BETTER AG
Top Qualität zu Herstellerpreisen

Odem

Nitrilhandschuhe

Produkt: Einweg-Nitrilhandschuhe

EN 455: Medizinische Handschuhe für den einmaligen Gebrauch

EN ISO 374: Chemieschutzhandschuhehe zum Schutz vor Viren

Spezifikation: 24 cm x 9,5 cm
Haltbarkeitsdauer: 5 Jahre
Farbe: Blau
Grösse: S, M, L, XL

Verpackungsbox:
Menge: 100 Stück/Box
Größe: 23 x 12,5 x 6 cm

Verpackungskarton:
Menge: 10 Box/Karton
Größe: 31,5 x 25,8 x 24,5 cm

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

www.OdemShop.de
info@OdemShop.de

DE: +49 30 62 93 34 20
CH: +41 71 58 80 248

SYNGUARD®

UNTERSUCHUNGSHANDSCHUHE AUS NITRIL

EIGENSCHAFTEN

- Ausgezeichnete Weichheit und Trageeigenschaft
- Hohe Griffigkeit durch texturierte Oberfläche und Fingerkuppen
- Gerollter Rand zum einfachen Anziehen
- Entspricht den Anforderungen für den Umgang mit Lebensmitteln
- Latexfrei, puderfrei und geruchsneutral

PRODUKTINFORMATION			
Material	Nitril	**Nicht aus Naturkautschuklatex hergestellt**	Ja
Verfügbare Größen	S,M,L,XL	**Farbe**	Blau
Länge des Handschuhs	≥240mm	**Löcherfrei (Inspektionsstufe I)**	AQL 1.5
Pudergehalt	Puderfrei	**Steril**	Nein
Fingerdicke (mm)	≥0.05	**Dicke der Handfläche (mm)**	≥0.05
Reißfestigkeit	≥6N vor und nach der Alterung	**Zugfestigkeit**	≥14MPA vor und nach der Alterung
Schutz gegen Bakterien und Pilze	Bestanden	**Schutz gegen 40% Natriumhydroxid (K) 30% Wasserstoffperoxyd (P) 37% Formaldehyd (T)**	＞30min
Schutz gegen Viren	Bestanden		
Abmessungen (±10mm)	S/80;M/95; L/110;XL/120	**Oberfläche**	Mikrotextur an den Fingern

VERPACKUNG UND LAGERUNG	
Verpackung	100 Stück/Box,10 Boxen/Karton
Größe der Box	230*125*60mm
Karton Abmessung	315*258*245mm
Haltbarkeitsdauer	5 Jahre
Anweisungen zur Lagerung	Vor direkter Sonneneinstrahlung schützen; kühl und trocken lagern. Von Ozon- oder Zündquellen fernhalten

NORMEN UND ZERTIFIZIERUNGEN

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

Anhui Intco Medical Products Co., Ltd

Examination Disposable Gloves Product Specification

Type	Disposable Nitrile Gloves, Powder free, Non Sterile,Ambidextrous												
Grade	Examination			**Surface**	Finger texture			**Glove Length(mm)**	≥240				
Material	NBR			**Packing**	100pcs/box,10boxes/ctn			**Weight(g)**	3.5±0.3 (Medium Size)				
Cuff	Beaded							**Powder Level**	≤2mg/glove				
Product	**Color**	**Size**	**Weight**	**cal Dimension**				**Physical Property**					
				Length (mm)	**Palm Width (mm)**	**Cuff Thickness(mm)**	**Finger Thickness(mm)**	**Palm Thickness(mm)**	**Force at break**		**Elongation**		**Water Test AQL**	**Appearance AQL**
									Before Aging	**After Aging**	**Before Aging**	**After Aging**		
Nitrile gloves	Blue/White/Purple	S	3.0g+-0.3	⩾240	85±5	0.07±0.03	0.10±0.03	0.08±0.03	6.0	6.0	500	400	AQL1.5	Critical AQL1.5 Major AQL2.5 Minor 4.0
		M	3.5g+-0.3		95±5				6.0	6.0	500	400	AQL1.5	Critical AQL1.5 Major AQL2.5 Minor 4.0
		L	4.0g+-0.3		110±5				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.	**sort**		**Critical defects**	**Major defects**	**Minor defects**
1	torn	big tearing	√	-	-
		scratch	≥3mm	≥2mm	-
		visible hole	≥3mm	≥3mm	-
2	dirt	greasy dirt	≥3mm,serious	1-2mm,visible	<2mm,slightly
		yellow dirt	√	-	-
3	black spots,impurities		uncountable	≥3mm or 0.5-3mm,>3/side	0.5-3mm,≤3/side
4	beading		broken;torn;none-beading	impurity;knot;black;bright PU≥ 3mm;inward≥10mm;minuteness(≤	inward<10mm;thin 0.5-0.8
5	sticky		-	sticky cuff severely	slightly
6	Extreme color variation		entirely,severely	finger,cuff,severely	cuff,slightly,unconspicuous
7	Bad smell		-	severely irritating smell	slight odor
8	Embedded foreign particles		insect,hair,etc.	-	-
	Protection against				
	40% Sodium Hydroxide (K)		>30Mins.		
	30% Hydrogen peroxide (P)				
	37% Formaldehyde (T)				

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

intertek
Total Quality. Assured.

