SNBE10013   SNBE10014   SNBE10015   SNBE10026   SNBE10027     SkU   Size   XS   M   L   XL     SkU   SNBE10033   SNBE10034   SNBE10035   SNBE10037   SNBE10037     SkU <td< td=""><td>Material</td><td></td><td>Nitrile</td><td></td><td>Not Made From</td><td>n Natural Rubber La</td><td>tex</td><td colspan="3">Yes</td></td<>	Material		Nitrile		Not Made From	n Natural Rubber La	tex	Yes		
Powder Content     Powder-Free     Sterile     No       Finger Thickness(mm)     ≥0.05     Palm Thickness (mm)     ≥0.05       Force at break     ≥6N before and after aging     Tensile strength     ≥14MPA before and after aging       Protection against Bacteria and Fungi     Pass     Protection against 40% Sodium Hydroxide (K) 30% Hydrogene perxide (P) 37% Formaldehyde (T)     >30min       Protection against Viruses     Pass     30% Hydrogene perxide (P) 37% Formaldehyde (T)     >30min       Dimensions(±10mm)     XS/70;S/80:M/95; L/110;XL/120     Surface     Micro-textured on fingers       ORDERING INFORMATION     XS/70;S/80:M/95; L/110;XL/120     Surface     Micro-textured on fingers       SkU     Blue     SNBE10013     SNBE10014     SNBE10015     SNBE10016     SNBE10017       SkU     White     SNBE10023     SNBE10024     SNBE10025     SNBE10026     SNBE10027       SkU     White     SNBE10033     SNBE10034     SNBE10035     SNBE10036     SNBE10037       Black     SNBE10033     SNBE10034     SNBE10035     SNBE10046     SNBE10047       PACKAGING AND STORAGE     200pcs/box,10boxes/ctn	Available Sizes		XS,S,M,L,2	XL	Color	Color			Blue, White, Violet, Black	
Finger Thickness(mm)   ≥0.05   Palm Thickness (mm)   ≥0.05     Force at break   ≥6N before and after aging   Tensile strength   ≥14MPA before and after aging     Protection against Bacteria and Fungi   Pass   Protection against 40% Sodium Hydroxide (K) 30% Hydrogen peroxide (P) 37% Formaldehyde (T)   >30min     Protection against Viruses   Pass   Surface   Micro-textured on fingers     ORDERING INFORMATION   XS/70;S/80;M/95; L/110;XL/120   Surface   Micro-textured on fingers     SKU   Blue   SNBE10013   SNBE10014   SNBE10015   SNBE10016   SNBE10017     SKU   Blue   SNBE10023   SNBE10024   SNBE10025   SNBE10026   SNBE10027     SKU   Violet   SNBE10033   SNBE10034   SNBE10035   SNBE10036   SNBE10037     Black   SNBE10033   SNBE10034   SNBE10035   SNBE10046   SNBE10047     PACKAGING AND STRAGE   230*125*60mm   200pcs/box,10boxes/ctn   200pcs/box,10boxes/ctn   SNBE10037     Blox size   230*125*60mm   215*26*245mm   245*130*80mm   415*270*258mm   415*270*258mm     Shelf Life   5 Years (recommended)    415*270*258mm	Glove Length		≥240mm		Freedom from	Freedom from Holes (Inspection level I)				
Force at break   ≥6N before and after aging   Tensile strength   ≥14MPA before and after aging     Protection against Bacteria and Fungi   Pass   Protection against 40% Sodium Hydroxide (K) 30% Hydrogen peroxide (P) 37% Formaldehyde (T)   >30min     Protection against Viruses   Pass   Strace   Micro-textured on fingers     ORDERING INFORMATION   XS/70;S/80;M/95; L/110;XL/120   Surface   Micro-textured on fingers     ORDERING INFORMATION   XS/70;S/80;M/95; L/110;XL/120   Surface   Micro-textured on fingers     ORDERING INFORMATION   XS/70;S/80;M/95; L/110;XL/120   Surface   Micro-textured on fingers     SKU   Size   XS   S   M   L   XL     SKU   Blue   SNBE10013   SNBE10014   SNBE10015   SNBE10016   SNBE10027     SKU   Violet   SNBE10033   SNBE10034   SNBE10035   SNBE10036   SNBE10037     Back   SNBE10033   SNBE10034   SNBE10035   SNBE10046   SNBE10047     PACKAGING AND STORE   230*125*0mm   240°sts0x,10boxes/ctn   240°sts0x,10boxes/ctn   SNBE10046   SNBE10047     Box size   230*125*0mm   215°sts28*245mm   415*270*258mm   <	Powder Content		Powder-Fr	ee	Sterile			No		
