SKYMED

Medyczne jednorazowe rękawice nitrylowe 2021

TERRAPOD
Sempre per Terra

SKYMED

„WIARA JEST NASZYM GŁÓWNYM RDZENIEM”

Z entuzjazmem zawsze dostarczamy naszym klientom produkt najwyższej jakości. Zapewnienie najlepszego produktu jest zatem kluczowe”

Sr.Gp.Capt.Kampee Kampeerayannon

CEO, Sufficiency Economy City Co., Ltd

Generalny Importer do Europy
Terrapod Sp. z o.o.
Ul. 27 Grudnia 5/5
61-737 Poznań

TERRAPOD
Sempre per Terra

SKYMED – NASZE RĘKAWICZKI

Nasze rękawiczki są importowane na najnowszych i najbardziej rygorystycznych kodach UDI-DI-PI.

Mają dwa raporty SGS:

1. Zlecony przed wysyłką przez producenta w Chinach
2. Zlecony przez spółkę Terrapod w Polsce.

Rękawiczki mają normę: ASTM F1671 na penetrację wirusów oraz ASTM 6978 z testem penetracji 15 cytostatyków w dynamicznych warunkach ACPP dla służby szpitalnej.

Nasz produkt jest zgłoszony do bazy URPL: URPL: ID 1608 9119 4562 Odprawiony na kodzie celnym HS 401511, z wskazaniem VAT 8%

Zgodnie z nową dyrektywą MDR 2017/745, unijne przepisy są bezpośrednio stosowane w każdym państwie członkowskim bez konieczności ich implementacji do prawa krajowego, a jednolite regulacje prawne w zakresie wyrobów medycznych obecnie obowiązują w całej Unii Europejskiej.

Skymed posiada i spełnia normy zarówno przepisów 2017/5745 jak i 2016/425, dla których posiadamy odpowiednie Deklaracje Zgodności. Fabryka produkująca rękawice posiada normę EN ISO 10993 i posiada certyfikat EN ISO 14971:2019, ISO 13485:2016 oraz inne normy dotyczące produkcji rękawic ochronnych, badawczych i medycznych.

Sam produkt spełnia i jest klasyfikowany jako rękawica medyczna zarówno przez testy EN 455-1,2,3,4 jak i EN374-1,2,3,4,5 z normą podniesioną do EN 374-5 VIRUS. Wszystkie te standardy są realizowane poprzez zgodność fabryki z normami ISO 16523 i ISO13485 oraz ISO 21420.

Zgodnie z nowym standardem MDR 2017/745 generalny importer posiada numer w bazie EUDAMED i zgłosił produkt do baz URPL, a także poddał go weryfikacji przez niezależne ośrodki badawcze wskazane przez bazę NANDO.

Opakowanie spełnia wszystkie zalecenia i normy, zarówno pod względem celnym, jak i medycznym.

Skymed posiada atest medyczny i przemysłowy, ale najważniejsze jest że, SKYMED chroni przed wirusami (w tym SARS-CoV-2), bakteriami i patogenami a produkt jest antyalergiczny.

Rękawice nitrylowe I klasy medycznej i III klasy ochronnej doskonale nadają się do stosowania w placówkach służby zdrowia wszelkiego rodzaju, ponieważ chronią przed płynami ustrojowymi, patogenami przenoszonymi przez krew i są wysoce odporne na przebicie. Rękawice nitrylowe klasy przemysłowej najlepiej nadają się do większości innych zadań, w tym do pracy z chemikaliami, żywnością, a nawet do użytku w domu.

Certyfikaty:	Certyfikat w trakcie	Pełen certyfikat
EN 1041:2008		✔
EN 1186		✔
EN 16523-1:2015 (EN 374-1)		✔
EN 13130-1:2004		✔
EN 374-1:2016		✔
EN 374-2:2016		✔
EN 374-3:2016		✔
EN 374-4:2013		✔
EN 374-5:2016		✔
EN 374-5:2016		✔
Virus EN 388:2016		✔
EN 420 EN ISO 21420		✔
EN 455-1		✔
EN 455-2		✔
EN 455-3		✔
EN 455-4		✔
EN ISO 10993-1:2018		✔
EN ISO 10993-5:2009		✔
EN ISO 10993-10:2016		✔
EN ISO 10993-11:2017		✔
EN ISO 10993-18:2005		✔
EN ISO 14971:2019		✔
ISO 13485:2016		✔
ASTM 6978-05 2019		✔
ASTM F1671		✔
FDA 510 (K)		✔
ISO 9001		✔
EC DOC /CE		✔
93/42/EEC		✔
2016/425		✔
MDR 2017/745		✔
UDI-DI-PI Code		✔
VIT	✔	
CIOP	✔	

Spis treści:

Declaration of Authority

Sufficiency Economy City Co., Ltd.
152 Moo 12, Tha Kwian , Watthana Nakhon, Sa Kaeo
Thailand 27160
www.skymed.center
sales@skymed.center , marketing@skymed.center

Manufacturer ***SUFFICIENCY ECONOMY CO. LTD*** *declares the fulfillment of basic requirements for medical devices, according of the Technical regulations on Medical devices, approved by UE DIRECTIVE 2017/742/EEC*
The declaration is made under the sole responsibility of the manufacturer.

The technical documentation for compliance purposes is stored at:

Terrapod Sp z o.o.,
27Grudnia 5/5 a,
61-737 POZNAN POLAND
Registr. number: 369988652
E-mail:kontakt@terrapod.pl

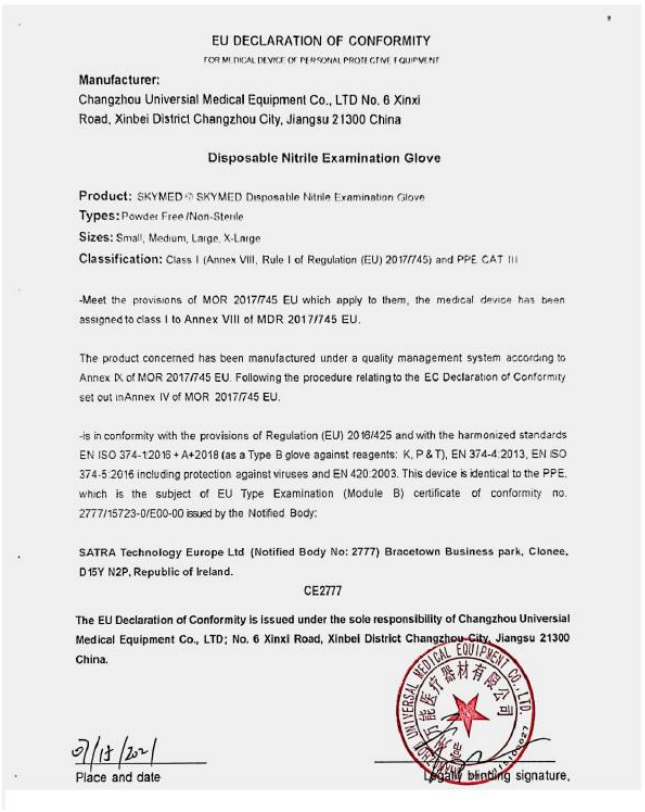
Place of issue:

Date of signing 25.05.2021

General Manager
Kampee Kampeerayannon
Senior Group Captain / CEO

Signature of Authorized person

Declaration of Conformity



EU DECLARATION OF CONFORMITY

FOR MEDICAL DEVICE OF PERSONAL PROTECTIVE EQUIPMENT

Manufacturer:
Changzhou Universial Medical Equipment Co., LTD No. 6 Xinxi Road, Xinbei District Changzhou City, Jiangsu 21300 China

Disposable Nitrile Examination Glove

Product: SKYMED® SKYMED Disposable Nitrile Examination Glove
Types: Powder Free /Non-Sterile
Sizes: Small, Medium, Large, X-Large
Classification: Class I (Annex VIII, Rule I of Regulation (EU) 2017/745) and PPE CAT III

-Meet the provisions of MOR 2017/745 EU which apply to them, the medical device has been assigned to class I to Annex VIII of MDR 2017/745 EU.

The product concerned has been manufactured under a quality management system according to Annex IX of MOR 2017/745 EU. Following the procedure relating to the EC Declaration of Conformity set out inAnnex IV of MOR 2017/745 EU.

-is in conformity with the provisions of Regulation (EU) 2016/425 and with the harmonized standards EN ISO 374-1:2016 + A+2018 (as a Type B glove against reagents: K, P & T), EN 374-4:2013, EN ISO 374-5:2016 including protection against viruses and EN 420:2003. This device is identical to the PPE, which is the subject of EU Type Examination (Module B) certificate of conformity no. 2777/15723-0/E00-00 issued by the Notified Body:

SATRA Technology Europe Ltd (Notified Body No: 2777) Bracetown Business park, Clonee, D15Y N2P, Republic of Ireland.