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

ISO 13485:2016 CERTIFICATION TM
intertek

SCC Accredited CB-MS OCSM Accrédité CCN TM
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

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:

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

Description:

Disposable Nitrile Gloves (Non-sterile).

Sizes:
6-11(XS-XXL)

Classification:

EN ISO 374-1:2016+A1:2018/Type B	Level	EN ISO 374-4:2019 Degradation %
40% Sodium hydroxide (K)	6	-68.1
30% Hydrogen peroxide (P)	2	30.5
37% Formaldehyde (T)	5	9.5

EN ISO 374-5:2016	Level
Protection against Bacteria and Fungi	Pass
Protection against Viruses	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 behalf of SATRA: 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:

1. 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.

INTCO
英科医疗

Document Number ：INTCO-CE-DC-NBR-001 Version: A/1

EU DECLARATION OF CONFORMITY

Manufacturer

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

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

Authorized Representative

*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

Annex 1 product code

Color	Product Code
Blue	NGV/B/H/PEM10013-NGV/B/H/PEM10018
	NGV/B/H/PEM20013-NGV/B/H/PEM20018
	SNV/B/H/PE10013-SNV/B/H/PE10018
	SNV/B/H/PE20013-SNV/B/H/PE20018
White	NGV/B/H/PEM10023-NGV/B/H/PEM10028
	NGV/B/H/PEM20023-NGV/B/H/PEM20028
	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
Black	NGV/B/H/PEM10043-NGV/B/H/PEM10048
	NGV/B/H/PEM20043-NGV/B/H/PEM20048
	SNV/B/H/PE10043-SNV/B/H/PE10048
	SNV/B/H/PE20043-SNV/B/H/PE20048
Pink	NGV/B/H/PEM10053-NGV/B/H/PEM10058
	NGV/B/H/PEM20053-NGV/B/H/PEM20058

Anhui 2021-04-16

Place , date

Quality Manager

Legally binding signature, Function

INTCO 英科医疗	安徽英科医疗制品有限公司 Anhui Intco Medical Products Co., Ltd.	文件编号 Doc No.	INTCO-PPE-NBR
		版　　本 Ver.	A0

EU Declaration of Conformity

1. PPE: Disposable Nitrile Gloves

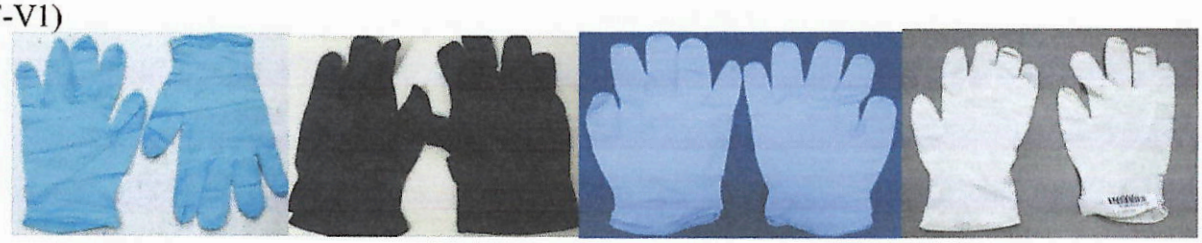
   Glove sizes available: XS, S, M, L, XL, XXL (6, 7, 8, 9, 10, 11)

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.

8. 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., Ltd.

签名 Signature 崔慧强

职位 Position Quality Manager

日期 Date 16-July-2020

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

Bella Xu

(Bella Xu)
Report Drafter

Authorized By

Leo Liu

(Leo Liu)
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.

Chemical/Microbiology Laboratory:
TÜV SÜD Products Testing (Shanghai) Co., Ltd.
B-3/4, No.1999 Du Hui Road, Minhang District
Shanghai
201108
P.R. China

Phone : +86 (21) 6037 6375
Fax : +86 (21) 6037 6345
Email: food.chem@tuv-sud.cn
Webpage: www.tuv-sud.cn

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:

Sample Name: Disposable Nitrile Gloves (NBR)
Sample Specification: /
Batch No./Date: /
Manufacturer: /

SAMPLE NO.	DESCRIPTION	PHOTOGRAPH
721652920	Blue Gloves	

TEST METHOD(S)

Penetration of Phi-X174 Bacteriophage Test
- in accordance with BS EN ISO 374-5:2016 Protective gloves against dangerous chemicals and micro-organisms 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 blood-borne 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±5)℃ 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.

