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PSB Singapore

TYPE TEST CERTIFICATE

Certificate No: TTCN 110556 0001 Rev. 00

Initial No: -

This Certificate is issued to	**Zhonghong Pulin Medical Products Co.,Ltd.** West Industrial Park, Luannan County, 063500 Tangshan City, Hebei Province PEOPLE'S REPUBLIC OF CHINA
Product:	Gloves Nitrile Disposable Exam Gloves
Brand:	Z/Z
Model:	-
Product Details:	Sizes XS, S, M, L & XL, Powder-Free, Blue, Nitrile, Examination Glove
Specification:	EN 455-1:2020 EN 455-2:2015 EN 455-3:2015
Test Report:	1. 7191244410-EEC/02-LDY 2. 7191240823-EEC20/01-LDY_CR1 3. 7191240823-EEC20/02-LDY_CR1 4. 7191240823-EEC20/03-LDY_CR1 5. 7191240823-EEC20/04-LDY_CR1
Date of Test Report:	2020-10-12 & 2020-11-11

Summary

A sample of the product has been tested and is found to meet with the requirements of the above specification.

Date of Original Issue:	2020-11-18	**Date of Expiry:**	2022-11-17

Digitally signed by Bolea Petru
Date: 2022.09.21 21:33:41 EEST
Reason: MoldSign Signature
Location: Moldova

Date of Last Revision: 2020-11-25

(YAN MUN MICHELLE NG)
TÜV SÜD PSB

PSB Singapore

TYPE TEST CERTIFICATE

Certificate No: TTCN 110556 0001 Rev. 00

Initial No: -

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Date of Last Revision: 2020-11-25

(YAN MUN MICHELLE NG)
TÜV SÜD PSB

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Test Report No. 7191240823-EEC20/01-LDY
dated 20 Oct 2020

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SUBJECT:

Testing of Gloves submitted by Zhonghong Pulin Medical Products Co.,Ltd. on 21 Jul 2020.

TESTED FOR:

Zhonghong Pulin Medical Products Co.,Ltd.
West Industrial Park,
Luannan County,
Tangshan City, China

TEST DATE:

22 Jul 2020 to 14 Aug 2020, 20 Oct 2020

DESCRIPTION OF SAMPLES:

S/N	Product Description	Colour	Lot No.	Size	Sample received (pieces)	Manufacturer
1	Nitrile Disposable Exam Gloves	Blue	20200428	S	400	Zhonghong Pulin Medical Products Co.,Ltd.

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

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

3. EN 455-3:2015 Medical glove for single use
   Part 3: Requirements and testing for biological evaluation
   - Clause 4.4 Powder-free gloves
   - Clause 4.6 Labelling

TÜV SÜD PSB

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https://www.tuvsud.com/en-sg
Co. Reg : 199002667R

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

RESULTS:

Sample: Nitrile Disposable Exam Gloves, Lot No. 20200428, Blue, Size S

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	0	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	246	Passed
	b) Width (mm)	For Size S: 80 ± 10	13	83	Passed
5	Strength a) Force at break (N)	For nitrile examination gloves: ≥ 6.0	13	7.6	Passed
	b) Force at break after challenge testing (N) 7 days at (70±2)°C	For nitrile examination gloves: ≥ 6.0	13	7.4	Passed

Table 3: Results for EN 455-2:2015 Clause 7

Clause	Tests	Requirements	Results	Inferred results
7	Labelling	Manufacturers shall label the glove and/or the packaging with the date of manufacture in accordance with EN ISO 15223-1:2012 and EN 1041:2008+A1:2013. Date of manufacture is defined as the packaging date.	Observed	Passed

RESULTS (cont'd):

Sample: Nitrile Disposable Exam Gloves, Lot No. 20200428, Blue, Size S

Table 4: 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.	0.52 mg per glove	Passed

Table 5: Results for EN 455-3:2015 Clause 4.6

Clause	Tests	Requirements	Results
4.6	Labelling	In addition to the labelling specified in EN 1041:2008+A1:2013 and the relevant symbols given in EN ISO 15223-1:2012, the following requirements apply:	
		a) medical gloves containing natural rubber latex shall be labelled on the packaging of at least the smallest packaging unit with the EN ISO 15223-1:2012 symbol for latex;	NA
		The labelling shall include the following or equivalent warning statement together with the symbol: '(Product) contains natural rubber latex which may cause allergic reactions, including anaphylactic responses';	NA
		b) the labelling shall include a prominent indication of whether the glove is powdered or powder-free;	Comply
		c) sterile powdered gloves shall be labelled with the following or equivalent: 'CAUTION: Surface powder shall be removed aseptically prior to undertaking operative procedures in order to minimize the risk of adverse tissue reactions';	NA
		d) for any medical glove containing natural rubber latex the product labelling shall not include: - any term suggesting relative safety, such as low allergenicity, hypoallergenicity or low protein; - any unjustified indication of the presence of allergens;	NA
		e) if the manufacturer labels the gloves with the protein content, the process limit, measured as specified in 5.3 shall be given.	NA
		Inferred results	Passed

REMARKS:

1. Labelling requirements are assessed based on submitted packaging artwork by client on 20 Oct 2020.
2. NA: Not applicable for the submitted sample.