Protection against Bacteria and Fungi   Pass   Protection against 40% Sodium Hydroxide (K) 30% Hydrogen peroxide (P) 37% Formaldehyde (T)   >30min     Protection against Viruses   Pass   Pass   Micro-textured on fingers     Dimensions(±10mm)   XS/70;S/80;M/95; L/110;XL/120   Surface   Micro-textured on fingers     ORDERING INFORMATION   XS/70;S/80;M/95; L/110;XL/120   Surface   Micro-textured on fingers     SkU   Blue   SNBE10013   SNBE10014   SNBE10015   SNBE10016   SNBE10017     SkU   Black   SNBE10023   SNBE10024   SNBE10025   SNBE10026   SNBE10027     PACKAGING AND STORAGE   Packaging   100pcs/box,10boxes/ctn   200pcs/box,10boxes/ctn   200pcs/box,10boxes/ctn     Box size   230*125*60mm   245*130*80mm   415*270*258mm   415*270*258mm     Shelf Life   5 Years (recommended)   Keep out of direct sunlight; store in a cool and dry place. Keep away from sources of ozone or ignition.	Finger Thickness	(mm)	≥0.05		Palm Thicknes	s (mm)		≥0.05		
Bacteria and Fungi Pass 40% Sodium Hydroxide (K) 30% Hydrogen peroxide (P) 37% Formaldehyde (T) >30min   Protection against Viruse Pass 30% Hydrogen peroxide (P) 37% Formaldehyde (T) >30min   Dimensions(±10mm) XS/70;S/80;M/95; L/110;XL/120 Surface Micro-textured on fingers   ORDERING INFORMATION SNBE10013 SNBE10014 SNBE10015 SNBE10016   SKU Blue SNBE10013 SNBE10014 SNBE10015 SNBE10016   KU Violet SNBE10023 SNBE10024 SNBE10025 SNBE10026 SNBE10027   KU Violet SNBE10033 SNBE10034 SNBE10035 SNBE10036 SNBE10037   Black SNBE10043 SNBE10044 SNBE10035 SNBE10036 SNBE10047   PACKAGING AND STORAGE 200pcs/box,10boxes/ctn 200pcs/box,10boxes/ctn SNBE10047   Back 230*125*60mm 245*130*80mm SNBE10046 SNBE10047   Back 230*125*60mm 245*130*80mm SNBE10046 SNBE10047   Shelf Life 5 Years (recommended) 415*270*258mm 415*270*258mm   Shelf Life 5 Years (recommended) Stresp eraward or ingition.	Force at break		≥6N before	e and after aging	Tensile strengt	h		≥14MPA be	ofore and after agin	
Protection against Viruses   Pass   37% Formaldehyte (T)   Micro-textured on fingers     Dimensions(±10mm)   XS/70;S/80;M/95; L/110;XL/120   Surface   Micro-textured on fingers     ORDERING INFORMATION   XS   S   M   L   XL     Size   XS   S   M   L   XL     White   SNBE10013   SNBE10014   SNBE10015   SNBE10026   SNBE10027     KU   White   SNBE10023   SNBE10024   SNBE10025   SNBE10026   SNBE10027     KU   SNBE10033   SNBE10034   SNBE10035   SNBE10036   SNBE10037     Black   SNBE10043   SNBE10044   SNBE10035   SNBE10036   SNBE10037     PACKAGING AND STRAGE   SNBE10043   SNBE10044   SNBE10045   SNBE10046   SNBE10047     Packaging   100pcs/box,10boxes/ctn   200pcs/box,10boxes/ctn   200pcs/box,10boxes/ctn   200pcs/box,10boxes/ctn   245*130*80mm     Carton Dimension   315*258*245mm   415*270*258mm   415*270*258mm   5   Strage Instruction Str			Pass		40% Sodium H	ydroxide (K)		>30min		
ORDERING INFORMATION     Size   XS   S   M   L   XL     Blue   SNBE10013   SNBE10014   SNBE10015   SNBE10016   SNBE10017     SKU   White   SNBE10023   SNBE10024   SNBE10025   SNBE10026   SNBE10027     Violet   SNBE10033   SNBE10034   SNBE10035   SNBE10036   SNBE10037     Black   SNBE10043   SNBE10044   SNBE10045   SNBE10046   SNBE10047     PACKAGING ALD STRAGE     Packaging   100pcs/box,10boxes/ctn   200pcs/box,10boxes/ctn   200pcs/box,10boxes/ctn     Box size   230*125*60mm   245*130*80mm   415*270*258mm     Shelf Life   5 Years (recommended)     Storage Instruction   Keep out of direct sunlight; store in a cool and dry block. Keep away for using to registion.	Protection against	Viruses	Pass			· · · · · ·				
SizeXSSMLXLBlueSNBE10013SNBE10014SNBE10015SNBE10016SNBE10017SKUWhiteSNBE10023SNBE10024SNBE10025SNBE10026SNBE10027VioletSNBE10033SNBE10034SNBE10035SNBE10036SNBE10037BlackSNBE10043SNBE10044SNBE10045SNBE10046SNBE10047PACKAGING AU STRAGEPackaging100pcs/strAtoSNBE10043SNBE10044SNBE10045SNBE10046SNBE10047Box size230*125*Cmm245*130*80m245*130*80mStatoSNBE1004SNBE1015StatoStatoStatoShelf Life5 Years (recommended)Stato (stato stato sta	Dimensions(±10m	ım)	XS/70;S/8	0;M/95; L/110;XL/120	Surface	Surface			Micro-textured on fingers	