CE2777

The EU Declaration of Conformity is issued under the sole responsibility of Changzhou Universial Medical Equipment Co., LTD; No. 6 Xinxi Road, Xinbei District Changzhou City, Jiangsu 21300 China.

Place and date

Legally binding signature,

EC Declaration of Conformity

Manufacturer:

Changzhou universal medical equipment Co., Ltd
No.6, Xinxi Road, Xinbei District,
Changzhou City, Jiangsu ProvinceThe peoples republic of China

whose single Authorized EU-Representative:

Luxus Lebenswelt GmbH
Kochstr.1, 47877, Willich, Germany
DIMDI: DE/0000047791
Lin Sun
Tel: 0049- 1715605732
E-mail: info.m@luxuslw.de

We, the manufacturer, herewith declare that the products

SKYMED GLOVES
Disposable Medical Nitrile Examination Gloves (non sterile)

meet the provisions of Directive 2017/745 which apply to them.

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

CE

following the procedure relating to the EC Declaration of Conformity set out in Annex VII of Directive 2017/745.

This Declaration of Conformity covers all medical devices as specified in the product list belonging to this declaration.

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

Manufacturer: Changzhou universal medical equipment Co., Ltd
Address:No.6, Xinxi Road, Xinbei District, Changzhou City, Jiangsu ProvinceThe peoples republic of China

Harmonized standards
Signature:
Name:
Position: Manager
Day of issue: December 2, 2020

LUXUS LEBENSWELT GMBH Kochstr. 1 Lin Sun Germany

EC Declaration of Conformity

Page 1/1

扫描全能王 创建

Sufficiency Economy City Co., Ltd.
152 Moo 12, Tha Kwian, Watthana Nakhon, Sa Kaeo
Thailand 27160
www.skymed.center
sales@skymed.center , marketing@skymed.center

Date : 5th July 2021

Allocation and Authorisation Letter

To whom it may concern

We, hereby declare and confirm that the **Terrapod Sp z o.o.**, in accordance with valid and duly executed contracts, has the right to sell the following product as the **Authorised Seller**:

1. Product: ***SKYMED NITRILE GLOVES***
   Disposable Nitrile Powder Free Gloves – Medical Grade
   Non-sterile, Ambidextrous, Straight Fingers, Beaded Cuff,
   Latex Free, Blue
2. Packaging: ***100 pieces/box***
   Languages: DE, EN, UA, PL, ES, IT, FR, NL, CZ
   Packaging in line with the EU regulations and USA regulations
3. Quality Standard: ***MDR Class I, PPE Category III, AQL ≤1.5***
   EN ISO 374-1, -2, -4, -5 (VIRUS)
   EN 455-1, -2, -3, -4
   CE 2777, EC REP, UDI number
4. Available Allocation: ***300,000,000 boxes during 12 months contract***

Sr.Gp.Capt. Kampee Kampeerayanon
CEO
Sufficiency Economy City Co., Ltd.

Bill Zhangjiansheng
CEO
ZMBY

TERRAPOD
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ZMBY CO., LTD.

SKYMED

ISO 13485:2016

CERTIFICATE ◆ 认证证书 ◆ CERTIFICATE ◆ 认证证书

POSI

CERTIFICATE

This is to certify that the Quality Management System of

Changzhou universalmedical equipment Co., Ltd.

Business License Number: 913204113141873659

Registered Address: No.6, Xinxi Road, Xinbei District,

Changzhou City, Jiangsu Province, China

Audit Address: No.6, Xinxi Road, Xinbei District,

Changzhou City, Jiangsu Province, China

applicable to

Production and Sales of Inspection Gloves

has been assessed and registered by POSI against the provisions of

ISO13485:2016

This registration is subject to the company maintaining a quality management system, to the above standard, which will be monitored by POSI.

Please consult the website: www.posicert.com

The certificate information is also available on the CNCA official website: http://cx.cnca.cn.

ANAB ACCREDITED MANAGEMENT SYSTEMS CERTIFICATION BODY

IAF MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT

General Manager

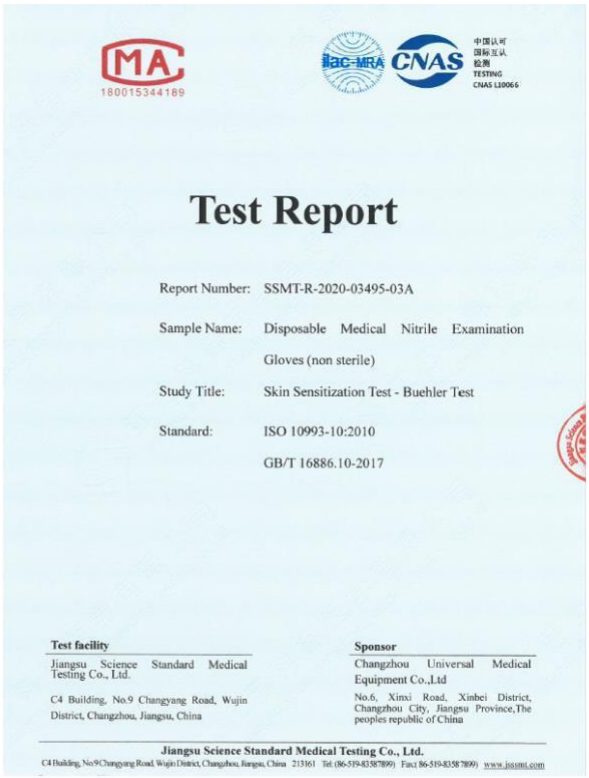
Certificate Registration No.: 381200159R0S

Initial issue date: 2020.12.18 Issue date: 2020.12.18 Valid until: 2023.12.17

Shanghai POSI Certification Co., Ltd.

Room 1002A, No.1500, Century Avenue, Pudong New Area, Shanghai ,China Email:info@posicert.com

ISO 10933



MA 180015344189

CNAS 中国认可 国际互认 检测 TESTING CNAS L10066

Test Report

Report Number: SSMT-R-2020-03495-03A

Sample Name: Disposable Medical Nitrile Examination Gloves (non sterile)

Study Title: Skin Sensitization Test - Buehler Test

Standard: ISO 10993-10:2010
GB/T 16886.10-2017

Test facility
Jiangsu Science Standard Medical Testing Co., Ltd.
C4 Building, No.9 Changyang Road, Wujin District, Changzhou, Jiangsu, China

Sponsor
Changzhou Universal Medical Equipment Co.,Ltd
No.6, Xinxi Road, Xinbei District, Changzhou City, Jiangsu Province,The peoples republic of China

Jiangsu Science Standard Medical Testing Co., Ltd.
C4 Building, No.9 Changyang Road, Wujin District, Changzhou, Jiangsu, China 213161 Tel:(86-519-83587899) Fax:(86-519-83587899) www.jssmtj.com

Report No.: SSMT-R-2020-03495-03A

Study verification and signature

The study was carried out in accordance with the standard operating procedure. The test process was conducted in compliance with the requirements of CNAS-CL01:2018 (ISO/IEC17025:2017, IDT) and RB/T214-2017.

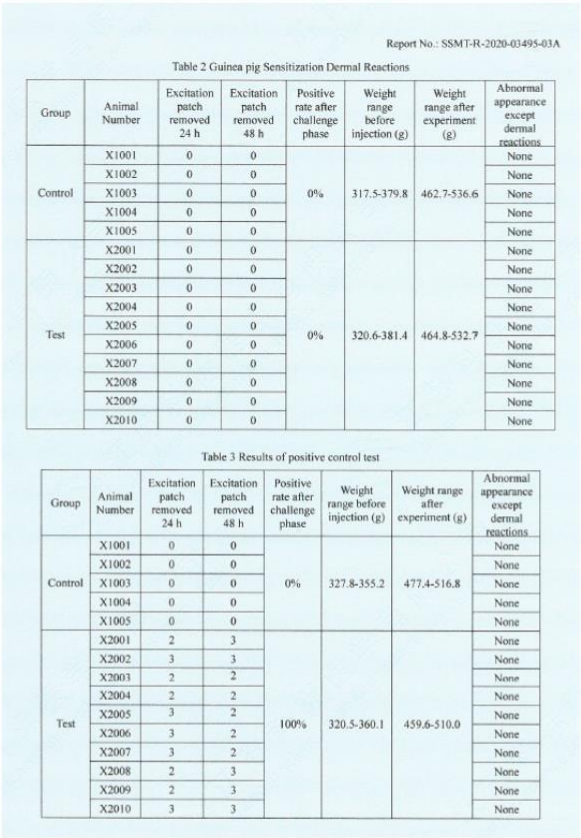
Date Received	2020-12-02
Technical Initiation Date	2020-12-07
Technical Completion Date	2021-01-07
Final Report Completion Date	2021-01-07

Edited by Molly Liu Date 2021.01.07

Checked by Sunri Han Date 2021.01.07

Approved by Jiang Tong Authorized signatory Date 2021.01.07

Jiangsu Science Standard Medical Testing Co., Ltd.