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:

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

1.8. Record the initial titer of the Phi-X174 bacteriophage challenge suspension used for the test . ((2 ±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.

TEST RESULT(S)

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

Chemical/Microbiology Laboratory:
TÜV SÜD Products Testing (Shanghai) Co., Ltd.
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Phone : +86 (21) 6037 6375
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Email: food.chem@tuv-sud.cn
Webpage: www.tuv-sud.cn

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

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

PSB Singapore

Add value.
Inspire trust.

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

TÜV SÜD PSB

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

PSB Singapore

METHOD OF TEST

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

1. 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.

6. A blank test was carried out exactly with the same procedure except Ultrapure Water was used.

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

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

* The breakthrough time is deemed to have occurred when the analytical equipment detects a permeation rate of 1 μg/cm^2/min.

PSB Singapore

RESULTS

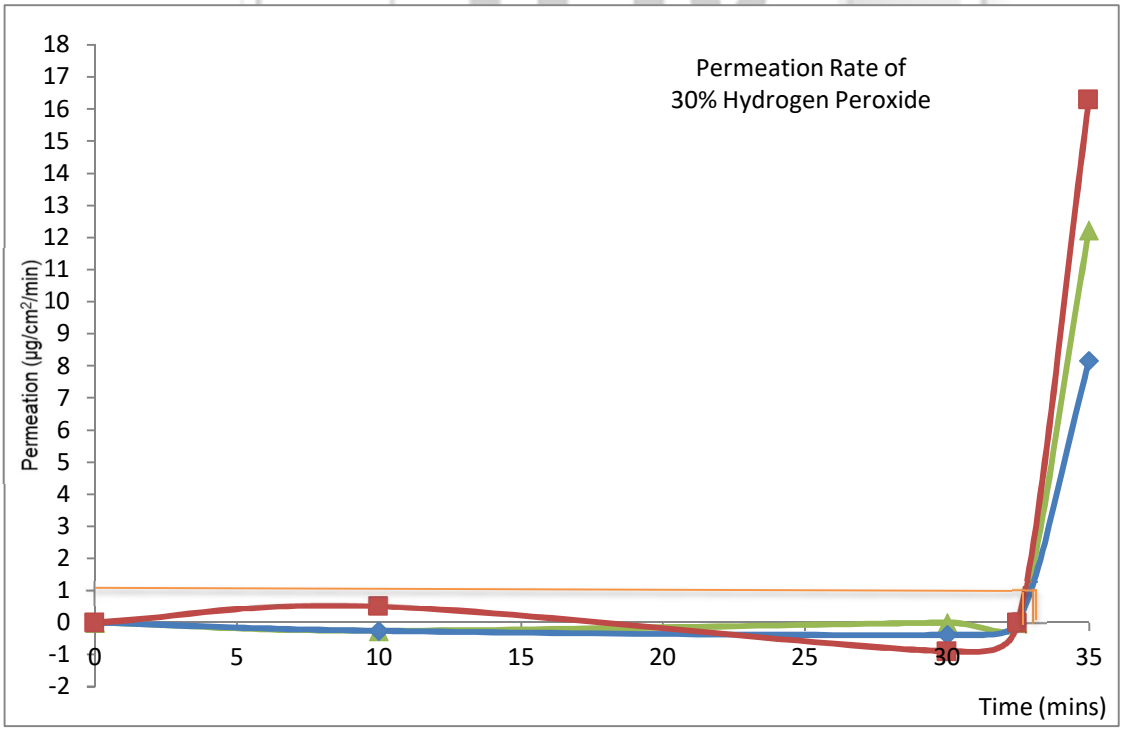
1. Determination of resistance to permeation by 30% Hydrogen Peroxide

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**
Disposable Nitrile Gloves (NBR)	1	34	34	34	2
	2	34			
	3	34			

1) Chemical transfer referred to the quantity of chemical which had passed through per cm^2 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
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PSB Singapore

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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

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.

TÜV SÜD PSB

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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. Tested Chemical: 30% Hydroxide Peroxide	Degradation Results (%)		NA
			Glove 1	32.8	
			Glove 2	29.4	
			Glove 3	29.4	
			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

Wong Bee Hui
Product Manager
Medical Health Services (NAM)

APPENDIX:

Photo: Disposable Nitrile Gloves (NBR)

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