Blue     SNBE10013     SNBE10014     SNBE10015     SNBE10016     SNBE10017       KU     White     SNBE10023     SNBE10024     SNBE10025     SNBE10026     SNBE10027       KU     Violet     SNBE10033     SNBE10034     SNBE10025     SNBE10026     SNBE10037       Violet     SNBE10033     SNBE10034     SNBE10035     SNBE10036     SNBE10037       Black     SNBE10043     SNBE10044     SNBE10045     SNBE10046     SNBE10047       PACKAGING AND STRAGE     I00pcs/box,10boxes/ctn     SNBE10044     SNBE10045     SNBE10046     SNBE10047       Box size     230*125*60mm     245*130*80mm     245*130*80mm     SNBE10047       Carton Dimension     315*258*245mm     415*270*258mm     415*270*258mm     SNBE1014       Shelf Life     5 Years (recommended)     Storage Instructions     Keep out of direct sunlight; store in a cool and dry block. Keep away from sources of ozone or ignition.										
KU White SNBE10023 SNBE10024 SNBE10025 SNBE10026 SNBE10027   Violet SNBE10033 SNBE10034 SNBE10035 SNBE10036 SNBE10037   Black SNBE10043 SNBE10044 SNBE10045 SNBE10046 SNBE10047   PACKAGING AND STORAGE   Packaging 100pcs/box,10boxes/ctn 200pcs/box,10boxes/ctn 200pcs/box,10boxes/ctn   Box size 230*125*60mm 245*130*80mm   Carton Dimension 315*258*245mm 415*270*258mm   Shelf Life 5 Years (recommended)   Storage Instructions Keep out of direct sunlight; store in a cool and dry place. Keep away from sources of ozone or ignition.	Si	ize		XS	S	м		L	XL	
SKU Violet SNBE10033 SNBE10034 SNBE10035 SNBE10036 SNBE10037   Black SNBE10043 SNBE10044 SNBE10045 SNBE10046 SNBE10047   PACKAGING AND STORAGE   Packaging 100pcs/box,10boxes/ctn 200pcs/box,10boxes/ctn SNBE10047   Box size 230*125*60mm 245*130*80mm SNBE10047   Carton Dimension 315*258*245mm 415*270*258mm SNBE10047   Shelf Life 5 Years (recommended) Storage Instructions Keep out of direct sunlight; store in a cool and dry place. Keep away from sources of ozone or ignition.			Blue	SNBE10013	SNBE10014	SNBE10015	SNBE10016		SNBE10017	
VioletSNBE10033SNBE10034SNBE10035SNBE10036SNBE10037BlackSNBE10043SNBE10044SNBE10045SNBE10046SNBE10047PACKAGING AND STORAGEPackaging100pcs/box,10boxes/ctn200pcs/box,10boxes/ctnBox size230*125*60mm245*130*80mmCarton Dimension315*258*245mm415*270*258mmShelf Life5 Years (recommended)Keep out of direct sunlight; store in a cool and dry place. Keep away from sources of ozone or ignition.	<u>ekni</u>		White	SNBE10023	SNBE10024	SNBE10025	SNBE10026		SNBE10027	
PACKAGING AND STORAGEPackaging100pcs/box,10boxes/ctn200pcs/box,10boxes/ctnBox size230*125*60mm245*130*80mmCarton Dimension315*258*245mm415*270*258mmShelf Life5 Years (recommended)Storage InstructionsKeep out of direct sunlight; store in a cool and dry place. Keep away from sources of ozone or ignition.	SKU	,	Violet	SNBE10033	SNBE10034	SNBE10035	SNBE10036		SNBE10037	
Packaging100pcs/box,10boxes/ctn200pcs/box,10boxes/ctnBox size230*125*60mm245*130*80mmCarton Dimension315*258*245mm415*270*258mmShelf Life5 Years (recommended)Storage InstructionsKeep out of direct sunlight; store in a cool and dry back. Keep away from sources of ozone or ignition.			Black	SNBE10043	SNBE10044	SNBE10045	SN	BE10046	SNBE10047	
Box size   230*125*60mm   245*130*80mm     Carton Dimension   315*258*245mm   415*270*258mm     Shelf Life   5 Years (recommended)   Storage Instructions   Keep out of direct sunlight; store in a cool and dry place. Keep away from sources of ozone or ignition.	PACKAGING A	ND ST	ORAGE							
Carton Dimension315*258*245mm415*270*258mmShelf Life5 Years (recommended)Storage InstructionsKeep out of direct sunlight; store in a cool and dry place. Keep away from sources of ozone or ignition.	Packaging		100pcs/bo	x,10boxes/ctn		200pcs/box,10	boxes/	ctn		
Shelf Life   5 Years (recommended)     Storage Instructions   Keep out of direct sunlight; store in a cool and dry place. Keep away from sources of ozone or ignition.	Box size		230*125*6	0mm		245*130*80mm				
Storage Instructions     Keep out of direct sunlight; store in a cool and dry place. Keep away from sources of ozone or ignition.	Carton Dimension 315*258*245mm				415*270*258m	m				
	Shelf Life 5 Years (recommended)									
STANDARDS AND CERTIFICATIONS	Storage Instructions Keep out of direct sunlight; store in a cool and dry place. Keep away from sources of ozone or ignition.									
	STANDARDS AND CERTIFICATIONS									