Report No.: SSMT-R-2020-03495-03A

Table 2 Guinea pig Sensitization Dermal Reactions

Group	Animal Number	Excitation patch removed 24 h	Excitation patch removed 48 h	Positive rate after challenge phase	Weight range before injection (g)	Weight range after experiment (g)	Abnormal appearance except dermal reactions
Control	X1001	0	0	0%	317.5-379.8	462.7-536.6	None
	X1002	0	0				None
	X1003	0	0				None
	X1004	0	0				None
	X1005	0	0				None
Test	X2001	0	0	0%	320.6-381.4	464.8-532.7	None
	X2002	0	0				None
	X2003	0	0				None
	X2004	0	0				None
	X2005	0	0				None
	X2006	0	0				None
	X2007	0	0				None
	X2008	0	0				None
	X2009	0	0				None
	X2010	0	0				None

Table 3 Results of positive control test

Group	Animal Number	Excitation patch removed 24 h	Excitation patch removed 48 h	Positive rate after challenge phase	Weight range before injection (g)	Weight range after experiment (g)	Abnormal appearance except dermal reactions
Control	X1001	0	0	0%	327.8-355.2	477.4-516.8	None
	X1002	0	0				None
	X1003	0	0				None
	X1004	0	0				None
	X1005	0	0				None
Test	X2001	2	3	100%	320.5-360.1	459.6-510.0	None
	X2002	3	3				None
	X2003	2	2				None
	X2004	2	2				None
	X2005	3	2				None
	X2006	3	2				None
	X2007	3	2				None
	X2008	2	3				None
	X2009	2	3				None
	X2010	3	3				None

EN 420

SATRA TECHNOLOGY **TECHNICAL REPORT**

Testing

Testing was carried out in accordance with EN ISO 21420: 2020 and EN 374-2: 2019.

Samples for testing were conditioned for at least 24 hours in a conditioned environment maintained at (23±2) °C and (50±5) % relative humidity.

Requirements

Table 1 – Requirements for EN ISO 21420: 2020 Clause 5.2 Dexterity

Performance level	1	2	3	4	5
Diameter of dexterity pin /mm	11.0	9.5	8.0	6.5	5.0

Table 2 - Requirements for EN ISO 374-2: 2019

Clause 7.2 Air leak	No leak to be detected
Clause 7.3 Water leak	No leak to be detected

SATRA TECHNOLOGY **TECHNICAL REPORT**

Test Results

Table 3 – EN ISO 21420:2020 Test Results.

Clause / Test	Requirement	Test Results				UoM (See note ♣)	Result
		Size	Length /mm 1	2	3		
5.1 Glove length, comfort and fit	N/A	5 Comfortable on fit	233	234	235	± 1.10 mm	N/A
		6 Comfortable on fit	240	240	239		
		7 Comfortable on fit	241	241	240		
		8 Comfortable on fit	239	239	238		
		9 Comfortable on fit	241	240	238		
		Size	Minimum pin diameter / mm				
5.2 Dexterity	See table 1	5	5.0			N/A	Level 5
		6	5.0				
		7	5.0				
		8	5.0				

Additional Information / Notes

Note ♣ – Estimated uncertainty of measurement applied at point of test (e.g. to applied force or to tolerance limits) to ensure product meets requirements of the standard.

SATRA TECHNOLOGY **TECHNICAL REPORT**

Polycyclic Aromatic Hydrocarbons (PAHs) Content - EN ISO 21420:2020

Test Method : With reference to test method PD CEN ISO/TS 16190:2013

Maximum Allowable Limit:	Each of all listed PAHs: 1.0 mg/kg

Tested Item(s)	Result			Conclusion
	Detected Analyte(s)	Conc.	Unit	
I001	ND	ND	mg/kg	PASS

Note / Key : ND = Not detected(<Detection Limit) Detection Limit (mg/kg) : Each : 0.2;
mg/kg = milligram per kilogram = ppm = part per million

Remark: The list of polycyclic aromatic hyrdocarbons is summarized in table of Appendix.

APPENDIX

List of Polynuclear Aromatic Hydrocarbons:

No.	Name of Analytes	CAS-No.	No.	Name of Analytes	CAS-No.
1	Chrysene	218-01-9	5	Dibenzo (a,h) anthracene	53-70-3
2	Benzo (a) pyrene	50-32-8	6	Benzo (b) fluoranthene	205-99-2
3	Benzo (e) pyrene	192-97-2	7	Benzo (j) fluoranthene	205-82-3
4	Benzo (a) anthracene	56-55-3	8	Benzo (k) fluoranthene	207-08-9

Dimethylformamide(DMFA) Content - EN ISO 21420:2020

Test Method : With reference to EN 16778:2016, and then analyzed by Gas Chromatograph Mass Spectrometer.

Analyte	Unit	Result Test Item(s) I001	Client's Requirement
Dimethylformamide(DMFA)	mg/kg	ND	1000
Conclusion	-	PASS	-

Note / Key : ND = Not detected (<Detection Limit) Detection Limit (mg/kg) : 5
mg/kg = milligram per kilogram = ppm = part per million

*** End of Report ***

EN 374

SATRA TECHNOLOGY

SATRA Technology Centre Ltd
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0248

Customer details: SATRA Technology Services (Dongguan) Ltd
Unit 110, Xinzhongyin Garden
Hongwei Road
Xiping, Nancheng District
DONGGUAN CITY
Guangdong Province
China
523079

SATRA reference: CHM0306070/2050/LC /B
Your reference: CHT0305808
Date of report: 25th January 2021
Samples received: 8th December 2020
Date(s) work carried out: 15th to 21st January 2021

TECHNICAL REPORT

SATRA Technology Services (Dongguan) Ltd:

Customer: Changzhou Universal Medical Equipment Co., Ltd
No.6, Xinxi Road,
Xinbei District,
Changzhou City
Jiangsu Province
China

Subject: EN ISO 374-4:2019 determination of resistance to degradation by dangerous chemicals on gloves described as Disposable Powder free Nitrile gloves referenced as WN-N001, colour: blue.

Conditions of Issue:

This report may be forwarded to other parties provided that it is not changed in any way. It must not be published, for example by including it in advertisements, without the prior, written permission of SATRA.

Results given in this report refer only to the samples submitted for analysis and tested by SATRA. Comments are for guidance only.

Tests marked # fall outside the UKAS Accreditation Schedule for SATRA. All interpretations of results of such tests and the comments based upon them are outside the scope of UKAS accreditation and are based on current SATRA knowledge.

A satisfactory test report in no way implies that the product tested is approved by SATRA and no warranty is given as to the performance of the product tested. SATRA shall not be liable for any subsequent loss or damage incurred by the client as a result of information supplied in the report.

The uncertainty of the results (UoM) in this report is based on a standard uncertainty multiplied by a coverage factor k=2, which provides a coverage probability of approximately 95%.

Report signed by: Lucy Cove
Position: Technologist
Department: Chemical & Analytical Technology

SATRA TECHNOLOGY

SATRA Technology Services (Dongguan) Ltd
Unit 110, Xinzhongyin Garden, Xiping
Nancheng District, Dongguan City
Guangdong Province, China
Tel: +86 (0) 769 22888020
email: info@satrafe.com

Customer details: Changzhou Universal Medical Equipment Co., Ltd
No.6, Xinxi Road,
Xinbei District,
Changzhou City
Jiangsu Province
China

SATRA reference: CHT0305808 /2049
Your reference: WN-N001
Date of report: 23 December 2020
Samples received: 4 December 2020
Date(s) work carried out: 11 December 2020

TECHNICAL REPORT

Subject: EN ISO 21420: 2020 size & dexterity & innocuousness test, EN ISO 374-2: 2019 air leak and water leak, EN ISO 374-5: 2016 viruses test on Disposable Powder free Nitrile gloves referenced as WN-N001, colour: blue, size: XS5, S6, M7, L8, XL9

Conditions of Issue:

This report may be forwarded to other parties provided that it is not changed in any way. It must not be published, for example by including it in advertisements, without the prior, written permission of SATRA.

Results given in this report refer only to the samples submitted for analysis and tested by SATRA. Comments are for guidance only.

A satisfactory test report in no way implies that the product tested is approved by SATRA and no warranty is given as to the performance of the product tested. SATRA shall not be liable for any subsequent loss or damage incurred by the client as a result of information supplied in the report.

The uncertainty of the results (UoM) in this report is based on a standard uncertainty multiplied by a coverage factor k=2, which provides a coverage probability of approximately 95%.