Yeo Poh Kwang
Associate Engineer

Lee Dai Yi
Engineer
Medical Health Services (NAM)

APPENDIX:

Photo 1: Nitrile Disposable Exam Gloves, Lot No. 20200428, Blue

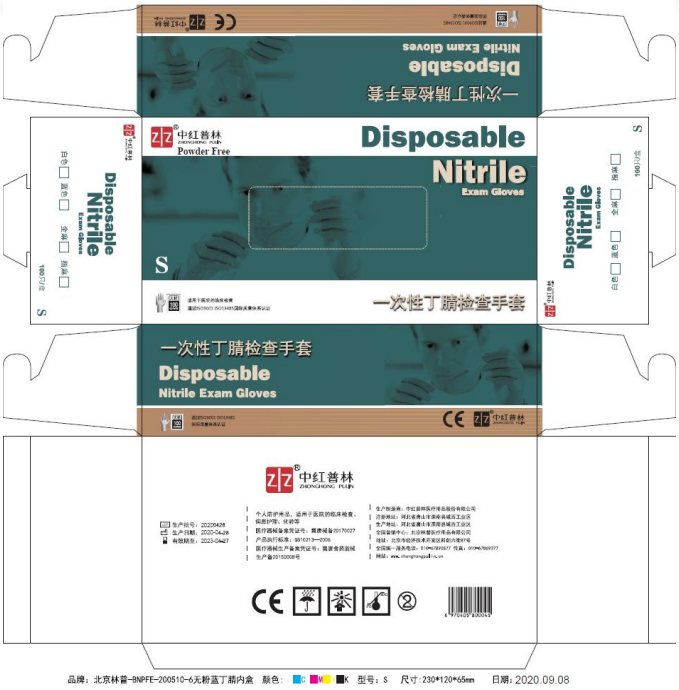

Photo 2: Packaging Artwork for Nitrile Disposable Exam Gloves, Lot No. 20200428, Blue

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Effective 01 September 2020

Test Report No. 7191240823-EEC20/02-LDY
dated 20 Oct 2020

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SUBJECT:

Testing of Gloves submitted by Zhonghong Pulin Medical Products Co.,Ltd. on 21 Jul 2020.

TESTED FOR:

Zhonghong Pulin Medical Products Co.,Ltd.
West Industrial Park,
Luannan County,
Tangshan City, China

TEST DATE:

22 Jul 2020 to 14 Aug 2020, 20 Oct 2020

DESCRIPTION OF SAMPLES:

S/N	Product Description	Colour	Lot No.	Size	Sample received (pieces)	Manufacturer
1	Nitrile Disposable Exam Gloves	Blue	20200428	M	400	Zhonghong Pulin Medical Products Co.,Ltd.

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

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

3. EN 455-3:2015 Medical glove for single use
   Part 3: Requirements and testing for biological evaluation
   - Clause 4.4 Powder-free gloves
   - Clause 4.6 Labelling

TÜV SÜD PSB

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1 Science Park Drive, #02-01
Singapore 118221
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RESULTS:

Sample: Nitrile Disposable Exam Gloves, Lot No. 20200428, Blue, Size M

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	3	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	245	Passed
	b) Width (mm)	For Size M: 95 ± 10	13	93	Passed
5	Strength a) Force at break (N)	For nitrile examination gloves: ≥ 6.0	13	6.9	Passed
	b) Force at break after challenge testing (N) 7 days at (70±2)°C	For nitrile examination gloves: ≥ 6.0	13	7.1	Passed

Table 3: Results for EN 455-2:2015 Clause 7

Clause	Tests	Requirements	Results	Inferred results
7	Labelling	Manufacturers shall label the glove and/or the packaging with the date of manufacture in accordance with EN ISO 15223-1:2012 and EN 1041:2008+A1:2013. Date of manufacture is defined as the packaging date.	Observed	Passed

RESULTS (cont'd):