Compliant with EN455-1:2020, EN455-2:2015, EN455-3:2015, EN455-4:2009 Compliant with EN ISO 374-1:2016+A1:2018, EN ISO 374-5:2016, EN ISO 21420



#### Anhui Intco Medical Products Co., Ltd

Address: Haitang road west and yinhua road north) Suixi Wuhu

Modern Industrial Park, Suixi Town, Huaibei City, Anhui

Province, P. R. China.

Tel:++86 21 34978818 Fax:+86 21 34978808

Web:www.intcomedical.com

						Exam	ination Disp	osable Glove	es Product Sp	ecificatio	n				
Туре						Dispo	sable Nitrile	Gloves, Pow	der free, Nor	n Sterile,A	hmbidext	rous			
Grade	E:	kamina	ation	Sur	Surface Finger textur				Glove Length(mm)			≥240			
Material		NBF	R	Packing 100pcs/box,10bo			s/box,10box	es/ctn	Weight(g)				3.5±0.3	(Medium Size)	
Cuff	ff Beaded							Powder	Level			<u>≤</u> 2r	ng/glove		
				cal Dime	nsion			Ph	ysical Prope	rty	-				
Product	Color	Size	Weight	Length	Palm Width	Cuff Thickness(	Finger Thickness(	Palm Thickness(	Force at	break	Elong	Elongation Water		Appearance AQL	
				(mm)	(mm)	mm)			Before	After	Before	After	AQL	Appearance AQL	
					(mm)	mm)	mm)	mm)	Aging	Aging	Aging	Aging			
	Blue/Wh	S	3.0g+-0.3		85±5				6.0	6.0	500	400	AQL1.5	Critical AQL1.5 Major AQL2.5 Minor 4.0	
Nitrile	ite/Purpl	М	3.5g+-0.3	≥240	95±5	0.07+0.03	0.07±0.03 0.10±0.03 0	0.08±0.03	6.0	6.0	500	400	AQL1.5	Critical AQL1.5 Major AQL2.5 Minor 4.0	
gloves	e	L	4.0g+-0.3	/ 240	110±5	0.07±0.05	0.1010.05	0.0010.05	6.0	6.0	500	400	AQL1.5	Critical AQL1.5 Major AQL2.5 Minor 4.0	
		XL	4.5g+-0.3		120±5				6.0	6.0	500	400	AQL1.5	Critical AQL1.5 Major AQL2.5 Minor 4.0	
No.		sor			Crit	ical defects		Major defects			Minor defects				
_			g tearing					-			-				
1	torn		cratch	≥3mm			≥2mm >3mm			-					
			easy dirt			≥3mm nm,serious					 <2mm,slightly				
2	dirt		llow dirt		201	√			-			-			
3	black		npurities		un	countable		≥3mm or 0.5-3mm,>3/side					0	.5-3mm,≤3/side	
4		beadi	ng	k	proken;to	rn;none-bea	ding	•	ty;knot;black vard>10mm;	, 0			inwar	d<10mm;thin 0.5-0.8	
5		stick	у			-		sticky cuff severely				slightly			
6	Extrem	ie colo	r variation		entir	ely,severely		finger,cuff,severely					cuff,slightly,unconspicuous		
7		Bad sn				-		severely irritating smell					slight odor		
8	Embedde	ed fore	ign particles		inse	ect,hair,etc.			-					-	
	Prot	ection	against												
			droxide (K)												
	30% Hydrogen peroxide (P) >30Mins.														
	37% Formaldehyde (T)														
	STANDARDS AND CERTIFICATIONS Compliant with EN455-1:2020, EN455-2:2015, EN455-3:2015, EN455-4:2009														
								•	.8, EN ISO 374						
					COL	inpliant with t	-11130 374-1:	2010+A1.201	.0, EN 150 374	-5.2010,	LIN 130 Z.	1420			



# **CERTIFICATE OF REGISTRATION**

This is to certify that the management system of:

# Anhui Intco Medical Products Co., Ltd.

Main Site: No. 6, Haitang South Road, Suixi Wuhu Modern Industrial Park, Suixi County, Huaibei City, Anhui Province, China 235100

has been assessed by Intertek as conforming to the requirements of:

## ISO 13485:2016

The quality management system is applicable to:

Manufacture of non sterile medical examination NBR (Nitrile Butadiene Rubber) and PVC (Poly Vinyl Chloride) gloves.

Certificate Number: 0102138-01

Initial Certification Date: June 01, 2020

Date of Certification Decision: June 9, 2021

Issuing Date: June 9, 2021

Valid Until: June 8, 2024





intertek

The SCC Accreditation Symbol is an official symbol of the Standards Council of Canada, used under licence.

Calin Moldovean President, Business Assurance

Intertek Testing Services NA Ltd., 1829, 32nd avenue, Lachine, QC, H8T 3J1, Canada





In the issuance of this certificate, Intertek assumes no liability to any party other than to the Client, and then only in accordance with the agreed upon Certification Agreement. This certificate's validity is subject to the organization maintaining their system in accordance with Intertek's requirements for systems certification. Validity may be confirmed via email at certificate validation@intertek.com or by scanning the code to the right with a smartphone. The certificate remains the property of Intertek, to whom it must be returned upon request.



Issued to:

Anhui Intco Medical Products Co., Ltd Haitang Road West and Yinhua Road North Suixi Wuhu Modern Industrial Park Suixi Town Huaibei City Anhui Province China

Notified Body: 2777

SATRA customer number: P20118

## **EU Type-Examination Certificate**

#### Certificate number: 2777/14815-02/E00-00

This EU Type-Examination Certificate covers the following product group(s) supported by testing to the relevant standards/technical specifications and examination of the technical file documentation: Following the EU Type-Examination this product group has been shown to satisfy the applicable essential health and safety requirements of Annex II of the PPE Regulation (EU) 2016/425 as a Category III product.

#### Product reference:

**Description:** 

Blue NGPF7000-7005 Black BNPF7000-7005 White WNPF7000-7005 Violet NGPF7000-V1-7005-V1

Disposable Nitrile Gloves (Non-sterile).