Report signed by: Gladys He
Position: Technologist
Department: China Testing

SATRA TECHNOLOGY

TECHNICAL REPORT

WORK REQUESTED

Samples described as Disposable Powder free Nitrile gloves referenced as WN-N001, colour: blue, size: XS5, S6, M7, L8, XL9 were received by SATRA on 4 December 2020 for testing in accordance with EN ISO 21420: 2020, EN ISO 374-2: 2019 and EN ISO 374-5: 2016.

SAMPLE SUBMITTED

Samples described as Disposable Powder free Nitrile gloves referenced as WN-N001, colour: blue, size: XS5, S6, M7, L8, XL9

TESTING REQUESTED

EN ISO 21420: 2020 Clause 5.1 – Sizing and measurement of gloves
EN ISO 21420: 2020 Clause 5.2 – Dexterity
EN ISO 21420: 2020 Clause 4.2 – Innocuousness of protective gloves
EN ISO 374-5: 2016 Clause 5.3 – Protection against viruses (ISO 16604: 2004 Procedure B)
EN 374-2: 2019 Clause 7.2 – Air leak
EN 374-2: 2019 Clause 7.3 – Water leak

CONCLUSION

The samples described Disposable Powder free Nitrile gloves referenced as WN-N001, colour: blue, size: XS5, S6, M7, L8, XL9 were found to achieve the following results:

EN ISO 21420: 2020 Clause 5.1 – See below table
EN ISO 21420: 2020 Clause 5.2 – Level 5
EN 374-2: 2019 Clause 7.2 – Pass
EN 374-2: 2019 Clause 7.3 – Pass
EN ISO 374-5: 2016 Clause 5.3 – Pass
EN ISO 21420: 2020 Clause 4.2 – Pass PAHs, pH value and DMFA

Detailed results are included on the following page(s)

SATRA TECHNOLOGY

TECHNICAL REPORT

Table 4 – EN ISO 374-2: 2019 Test Results

Clause / Test	Test Results		UoM	Result
7.2 Air leak test	Total air pressure used	2.9 kPa	NA	Pass
	Sample size	Leaks		
	5	No leaks detected		
	6	No leaks detected		
	7	No leaks detected		
	8	No leaks detected		
	9	No leaks detected		
7.3 Water leak test	Sample size	Leaks	NA	Pass
	5	No leaks detected		
	6	No leaks detected		
	7	No leaks detected		
	8	No leaks detected		
	9	No leaks detected		

TERRAPOD
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ZMBY CO.,LTD.

SKYMED

SATRA TECHNOLOGY

TECHNICAL REPORT

Protection Against Viruses Test Results

Testing was conducted at a third-party laboratory and reported under their reference 20R007214. The laboratory is CNAS accredited to ISO 17025: 2017 with ISO 16604: 2004 included in their accreditation schedule.

Table 1 – Resistance to penetration by blood-borne pathogens results

Sample description:		Disposable Powder free Nitrile gloves referenced as WN-N001, colour: blue, size: XS5, S6, M7, L8, XL9				
Test method	**Specimen**	**Step 1 (0 kPa, 5 min)**	**Step 2 (14 kPa, 1min)**	**Step 3 (0kPa, 4min)**	**Assay titer (PFU /mL)**	**Comment**
ISO 16604: 2004 Procedure B Using retaining screen	+ control	seen	seen	seen	seen	Acceptable
	- control	None seen	None seen	None seen	< 1	Acceptable
	1	None seen	None seen	None seen	< 1	Pass
	2	None seen	None seen	None seen	< 1	Pass
	3	None seen	None seen	None seen	< 1	Pass

SATRA TECHNOLOGY

TECHNICAL REPORT

Innocuousness Testing

Testing was conducted at a third-party laboratory and reported under their reference A201209024001. The laboratory is CNAS accredited to ISO 17025: 2017.

Sample Item	Sample Description	Location	Style
I001	Disposable Powder free Nitrile gloves referenced as WN-N001, colour: blue	Gloves	-

pH Value - EN ISO 21420:2020

Test Method I : With reference to EN ISO 4045:2018, analyzed by pH meter.
Test Method II: With reference to ISO 3071:2020, analyzed by pH meter.

Requirement:	3.5-9.5

-	Unit	Result
Test Item(s)	-	I001
Test Method	-	II
Parameter	-	-
pH Value of Extracting Solution	-	5.46
Temp. of Aqueous Extract	deg. C	25.2
pH Value of Aqueous Extract	-	7.5
Difference Figure	-	-
Conclusion	-	PASS

Note / Key : deg. C = degree Celsius (°C) Temp. = Temperature
Remark: Result(s) was (were) reported the average value from two trials.

Changzhou Universal Medical Equipment Co., Ltd
SATRA Reference: CHT0305808 /2049
Date: 23 December 2020 (Page 7 of 10)
Signed: Gladys He, China Testing

SATRA TECHNOLOGY

TECHNICAL REPORT

0248

RESULTS:

Sample description:	Disposable Powder free Nitrile gloves referenced as WN-N001, colour: blue		
Challenge chemical:	40% Sodium hydroxide (CAS: 1310-73-2)		
Test temperature / °C:	(23 ± 1)		
Degradation / %:	Glove 1	Glove 2	Glove 3
	-48.6	-90.7	-123.9
Mean degradation (DR) / %:	-87.7		
Standard deviation (σ_{DR}) / %:	37.7		
UoM / ± %:	6.4		
Appearance of samples after testing:	Swollen		

Sample description:	Disposable Powder free Nitrile gloves referenced as WN-N001, colour: blue		
Challenge chemical:	30% Hydrogen peroxide (CAS: 7722-84-1)		
Test temperature / °C:	(23 ± 1)		
Degradation / %:	Glove 1	Glove 2	Glove 3
	4.1	36.3	15.4
Mean degradation (DR) / %:	18.6		
Standard deviation (σ_{DR}) / %:	16.4		
UoM / ± %:	7.9		
Appearance of samples after testing:	Swollen		

Sample description:	Disposable Powder free Nitrile gloves referenced as WN-N001, colour: blue		
Challenge chemical:	37% Formaldehyde (CAS: 50-00-0)		
Test temperature / °C:	(23 ± 1)		
Degradation / %:	Glove 1	Glove 2	Glove 3
	5.8	-42.0	-29.8
Mean degradation (DR) / %:	-22.0		
Standard deviation (σ_{DR}) / %:	24.9		
UoM / ± %:	6.9		
Appearance of samples after testing:	Swollen		

NOTE: Where the test specimens gave an increased puncture force after chemical exposure, the result is reported as a negative degradation.

SATRA Technology Services (Dongguan) Ltd
SATRA Reference: CHM0306070/2050/LC/B
Date: 25th January 2021 (Page 3 of 5)
Signed:

EN 455

Test Report No. 7191243138-EEC20-LDY
dated 17 Sep 2020

PSB Singapore

Add value. Inspire trust.

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:

Testing of Gloves submitted by Changzhou Universal Medical Equipment Co., Ltd on 26 Aug 2020.

TESTED FOR:

Changzhou Universal Medical Equipment Co., Ltd
No.6, Xinxi Road,
Xinbei District, Changzhou City
Jiangsu Province

TEST DATE:

26 Aug 2020 to 09 Sep 2020

DESCRIPTION OF SAMPLES:

S/N	Product Description	Colour	Lot No.	Size	Sample received (pieces)	Manufacturer
1	Disposable medical examination gloves (non sterile)	Purple	(see Remark 1)	XL	400	Changzhou Universal Medical Equipment Co., Ltd

Lot size as specified by client: 150,001 to 500,000 pieces

TÜV SÜD PSB

RaC-MRA

Accredited Laboratory SAC-SINGLAS

The results reported herein have been performed in accordance with the terms of accreditation under the Singapore Accreditation Council - Inspections/Calibrations/Tests marked "Not SAC-SINGLAS Accredited" in this Report are not included in the SAC-SINGLAS Accreditation Schedule for our inspection body/laboratory.

Laboratory:
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Singapore 118221

Phone: +65 6885 1333
Fax: +65 6779 8670
E-mail: enquiries@tuvsud.com
https://www.tuvsud.com/en-sg
Co.Reg: 199002ba3R

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

Test Report No. 7191243138-EEC20-LDY
dated 17 Sep 2020

PSB Singapore

METHOD OF TEST:

1. EN 455-1:2020 Medical gloves for single use
   Part 1: Requirements and testing for freedom from holes
2. EN 455-2:2015 Medical gloves for single use
   Part 2: Requirements and testing for physical properties
   - Clause 4 Dimensions
   - Clause 5 Strength
3. EN 455-3:2015 Medical glove for single use
   Part 3: Requirements and testing for biological evaluation
   - Clause 4.4 Powder-free gloves

RESULTS:

Sample: Disposable medical examination gloves (non sterile), Purple, Size XL

Table 1: Results for EN 455-1:2020

Clause	Tests	Requirements	No. of non-compliers allowed (pieces)	Number tested (pieces)	Actual no. of non-compliers found (pieces)	Inferred results
4 5	Freedom from holes	Shall not leak	10	315	8	Passed

Table 2: Results for EN 455-2:2015 Clauses 4-5

Clause	Tests	Requirements (Median)	Number tested (pieces)	Results (Median)	Inferred results
4	Dimensions a) Length (mm)	≥ 240	13	243	Passed
	b) Width (mm)	For Size XL: ≥ 110	13	114	Passed
5	Strength a) Force at break (N)	For nitrile examination gloves: ≥ 6.0	13	7.1	Passed
	b) Force at break after challenge testing (N) 7 days at (70±2)°C	For nitrile examination gloves: ≥ 6.0	13	7.3	Passed

Table 3: Results for EN 455-3:2015 Clause 4.4

Clause	Tests	Requirements	Results / Remarks	Inferred results
4.4 5.2	Powder-free gloves	For powder-free gloves: The total quantity of powder residues shall not exceed 2 mg per glove.	0.27 mg per glove	Passed

常州万能医疗器材有限公司
Changzhou Universal Medical Equipment Co., Ltd

检验检测报告 Inspection and Testing Report

No: WN007 共5页 第1页 Five pages 1st page

单位 Company	常州万能医疗器材有限公司 地址：常州市新北区信息大道6号 Changzhou Universal Medical Equipment Co., Ltd Address: No.6, Xinxi Road, Xin Bei District, Changzhou City				
样品信息 Sample Information	一次性医用丁腈检查手套（非灭菌） Disposable Medical Nitrile Examination Gloves (Non-sterile)				
检验性质 Nature of Inspection	检测 Testing	测试开始日期 Testing Start Date	2020年7月23日 July 23rd, 2020	报告日期 Report Date	2021年2月1日 February 1st, 2021
判定依据 Judgment basis	EN 455-4 2009《储存测定实验和要求》 EN 455-4 2009《Storage determination experiment and requirements》				
综合检验结论 Comprehensive inspection conclusion					

	检验检测项目 Inspection and testing items	判定依据 Judgment basis	判定 Judgment
检验检测 Inspection and testing	针孔Pinhole	EN 455-1 2020	合格 Qualified
	尺寸Dimension	EN 455-2 2015	合格 Qualified
	抗撕强力Tear strength	EN 455-2 2015	合格 Qualified

备注 Remark: 本报告中检验检测项目均在相应标准规定的条件下进行（有注明的除外）。复印件、副本未重新加盖报告书确认章无效。
The inspection and testing items in this report are all carried out under the environmental conditions specified by the corresponding standards (except specified items) Copies, duplicates without re-stamping the report confirmation is invalid

签发Signed by: Eric

检验检测第一批次报告附页
Report attachment to the first batch of inspection and testing

测试日期：2020年7月23日 date: 月 日 2020

No: WN007 共5页 第3页 Five pages 3rd page

检验检测项目 Inspection and testing items	要求Requirement	不合格允许（个）Allowance of disqualification (piece)	测试数量（个）Testing quantity (piece)	实际数量不合格者找到（个）Disqualification found in actual quantity (piece)	判定 Judgement	备注 Remark
针孔Pinhole	不得泄露 No leakage	12	500	2	合格 Qualified	

项目Item	检验检测项目 Inspection and testing items	要求Requirement	测试的数量 Testing quantity (piece)	结果Result	判定 Judgement	备注 Remark
尺寸Dimension	长度 Length (mm)	≥240	13	243	合格 Qualified	
	宽度Width (mm)	≥110	13	114	合格 Qualified	
拉断强力Tear strength	断裂力 Breakage force (N)	≥6	13	7.5	合格 Qualified	
	断裂力使用后测试（N）7天（70±2）摄氏度7 days after breakage force is used (70±2) Celsius	≥6	13	7.3	合格 Qualified	

1. 本实验共抽取了3000只样品，共分为3批次，本次检测周期为7天。2. 本次实验在本公司实验室中进行。本次测试温度为70±2摄氏度（实验室环境湿温度为受控状态）1. A total of 3,000 samples were taken in this experiment, divided into 3 batches, and the test cycle is 7 days. 2. This experiment is carried out in our company's laboratory. The temperature of this test is 70±2 degrees Celsius, and the temperature and humidity in the laboratory are under controlled conditions.

备注Remark	（本栏空白）This column is blank

CCI Report

CCI(BEIJING) INTERNATIONAL BUSINESS SERVICE CO.,LTD
ADD: Suite 6175, No.9 Haifu Rd, Dalian Bonded Area, Free Trade Zone, Liaoning
Tel: 0086-411-39887856 Fax:0086-411-39887603
Website: www.cci-china.cc
Email: angel@cci-china.cc
Skype:cci.daivd

According to the client's request, the inspector checked the factory condition, the results with pictures show below:

Factory:

Factory:

Factory:

Pilde cartons:

Pilde cartons:

CCI(BEIJING) INTERNATIONAL BUSINESS SERVICE CO.,LTD
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3. Package:

Carton Color	White			Package Specification			Attached in pictures					
Dunage	N			Size of carton			Attached in pictures					
Sample number	01-03 Size M, 04-06 Size L, 07-09 Size S, 10-12 Size XL											
	01	02	03	04	05	06	07	08	09	10	11	12
	Size M			Size L			Size S			Size XL		
Weight(g)	5160	5120	5180	5200	5260	5220	5260	5240	5200	5340	5280	5220
Package weight(g)	767	767	767	767	767	767	767	767	767	767	767	767
Caclulated net weight(g)	4393	4353	4413	4433	4493	4453	4493	4473	4433	4573	4513	4453

Package pictures:

Gross weight per carton:

Gross weight per carton:

Weight of empty carton:

Weight of empty box:

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Email: angel@cci-china.cc
Skype:cci.daivd

Water leakage test:

Water leakage test:

Inspection time	July 9th, 2021					
Specification	Size(mm)		Thickness(mm)			No. Of pcs per box
	Weigh t(g)	Lengt h	Cuff	Palm	Finger tip	
M	4.4	238	6.0	6.5	11.8	100
M	4.4	240	6.1	6.7	11.9	100
M	4.4	236	5.8	6.6	12.1	100
L	4.5	237	6.0	6.9	12.6	100
L	4.5	239	6.0	7.1	12.4	100
L	4.4	240	5.8	7.0	12.1	100
XL	4.6	240	6.2	7.0	12.1	100
XL	4.5	241	6.0	7.1	11.8	100
XL	4.6	242	5.9	6.9	12.2	100
S	4.3	236	5.8	6.8	12.1	100
S	4.4	238	5.8	6.6	12.0	100

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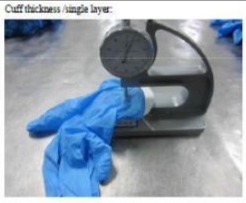
Cuff thickness /single layer:



Finger thickness/2 layers:

Tensile test:

Tensile test:

Firmness test:

Firmness test:

SGS Report

SGS-P-7.4-01-F02-CRS-HL-EPM

Report No.: TSNWT00084623

8. Inspection Environment:

Lighting :	Daylight Sufficient
Inspection place :	Factory workshop
Inspection done on:	Table
Cleanliness :	Clean
Weather condition:	Dry
Cargo storage:	Orderly, easy to count