Sizes: 6-11(XS-XXL)

#### Classification:

EN ISO 374-1:2016+A1:2018/Type B	Level	EN ISC
40% Sodium hydroxide (K)	6	
30% Hydrogen peroxide (P)	2	
37% Formaldehyde (T)	5	

#### EN ISO 374-5:2016

Level Protection against Bacteria and Fungi Pass Protection against Viruses

#### O 374-4:2019 Degradation % -68.1 30.5 9.5

Pass

Standards/Technical specifications applied: EN ISO 21420:2020; EN ISO 374-1:2016+A1:2018; EN ISO 374-5:2016

Technical reports/Approval documents: SATRA: CHT0296241/2012, CHM0298100/2020/EN/A, CHM0298100/2020/EN/B SGS: CH:TX:1142011147, CH:TX:1142011145-1, CH:TX:1142011148 TUV: 7191234075-CHM20-02-TSL, 7191235025-EEC20-WBH\_CR1, 721652920

Signed	on	bobalf	of	SVID	٨.
Signeu	UII	Denaii	01	SAIN	А.

Ting Huang

**Ting Huang** 



Geoff Graham

Date first issued: 20/07/2020 Date of issue: 26/07/2020

Expiry date: 20/07/2025

### **TERMS AND CONDITIONS**

The following conditions apply in addition to SATRA's standard terms and conditions of business and those given in the current certification agreement.

The certificate holder is licensed to mark the products detailed within this certificate in accordance with Annex V (Module B) of the Regulation (EU) 2016/425 of the European Parliament and of the council of 9th March 2016 on personal protective equipment once you have drawn up an EU declaration of product conformity.

Please note:

- Where the product is classified as category III then CE Marking of production is reliant on current compliance with Regulation 2016/425 module C2 or Module D. (Except that specifically produced to fit an individual user).
- 2. Full details of the scope of the certification and product(s) certified are contained within the manufacturer's technical documentation.
- 3. Where a translation of this certificate exists, the English language version shall be considered as the authoritative text.
- 4. Certification is limited to production undertaken at the sites listed in the manufacturers technical documentation.
- 5. Ongoing manufactured product shall be consistent with the product(s) certified and listed on this certificate.
- 6. The Manufacturer shall inform SATRA of any changes to the certified product or technical documentation.
- 7. Where results obtained during type testing are within the budget of uncertainty when compared to the pass requirement, classification or performance level, then it is the responsibility of the manufacturer to ensure that the factory production control and manufacturing tolerances are such that the product placed on the market meets with the stated requirements, classifications or performance levels.
- 8. This certificate shall be kept together with the relevant technical documentation in a safe place by the client named on this certificate. Production of this certificate and other documentation may be required by a representative of the EC member state government.
- 9. This certificate relates only to the condition of the testable items at the time of the certification procedure and is subject to the expiry date shown.
- 10. SATRA reserves the right to withdraw this certificate if it is found that a condition of manufacture, design, materials or packaging have been changed and therefore no longer comply with the requirements of Regulation 2016/425.



Version: A/1

#### **EU DECLARATION OF CONFORMITY**

Manufacturer

#### Authorized Representative

Name: Anhui Intco Medical Products

Co.,Ltd.

*Address:* No. 6, Haitang South Road, Suixi Wuhu Modern Industrial Park, Suixi County, Huaibei City, Anhui Province Name:Lotus NL B.V.

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

Declares that the MDR described hereafter

Product name and model:

#### **Disposable Nitrile Exam Gloves**

#### EMDN code: T01020204

Model:XS/S/M/L/XL/XXL

Product Code: See the following annex I

Basic UDI-DI: 697306977NitrileFR

SRN: CN-MF-000002356

This declaration of conformity is issued under the sole responsibility of the manufacturer:

Anhui Intco Medical Products Co., Ltd.

Conformity Assessment Route: Annex II and Annex III according to EU 2017/745.

Applicable Standard:

EN ISO 13485:2016; EN 14971:2019; EN 1041:2008; EN 15223-1:2016

EN 455-1:2000; EN 455-2:2015; EN 455-3:2015; EN 455-4:2009;

ISO 10993-1:2018; ISO 10993-10:2010. ISO 10993-11:2017

Meet the provisions of the Council Regulation EU 2017/745 and Annex I which apply to them, The medical device has been assigned to Class I, based on rule 1 & rule 5 of Annex VIII Chapter III of the Regulation EU 2017/745 MDR. It bears the mark

## CE

We agree to develop, implement and maintain a documented post-production monitoring process



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

#### Annex 1 product code

Color	Product Code
	NGV/B/H/PEM10013-NGV/B/H/PEM10018
DI	NGV/B/H/PEM20013-NGV/B/H/PEM20018
Blue	SNV/B/H/PE10013-SNV/B/H/PE10018
	SNV/B/H/PE20013-SNV/B/H/PE20018
	NGV/B/H/PEM10023-NGV/B/H/PEM10028
XX71.:4	NGV/B/H/PEM20023-NGV/B/H/PEM20028
White	SNV/B/H/PE10023-SNV/B/H/PE10028
	SNV/B/H/PE20023-SNV/B/H/PE20028
Voilet	NGV/B/H/PEM10033-NGV/B/H/PEM10038
	NGV/B/H/PEM20033-NGV/B/H/PEM20038
	SNV/B/H/PE10033-SNV/B/H/PE10038
	SNV/B/H/PE20033-SNV/B/H/PE20038
	NGV/B/H/PEM10043-NGV/B/H/PEM10048
	NGV/B/H/PEM20043-NGV/B/H/PEM20048
Black	SNV/B/H/PE10043-SNV/B/H/PE10048
	SNV/B/H/PE20043-SNV/B/H/PE20048
D: 1	NGV/B/H/PEM10053-NGV/B/H/PEM10058
Pink	NGV/B/H/PEM20053-NGV/B/H/PEM20058

Anhui 2021-04-16

Place , date

Quality Manager Legally binding signature, Function 1010



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#### **EU Declaration of Conformity**

1. PPE: Disposable Nitrile Gloves

Glove sizes available: XS, S, M, L, XL, XXL (6, 7, 8, 9, 10, 11)

2. Manufacturer Name: Anhui Intco Medical Products Co., Ltd.

Address: (Haitang Road West and Yinhua Road North) Suixi Wuhu Modern Industrial Park, Suixi Town, Huaibei City, Anhui, China

3. This declaration of conformity is issued under the sole responsibility of the manufacturer: Anhui Intco Medical Products Co., Ltd.

4. Object of the declaration: Disposable Nitrile Gloves (Blue-NGPF;Black -BNPF; White-WNPF; Violt -NGPF-V1)



5. The object of the declaration described in point 4 is in conformity with the relevant Union harmonisation legislation: Regulation (EU)2016/425.

6. References to the relevant harmonised standards used, including the date of the standard, or references to the other technical specifications, including the date of the specification, in relation to which conformity is declared: EN ISO 21420:2020, EN ISO 374-1:2016 +A1:2018, EN374-2:2014, EN ISO 374-5:2016.

7. The notified body SATRA Technology Europe Ltd (Number: 2777) performed the EU type-examination (Module B) and issued the EU type-examination certificate.

The PPE is subject to the conformity assessment procedure Module C2 under surveillance of the notified body: SATRA Technology (Number: 2777),

Adress: Bracetown Business Park Clonee, D15 YN2P, Ireland.

Signed for and on behalf of: Anhui Intco Medical Products Co 崔忠强 签名 Signature 职位 Position Quality Manage 日期 Date 6. July-



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SUBJECT	Microbiological Analysis
TEST LOCATION	TÜV SÜD China
	TÜV SÜD Products Testing (Shanghai) Co., Ltd. B-3/4, No.1999 Du Hui Road, Minhang District Shanghai 201108, P.R. China
CLIENT NAME	Anhui Intco Medical Products Co., Ltd
CLIENT ADDRESS	No.1 Haitang Road, Suixi District economic development area, Huaibei City, Anhui Province.
TEST PERIOD	24-Mar-2020~20-Apr-2020
TEST REQUEST	Penetration of Phi-X174 Bacteriophage Test - with reference to ISO 16604-2004, BS EN ISO 374-5:2016
Prepared	By SUD Estimation is a second
Bella	Xu and the second secon
(Bella Xu) Report Drafte	er Authorized Signatory

Note: (1) General Terms & Conditions as mentioned overleaf. (2) The results relate only to the items tested.(3) The test report shall not be reproduced except in full without the written approval of the laboratory.(4) Without the agreement of the laboratory , the client is not authorized to use the test results for unapproved propaganda.

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Regional Head Office: TÜV SÜD Certification and Testing (China) Co., Ltd. No.151 Heng Tong Road Shanghai 200 070 P.R.China





#### **RECEIPT DATE / TEST DATE**

24-Mar-2020/ 24-Mar-2020

#### THE FOLLOWING SAMPLE(S) WAS/WERE SUBMITTED

#### BY/ ON BEHALF OF THE CLIENTS AS:

Disposable Nitrile Gloves (NBR) Sample Name:

Sample Specification: /

Batch No./Date:

Manufacturer:

SAMPLE NO.	DESCRIPTION	PHOTOGRAPH
721652920	Blue Gloves	1 2 3 4 5 6 7 4 9 m H HOMAIS E MANDARIN MANARAN 721652920

#### **TEST METHOD(S)**

Penetration of Phi-X174 Bacteriophage Test

- in accordance with BS EN ISO 374-5:2016 Protective gloves against dangerous chemicals and microorganisms Part 5: Terminology and performance requirements for micro-organisms risks, 5.3 Protection against viruses. Test method with reference to ISO 16604-2004 Clothing for protection against contact with blood and body fluids -Determination of resistance of protective clothing materials to penetration by bloodborne pathogens — Test method using Phi-X174 bacteriophage

#### REQUIREMENT

- Exposure Procedure: B

Sampling Size: 75mm×75mm

Negative control: Polyethylene material

Positive control: 0.04 µm microporous membrane

Prior to testing, condition all test specimens and controls for a minimum of 24 hours at (21 $\pm$ 5) $^{\circ}$ C and

30%~80% relative humidity.

#### **TEST ORGANISM(S)**

Bacteriophage ATCC 13706-B1

#### PROCEDURE

- 1. Compatibility testing
  - 1.1. Test three specimens representing each material type to be tested.
  - 1.2. With the sterile cell placed horizontally on the laboratry bench, insert the specimen in the test cell with the back of the hand and the palm of the hand toward the cell reservoir.
  - 1.3. Assemble the test cell. Torque the bolts in the test cell to 13.6 N m each.