9. Attachment


1 factory gate.JPG


2 storage(1).JPG


2 storage(2).JPG


2 storage(3).JPG

Inspector: Devin Pei Factory Representative: Mrs.Xiong

SGS-P-7.4-01-F02-CRS-HL-EPM

Report No.: TSNWT00084623

Weight check	8pcs/size	S size: 4.2g, 4.3g, 4.3g, 4.3g, 4.4g, 4.3g, 4.3g, 4.4g. M size: 4.4g, 4.4g, 4.4g, 4.4g, 4.4g, 4.4g, 4.4g, 4.4g, 4.5g. L size: 4.4g, 4.5g, 4.5g, 4.5g, 4.4g, 4.5g, 4.5g, 4.4g. XL size: 4.8g, 4.7g, 4.8g, 4.7g, 4.7g, 4.7g, 4.9g, 4.8g.	N/A
Water leakage test	500pcs	Acceptable (No found leakage)	Fill fully in the glove with water and wait for 4min
Smell check	500pcs	Acceptable	No odor
Unit pack quantity check	3packs/size	M size:100pcs, 100pcs, 100pcs. L size: 100pcs, 100pcs, 100pcs. XL size: 100pcs, 100pcs, 100pcs.	Artwork:100pcs/box
Fitting function check	8pcs/size	Acceptable	The glove should cover each finger and the palm of the hand until the wrist.
Tensile strength test	8pcs/size	Size S: 9.8N, 580%, 9.2N, 590%, 8.2N, 570%,8.8N, 580%, 8.4N, 580%,7.6N, 560%, 8.2N, 550%,7.9N, 570%, 8.6N, 610%,8.1N, 570%, 7.4N, 600%,7.2N, 5890%, 7.8N, 570%, Size M: 8.5N, 570%, 9.5N, 610%, 7.2N, 540%,8.2N, 570%, 7.8N, 620%,7.5N, 570%, 8.3N, 580%,8.3N, 580%, 9.8N, 610%,8.4N, 550%, 7.1N, 570%,7.9N, 550%, 8.8N, 570%, Size L: 7.9N, 540%, 6.6N, 510%, 8.4N, 570%,7.8N, 570%, 10.1N, 610%,8.2N, 560%, 9.3N, 590%,7.8N, 580%, 7.5N, 540%,9.2N, 560%, 9.2N, 620%,9.0N, 550%, 9.1N, 580%, Size XL: 8.7N, 560%, 9.2N, 590%, 8.8N, 580%,8.8N, 590%, 8.4N, 550%,9.1N, 580%, 9.1N, 570%,7.5N, 580%, 8.4N, 570%,7.6N, 580%, 8.4N, 550%,8.0N, 570%, 7.7N, 540%,	The breaking force shall not be less than 6N Ultimate elongation: 500% Min.

Inspector: Devin Pei Factory Representative: Mrs.Xiong

SGS-P-7.4-01-F02-CRS-HL-EPM

Report No.: TSNWT00084624

Problem Remark:

1. Actual found CE mark on carton and color box, but the shape of logo was a little different from standard request on 93/68/EEC (CE Marking Directive), and height of CE mark on box was about 4mm, but standard required the height of CE mark minimum height was 5mm.


CE size check(1).JPG


CE size check(2).JPG

2. For long barcode on color box, it can't be scanned by SGS scanner, but can be scanned by mobile phone.


Remark-1 long barcode can't be scanned by SGS scanner.JPG


Remark-1 long barcode can't be scanned by SGS scanner.JPG

Inspector: Marco Zhong Factory Representative: Ms. Xiong

SGS-P-7.4-01-F02-CRS-HL-EPM

Report No.: TSNWT00084624


Remark-1 long barcode can't be scanned by SGS scanner.JPG


Remark-1 long barcode can't be scanned by SGS scanner.JPG

3.Actually found the factory name was "Jiangxi Hongda Medical Equipment Group Ltd.", but "Changzhou Universal Medical Equipment Co., Ltd." was showed on export carton, color box and certificate of conformity.

4.No reference sample available for comparison during inspection.

5.No received spec. during inspection, please refer to photos and actual finding for details.

6.No found PO number and carton number on bulk. The cargo that SGS inspected was only through the factory responsible person assignment.

7.Unable to check product material identification on site.

8.Actual found executive standard "EN455-1,2,3,4 / MDR 2017/745 and ISO374-1,2,4,5" printed on the master carton & color box, and "GB4806.11-2016 / EN374-1:2016 + A1:2018 Type B / EN374-5:2016" printed on the certificate label.

9.The manufacturer of certificates was "Changzhou Universal Medical Equipment Co., Ltd". It conformed with bulk, but actually inspection factory name was "Jiangxi Hongda Medical Equipment Group Ltd.".

1. Quantity: Conform

No	Style / Item/ Article	P.O. No.	Order Qty.	Inspection Qty. (Presented Qty. for insp.)		Number of Cartons	
				Packed	Not Packed	Packed	Not packed
1	S	N/A	1540000	1540000	0	1540	0
2	M	N/A	4560000	4560000	0	4560	0
3	L	N/A	4880000	4880000	0	4880	0
4	XL	N/A	1220000	1220000	0	1220	0
		Total:	12200000	12200000	0	12200	0

2. Style & Color Conformity: Subject to client's evaluation

Comments:

-No ref. sample was available for comparison during inspection.

Inspector: Marco Zhong Factory Representative: Ms. Xiong

UDI Code

7 Tensile strength(2).JPG

7 Tensile strength(3).JPG

8 UDI code scanned check(1).JPG

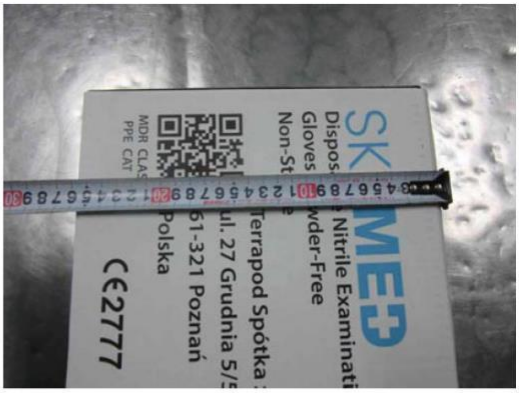
8 UDI code scanned check(2).JPG

8 UDI code scanned check(3).JPG

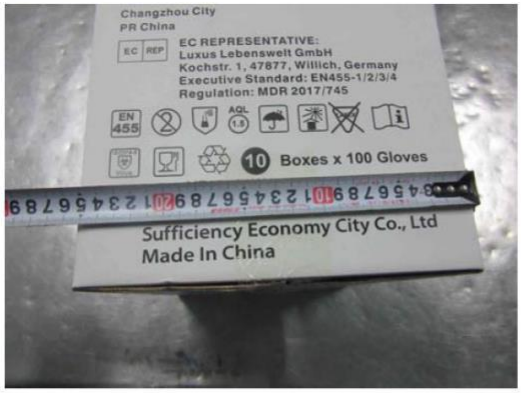
8 UDI code scanned check(4).JPG

Karton

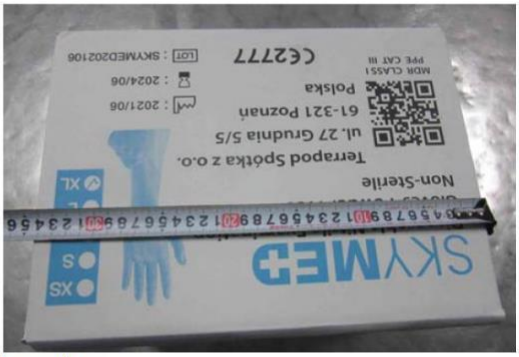
Carton size:



Carton size:



Carton size:



Carton thickness:

Open carton:

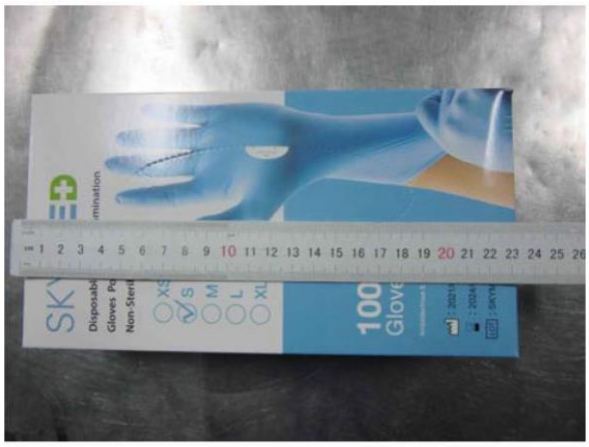
Open carton:

Pilde cartons:

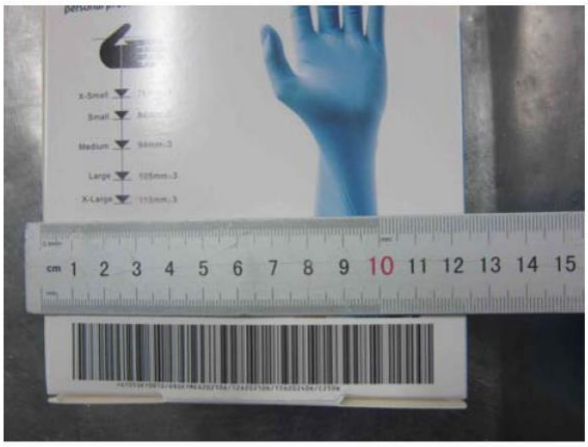
Pilde cartons:

Box

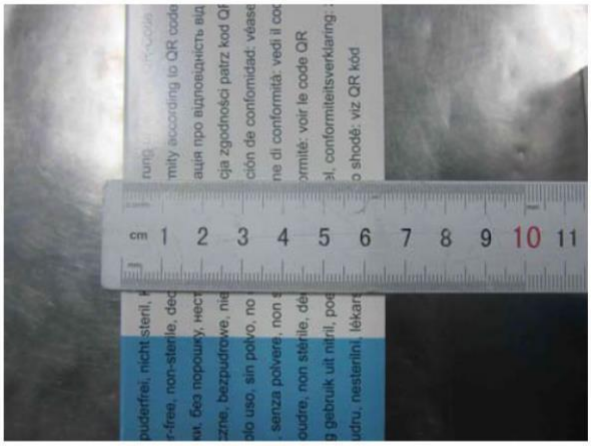
Box size:



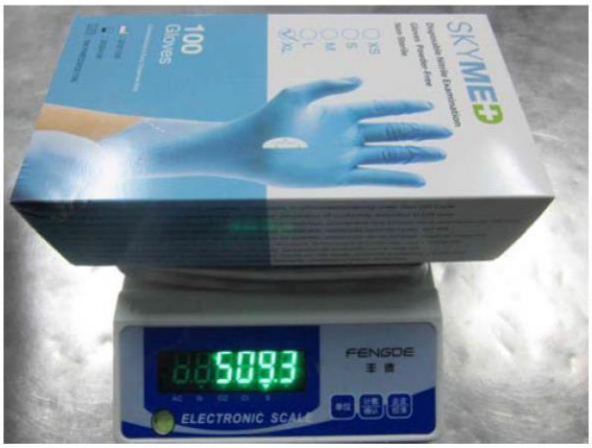
Box size:



Box size:



Box weight:



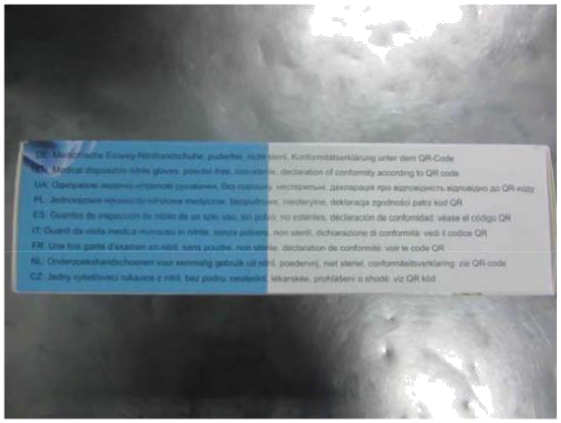
Box weight:

Box: L

Box: L

Box: L

Box: L



Box: L

Box: L

Rękawiczki

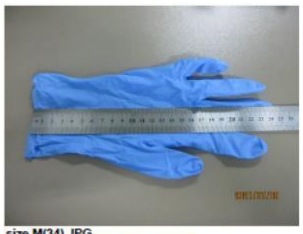
Open box:

Open box:

size S(25).JPG

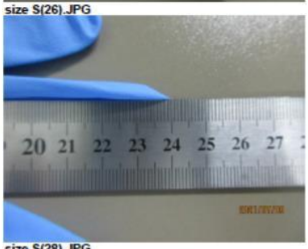
size S(26).JPG

size M(33).JPG

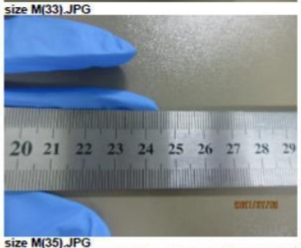


size M(34).JPG

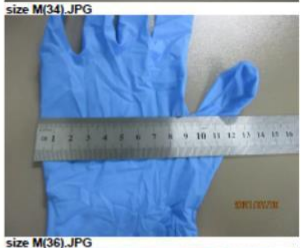
size S(27).JPG



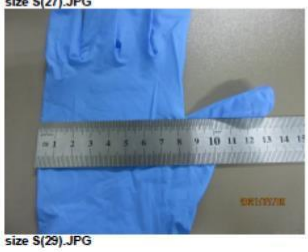
size S(28).JPG



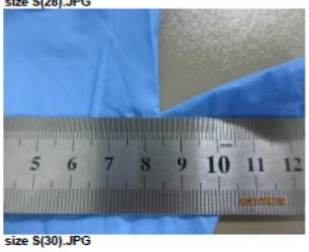
size M(35).JPG



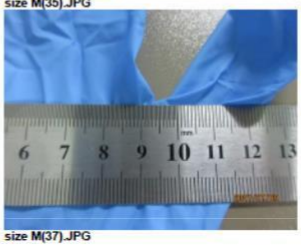
size M(36).JPG



size S(29).JPG



size S(30).JPG



size M(37).JPG

size M(38).JPG

Zgodność z Rozporządzeniem (UE) 2016/425 o środkach ochrony indywidualnej oraz normami zharmonizowanymi :
EN ISO 374 - 1 : Rękawice Chroniące przed substancjami a chemicznymi i mikroorganizmami cz. 1
EN 374 – 2: Rękawice Chroniące przed substancjami chemicznymi i mikroorganizmami cz. 2 Wyznaczanie
EN 16523 - 1 : Odporność na przenikanie czynników chemicznych
EN 374 – 4 : Badanie degradacji
EN ISO 374 -5 : Odporność na bakterie grzyby i wirusy plus EN ISO 374-5 VIRUS na Sars -2-Cov
EN 420 : Rękawice ochronne. Wymagania ogólne i metody
przenikalność dla wirusów zgodnie z ASTM F1671 (szczelność dla wirusów)
przenikalność dla cytostatyków 15 ASTM 6978
posiadające dokument przydatności do kontaktu z żywnością z adekwatnym piktogramem na opakowaniu
Zgodność :MDD 93/42/EEC & 2007/47/EC/ MDR 2017/745 wyrobach medycznych wyrób klasy I (informacja na opakowaniu i w Deklaracji Zgodności)
zgodność z Rozporządzeniem (UE) 2016/425 o środkach ochrony indywidualnej wyrób 3 kategorii typ B,(informacja na opakowaniu i w Deklaracji Zgodności)
zgodność z EN 455, dla produktów medycznych Określona wymagania i podaje metodę badania rękawic medycznych do jednorazowego użytku na obecność mikrouszkodzeń. Norma posługuje się pojęciem AQL 1,5 (Acceptable Quality Level – Akceptowalny Poziom Jakości).
EN 455-2 Wymagania i badania dotyczące właściwości fizycznych. Norma określa wymagania oraz podaje metody badawcze właściwości fizycznych rękawic medycznych jednorazowego użytku (rękawic chirurgicznych, rękawic diagnostycznych/zabiegowych i innych) w celu zagwarantowania, iż zapewniają one i utrzymują w czasie użytkowania odpowiedni poziom ochrony przed wzajemnym zakażeniem i zanieczyszczeniem zarówno pacjenta, jak i użytkownika.
EN 455-3 Wymagania i badania w ocenie biologicznej. Norma określa wymagania dotyczące oceny bezpieczeństwa biologicznego rękawic medycznych do jednorazowego użytku. W treści normy zostały zdefiniowane wymagania dotyczące oznakowania i pakowania rękawic oraz ujawniania informacji o zastosowanych metodach badania. Norma określa przegląd immunologicznych metod badań w celu oznaczania wymywanych białek i alergenów.
EN ISO 374- 1, badania na przenikalność dla wirusów zgodnie z EN ISO 374- 5 VIRUS oraz ASTM F1671
piktogram potwierdzający dopuszczenie rękawic do kontaktu z żywnością umieszczone fabrycznie przez producenta na opakowaniu raz potwierdzone dokumentami producenta
9Badania na przenikanie: Izopropanol 70% min. na poziomie 2 ochrony, formaldehyd 37% min. na poziomie 6, 50% aldehy I glutarowy min. na poziomie 6 ochrony , wodorotlenek sodu 40 % min. na 6 poziomie ochrony
Mikroteksturowane z dodatkową widoczną teksturą na końcach palców, polimeryzowane obustronnie, wewnętrznie
grubość na mankiecie maksymalnie 0,09 -0,092mm
grubość dłoń maksymalnie 0,14 -0,13 mm
grubość palce maksymalnie 0,21-0,19 mm
długość rękawicy minimum 240-242 mm
konstrukcja pojedynczego opakowania rękawic poprzez perforację
waga pojedynczej rękawiczki między 4,2 a 5,4 gram, co potwierdza pełną ochronę i doskonały wyrób materiałowy.
Rękawiczki są bez lateksu, przebadane na kilkanaście alergenów i są antyalergiczne. Wewnętrzna warstwa jest miękka, nieuczulająca delikatnie przylegająca do skóry a skład zgodnie z certyfikatami sprawia, ze dłonie są bezpieczne i nie występują na skórze żadne podrażnienia.