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- 1.4. With the cell remaining in the horizontal position on the laboratory bench, place a 2.0 μL aliquot of the Phi-X174 bacteriophage in bacteriophage nutrient broth, containing a total of 900-1200 PFU, near the middle of each piece of test specimen.
- 1.5. Prepare a control by adding a 2.0 µL aliquot from the same suspension directly into 5.0 mL of sterile bacteriophage nutrient broth.
- 1.6. After 60 min, quantitatively assay by adding 5.0mL of sterile bacteriophage nutrient broth onto the surface of the specimen.
- 1.7. Calculate the ratio of the control assay titer to the test material assay titer using the following equation:

 $ratio = \frac{\text{control assay titer (PFU/mL)}}{\text{test material assay titer (PFU/mL)}} = 1.1$ 

- 1.8. Record the initial titer of the Phi-X174 bacteriophage challenge suspension used for the test . (  $(2 \pm 1)x10^8$  PFU/mL times the ratio calculated.)
- 2. Test procedure
  - 2.1. Prepare the bacteriophage challenge suspension (40-44 mN/m) for the test.
  - 2.2. With the sterile cell placed horizontally on the laboratry bench, insert the specimen in the test cell with the back of the hand and the palm of the hand toward the cell reservoir.
  - 2.3. Assemble the test cell. Torque the bolts in the test cell to 13.6 N·m each.
  - 2.4. Mount the test cell in the test apparatus in a vertical position and close the drain valve.
  - 2.5. Penetration test: If liquid appears to penetrate through the test specimens at anytime during the test, terminate the test.
    - (1) Carefully fill the test cell reservoir with approximately 60 mL of the Phi-XI74 bacteriophage challenge suspension
    - (2) Step1: Observe for 5 min at 0 psi.
      - Step2: Slowly increase the pressure to 2.0 psi at the rate of no more than 0.5 psi/s, keep the pressure at 2.0 psi, observe for 1 min.
      - Step3: Slowly decrease the pressure to 0 psi at the rate of no more than 0.5 psi/s, observe for 54 min.
    - (3) At the end of the time period, open the drain valve and drain the test cell of the
  - bacteriophage challenge suspension. Dilute and assay the bacteriophage concentration. 2.6. Specimen surface assay procedure
    - (1) With the sterile cell placed horizontally on the laboratory bench. Slowly add 5.0 mL of sterile bacteriophage nutrient broth onto the exposed surface of the specimen.
    - (2) Gently swirl the test cell for approximately 1 min. Assay the liquid soon after collecting.
  - 2.7. Remove the specimen from the test cell and prepare the test cell for sterilization.
- 3. Test controls
  - 3.1. The negative control was negative for bacteriophage penetration.
  - 3.2. The positive control was positive for bacteriophage penetration.
  - 3.3. Record the final titer of the bacteriophage challenge at the conclusion of the 60 min test.

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#### **TEST RESULT(S)**

			Final	Test Results				
Test Items		Initial titer PFU/ml	titer PFU/ml	Step1	Step2	Step3	Assay titer (PFU/mI)	Pass/Fail
	Control(+)	1.9x10 <sup>8</sup>	1.8x10 <sup>8</sup>	None Seen	Seen	-	-	Acceptable
Depetration of	Control(-)	1.9x10 <sup>8</sup>	1.8x10 <sup>8</sup>	None Seen	None Seen	None Seen	<1	Acceptable
Penetration of Phi-X174	-1	1.9x10 <sup>8</sup>	1.8x10 <sup>8</sup>	None Seen	None Seen	None Seen	<1	Pass
Bacteriophage	-2	1.9x10 <sup>8</sup>	1.8x10 <sup>8</sup>	None Seen	None Seen	None Seen	<1	Pass
	-3	1.9x10 <sup>8</sup>	1.8x10 <sup>8</sup>	None Seen	None Seen	None Seen	<1	Pass

Note:

1.PFU: Plaque Forming Unit.

2. This report is for internal use only such as internal scientific research , education, quality control, product R&D.

-END OF THE TEST REPORT-



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#### TEST REPORT: 7191234075-CHM20-02-TSL

Date: 26 MAR 2020

Tel: +65 68851312 Fax: +65 67784301

Client's Ref:

Email: zhou.xiao@tuv-sud-psb.sg

**Note:** This report is issued subject to the Testing and Certification Regulations of the TÜV SÜD Group and the General Terms and Conditions of Business of TÜV SÜD PSB Pte Ltd. In addition, this report is governed by the terms set out within this report.

#### SUBJECT

Determination of Glove Resistance to Permeation by 30% Hydrogen Peroxide

#### **CLIENT**

Anhui Intco Medical Products Co, Ltd No.1 Haitang Road Suixi District Economic Development Area Huaibei City, Anhui Province China

#### SAMPLE SUBMISSION DATE

13 Mar 2020

#### **DESCRIPTION OF SAMPLE**

One packet of glove sample labeled as follows was received.

No	Product Description	Colour	Sample Received (pieces)	Manufacturer
1	Disposable Nitrile Gloves (NBR)	Blue	20	Anhui Intco Medical Products Co, Ltd



#### DATE OF ANALYSIS

16 Mar 2020 - 25 Mar 2020



Laboratory: TÜV SÜD PSB Pte. Ltd. No.1 Science Park Drive Singapore 118221 Phone : +65-6885 1333 Fax : +65-6776 8670 E-mail: enquiries@tuv-sud-psb.sg www.tuv-sud-psb.sg Co. Reg : 199002667R Regional Head Office: TÜV SÜD Asia Pacific Pte. Ltd. 1 Science Park Drive, #02-01 Singapore 118221 TUV®



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#### METHOD OF TEST

#### Determination of material resistance to permeation by chemicals : By EN 16523-1:2015

- The palm area of the glove sample was mounted between two halves of a test cell. The test cell consisted of a two-compartment cell with 30% Hydrogen Peroxide on glove's normal outside surface and Ultrapure Water on the glove's normal inside surface. Testing were carried out at ambient temperature (23°C ± 2°C).
- 2. The collecting medium were sampled and analysed for 30% Hydrogen Peroxide at 10 min (class 1), 30 min (class 2), 60 min (class 3), 120 min (class 4), 240 min (class 5) and 480 min (class 6).
- 3. The extracts were then analysed by UV Spectrophotometer. The results were used to calculate the permeation rate of 30% Hydrogen Peroxide through the glove material. Based on the result, the minimum rate of sampling was determined.
- 4. The tests were repeated at 10 min, 30min and the sampling interval of 150 sec and collected until 60 mins.
- 5. The extracts were then analysed by UV Spectrophotometer for the Normalised Permeation Rate.

Breakthrough Time (mins) *	Types of Level
> 10	Class 1
> 30	Class 2
> 60	Class 3
> 120	Class 4
> 240	Class 5
> 480	Class 6

Table 1 : Classification of Glove Levels According to Breakthrough Time (EN 374-1 : 2003)

\* The breakthrough time is deemed to have occurred when the analytical equipment detects a permeation rate of 1  $\mu$ g/cm<sup>2</sup>/min.



#### **RESULTS**

#### 1. Determination of resistance to permeation by 30% Hydrogen Peroxide

Table 2 : Normalised Breakthrough Results for "Disposable Nitrile Gloves (NBR)" in 30% Hydrogen Peroxide

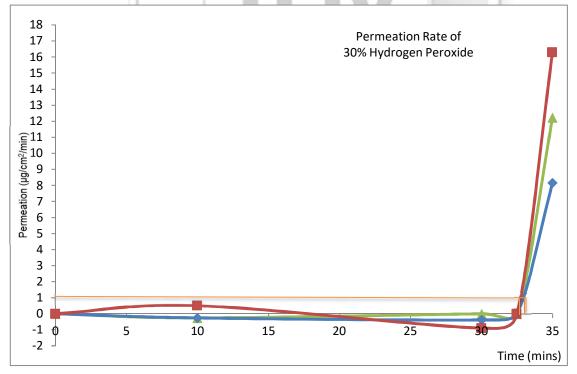
30% Hydrogen Peroxide								
Sample	Sample Location on Palm Area	Normalised Breakthrough Time (mins)	Mean Breakthrough Time (mins)	Lowest Value (mins)	Level			
	1	34			l			
Disposable Nitrile Gloves (NBR)	2	34	34	34	2			
	3	34						

1) Chemical transfer referred to the quantity of chemical which had passed through per cm<sup>2</sup> of glove sample at the termination of the test.

2) The thickness of the glove was 0.10 mm.

3) Slight color change was observed on the glove test specimen after the test.

According to Table 2, the breakthrough time for "Disposable Nitrile Gloves (NBR)" occurred after 30 mins. It was concluded that the sample belonged to class 2.





MS TAN SER LING TECHNICAL EXECUTIVE

DR XIAO ZHOU PRODUCT MANAGER MICROCONTAMINATION DIAGNOSIS CHEMICAL & MATERIALS

### TEST REPORT: 7191234075-CHM20-02-TSL 26 MAR 2020



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July 2011



#### Test Report No. 7191235025-EEC20-WBH\_CR1 (re-issue dated: 27 Apr 2020) dated 22 Apr 2020



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#### SUBJECT:

Testing of Disposable Nitrile Gloves (NBR) submitted by Anhui Intco Medical Products Co, Ltd on 30 Mar 2020.

#### TESTED FOR:

Anhui Intco Medical Products Co, Ltd No.1 Haitang Road, Suixi District Economic Development Area, Huaibei City, Anhui Province

#### TEST DATE:

16 Apr 2020

#### **DESCRIPTION OF SAMPLES:**

S	/N	Product Description	Colour	Sample received (pieces)	Manufacturer
	1	Disposable Nitrile Gloves (NBR)	Blue	20	Anhui Intco Medical Products Co, Ltd

10.00

#### METHOD OF TEST:

BS EN ISO 374-4:2019 Protective gloves against dangerous chemicals and micro-organisms – Part 4: Determination of resistance to degradation by chemicals

#### AMENDMENT:

The following amendment was made on 27 Apr 2020: The "METHOD OF TEST" was amended to reflect the latest test standard.



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Regional Head Office: TÜV SÜD Asia Pacific Pte. Ltd. 1 Science Park Drive, #02-01 Singapore 118221 TUV





#### RESULTS:

Sample: Disposable Nitrile Gloves (NBR)

#### Table: Results for BS EN ISO 374-4:2019 Clause 5.3

Clause	Test	Requirements	Results		Inferred Result
5.3	Degradation	The degradation (DR) shall be determined according to BS EN ISO 374-4:2019 for each chemical claimed in the marking and reported in the user instruction.	Degradation Results (%)		
			Glove 1	32.8	NA
			Glove 2	29.4	
			Glove 3	29.4	
		Tested Chemical: 30% Hydroxide Peroxide	Average	30.5	
			Standard Deviation	2.0	

#### REMARKS:

1. For Clause 5.3 Degradation, the test specimens will be 3 gloves and 6 specimens will be cut from each glove. For each glove, 3 specimens will be exposed to the challenge chemical (30% Hydroxide Peroxide) and 3 specimens will be unexposed. After prepare the specimens, and exposed to 30% Hydroxide Peroxide for 1 hour, puncture the specimen and record the peak force required.



Yeo Poh Kwang Higher Associate Engineer bhrs Hu

Wong Bee Hui Product Manager Medical Health Services (NAM)

#### APPENDIX:



Photo: Disposable Nitrile Gloves (NBR)



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