Testy na cytostatyki:

TESTING CHEMOTHERAPY DRUGS:

Table 1. List of the Testing Chemotherapy Drugs, Sources, and Expiration Dates

TESTING CHEMOTHERAPY DRUGS	DRUG SOURCE
Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)	Sigma Aldrich; Lot# 016M4028V; Expires 09/2017
Cisplatin, 1.0 mg/ml (1,000 ppm)	Fresenius Kabi; Lot# 6114286; 01/2018
Cyclophosphamide (Cytoxan), 20.0 mg/ml (20,000ppm)	Sigma Aldrich; Lot# BCBM8984V; Expiration 04/2017
Cytarabine, 100 mg/ml (100,000 ppm)	Sigma Aldrich; Lot# LRAA8717; Expiration 01/2018
Dacarbazine (DTIC), 10.0 mg/ml (10,000 ppm)	Teva; Lot# 31318323B; Expiration 10/8/2017
Doxorubicin Hydrochloride, 2.0 mg/ml (2,000 ppm)	Sigma Aldrich; Lot# SLBM7382V; Expiration 08/2017
Etoposide (Toposar), 20.0 mg/ml (20,000 ppm)	Teva; Lot# 31321666B; Expiration 09/2019
Fluorouracil, 50.0 mg/ml (50,000 ppm)	Accord; Lot# PT04300; Expiration 10/2018
Ifosfamide, 50.0 mg/ml (50,000 ppm)	Sigma Aldrich; Lot# 106K1063V; Expiation 12/2017
Methotrexate, 25 mg/ml, (25,000 ppm)	Teva; Lot# 16A28MA, Expiration 01/2018
Mitomycin C, 0.5 mg/ml (500 ppm)	Sigma; Lot# MKBR2210V; Expiration 03/2017
Mitoxantrone, 2.0mg/ml (2,000ppm)	Sigma Aldrich; Lot# MKBR2210V; Expiration 11/2017
Paclitaxel (Taxol), 6.0 mg/ml (6,000 ppm)	Hospira; Lot# C126865AA; Expiration 12/2017
Thiotepa, 10.0 mg/ml (10,000 ppm)	Sigma Aldrich; Lot# SLBQ8871V; Expiration 02/2018
Vincristine Sulfate, 1.0 mg/ml (1,000 ppm)	Sigma Aldrich; Lot# SLBQ9329V; Expiration 01/2018

TEST DRUG AND CONCENTRATION	COLLECTION MEDIUM
Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)	10% Ethanol Aqueous Solution
Cisplatin, 1.0 mg/ml (1,000 ppm)	Distilled Water
Cyclophosphamide (Cytoxan), 20.0 mg/ml (20,000ppm)	Distilled Water
Cytarabine, 100 mg/ml (100,000 ppm)	Distilled Water
Dacarbazine (DTIC), 10.0 mg/ml (10,000 ppm)	Distilled Water
Doxorubicin Hydrochloride, 2.0 mg/ml (2,000 ppm)	Distilled Water
Etoposide (Toposar), 20.0 mg/ml (20,000 ppm)	Distilled Water
Fluorouracil, 50.0 mg/ml (50,000 ppm)	9.20 pH Sodium Hydroxide Solution
Ifosfamide, 50.0 mg/ml (50,000 ppm)	Distilled Water
Methotrexate, 25 mg/ml, (25,000 ppm)	Distilled Water
Mitomycin C, 0.5 mg/ml (500 ppm)	Distilled Water
Mitoxantrone, 2.0mg/ml (2,000ppm)	Distilled Water
Paclitaxel (Taxol), 6.0 mg/ml (6,000 ppm)	30% Methanol Aqueous Solution
Thiotepa, 10.0 mg/ml (10,000 ppm)	Distilled Water
Vincristine Sulfate, 1.0 mg/ml (1,000 ppm)	Distilled Water

TESTING CONDITIONS:

Standard Test Method Used:	ASTM D 6978-05
Deviation From Standard Test Method:	Used 1" Permeation Cell
Analytical Method:	UV/VIS Spectrometry
Testing Temperature:	35.0°C ± 2.0
Collection System:	Closed Loop
Specimen Area Exposed:	5.067 cm2
Selected Data Points:	25/test
Number of Specimens Tested:	3/test
Location Sampled From:	Cuff area

TESTING CHEMOTHERAPY DRUGS	WAVELENGTH (nm)
Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)	229
Cisplatin, 1.0 mg/ml (1,000 ppm)	199
Cyclophosphamide (Cytoxan), 20.0 mg/ml (20,000ppm)	200
Cytarabine, 100 mg/ml (100,000 ppm)	272
Dacarbazine (DTIC), 10.0 mg/ml (10,000 ppm)	320
Doxorubicin Hydrochloride, 2.0 mg/ml (2,000 ppm)	232
Etoposide (Toposar), 20.0 mg/ml (20,000 ppm)	205
Fluorouracil, 50.0 mg/ml (50,000 ppm)	269
Ifosfamide, 50.0 mg/ml (50,000 ppm)	200
Methotrexate, 25 mg/ml, (25,000 ppm)	303
Mitomycin C, 0.5 mg/ml (500 ppm)	217
Mitoxantrone, 2.0mg/ml (2,000ppm)	242
Paclitaxel (Taxol), 6.0 mg/ml (6,000 ppm)	231
Thiotepa, 10.0 mg/ml (10,000 ppm)	199
Vincristine Sulfate, 1.0 mg/ml (1,000 ppm)	220

Testing Chemotherapy Drugs	Thickness (mm)			Average (mm)	Weight/Unit Area (g/m2)
	Sample 1	Sample 2	Sample 3		
Carmustine (BCNU)	0.046	0.049	0.047	0.047	
Cisplatin	0.045	0.050	0.046	0.047	
Cyclophosphamide (Cytoxan)	0.047	0.043	0.048	0.046	
Cytarabine	0.047	0.044	0.048	0.046	
Dacarbazine (DTIC)	0.048	0.049	0.045	0.047	
Doxorubicin Hydrochloride	0.050	0.052	0.046	0.049	
Etoposide (Toposar)	0.048	0.052	0.046	0.049	
Fluorouracil	0.048	0.047	0.045	0.047	52.3
Ifosfamide	0.044	0.049	0.048	0.047	
Methotrexate	0.045	0.047	0.054	0.049	
Mitomycin C	0.047	0.050	0.044	0.047	
Mitoxantrone	0.046	0.047	0.053	0.049	
Paclitaxel (Taxol)	0.048	0.042	0.044	0.045	
Thiotepa	0.047	0.049	0.043	0.047	
Vincristine Sulfate	0.045	0.044	0.048	0.046	

TEST CHEMOTHERAPY DRUG AND CONCENTRATION	MINIMUM BREAKTHROUGH DETECTION TIME (Specimen 1/2/3) (Minutes)	STEADY STATE PERM. RATE (Specimen 1/2/3) ($\mu g/cm^2$/minute)	OTHER OBSERVATIONS
Carmustine (BCNU) 3.3 mg/ml (3,300 ppm)	14.7 (15.1,14.7,16.8)	0.6 (0.5,0.5,0.7)	Moderate swelling and no degradation
Cisplatin 1.0 mg/ml (1,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Cyclophosphamide (Cytoxan) 20 mg/ml (20,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Cytarabine, 100 mg/ml (100,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Dacarbazine (DTIC) 10.0 mg/ml (10,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Doxorubicin Hydrochloride 2.0 mg/ml (2,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Etoposide (Toposar) 20.0 mg/ml (20,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Fluorouracil 50.0 mg/ml (50,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Ifosfamide, 50.0 mg/ml (50,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Methotrexate 25 mg/ml (25,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Mitomycin C 0.5 mg/ml (500 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Mitoxantrone, 2.0mg/ml (2,000ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Paclitaxel (Taxol) 6.0 mg/ml (6,000 ppm)	No breakthrough up to 240 min.	N/A	Moderate swelling and no degradation
Thiotepa 10.0 mg/ml (10,000 ppm)	58.8 (110.0,58.8,67.0	0.5 (0.3,0.5,0.6)	Slight swelling and no degradation
Vincristine Sulfate 1.0 mg/ml (1,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation

Rękawiczki są przebadane w niezależnym laboratorium na cytostatyki w ramach dopuszczenia rękawic do kontaktu w leczeniu chemioterapią. Lub kontaktu z lekami, substancjami medycznymi lub chemicznymi używanymi w służbie zdrowia

Jak zamówić tak doskonały towar?

Zamówienia rękawiczek możliwe są przez naszych dystrybutorów, lub też bezpośrednio w firmie.

1.Towar z importu drogą kolejową/morską/lądową w zależności od zamówienia

Minimalny czas dostawy 23 dni, maksymalny 3 miesiące, w zależności od rodzaju transportu

2.Towar na miejscu OTG ŁÓDŹ (gotowy w magazynie- odnawialny stock) Odprawiony, gotowy do odbioru

Cena uzależniona od ilości towaru zamawianego przez klienta

Kontakt:

Email: kontakt@terrapod.pl
www.terrapod.pl

Wszelkie certyfikaty nie dodane w katalogu a wskazane w informacji o certyfikatach marki SKYMED dostępne na życzenie klienta.