Sample: Nitrile Disposable Exam Gloves, Lot No. 20200428, Blue, Size M

Table 4: 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.	1.08 mg per glove	Passed

Table 5: Results for EN 455-3:2015 Clause 4.6

Clause	Tests	Requirements	Results
4.6	Labelling	In addition to the labelling specified in EN 1041:2008+A1:2013 and the relevant symbols given in EN ISO 15223-1:2012, the following requirements apply:	
		a) medical gloves containing natural rubber latex shall be labelled on the packaging of at least the smallest packaging unit with the EN ISO 15223-1:2012 symbol for latex;	NA
		The labelling shall include the following or equivalent warning statement together with the symbol: '(Product) contains natural rubber latex which may cause allergic reactions, including anaphylactic responses';	NA
		b) the labelling shall include a prominent indication of whether the glove is powdered or powder-free;	Comply
		c) sterile powdered gloves shall be labelled with the following or equivalent: 'CAUTION: Surface powder shall be removed aseptically prior to undertaking operative procedures in order to minimize the risk of adverse tissue reactions';	NA
		d) for any medical glove containing natural rubber latex the product labelling shall not include: - any term suggesting relative safety, such as low allergenicity, hypoallergenicity or low protein; - any unjustified indication of the presence of allergens;	NA
		e) if the manufacturer labels the gloves with the protein content, the process limit, measured as specified in 5.3 shall be given.	NA
		Inferred results	Passed

REMARKS:

1. Labelling requirements are assessed based on submitted packaging artwork by client on 20 Oct 2020.
2. NA: Not applicable for the submitted sample.

Yeo Poh Kwang
Associate Engineer

Lee Dai Yi
Engineer
Medical Health Services (NAM)

APPENDIX:

Photo 1: Nitrile Disposable Exam Gloves, Lot No. 20200428, Blue

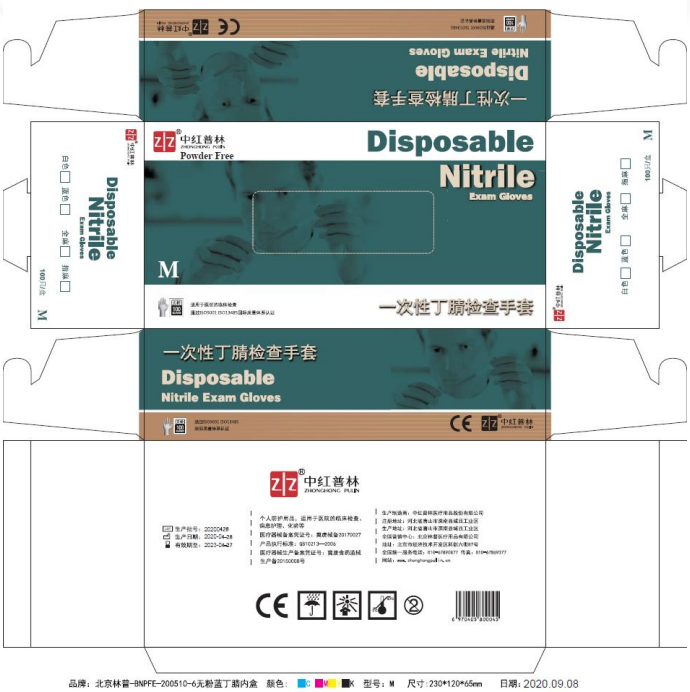

Photo 2: Packaging Artwork for Nitrile Disposable Exam Gloves, Lot No. 20200428, Blue

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Effective 01 September 2020

Test Report No. 7191240823-EEC20/03-LDY
dated 20 Oct 2020

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SUBJECT:

Testing of Gloves submitted by Zhonghong Pulin Medical Products Co.,Ltd. on 21 Jul 2020.

TESTED FOR:

Zhonghong Pulin Medical Products Co.,Ltd.
West Industrial Park,
Luannan County,
Tangshan City, China

TEST DATE:

22 Jul 2020 to 14 Aug 2020, 20 Oct 2020

DESCRIPTION OF SAMPLES:

S/N	Product Description	Colour	Lot No.	Size	Sample received (pieces)	Manufacturer
1	Nitrile Disposable Exam Gloves	Blue	20200428	L	399	Zhonghong Pulin Medical Products Co.,Ltd.

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

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

3. EN 455-3:2015 Medical glove for single use
   Part 3: Requirements and testing for biological evaluation
   - Clause 4.4 Powder-free gloves
   - Clause 4.6 Labelling

TÜV SÜD PSB

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Co. Reg : 199002667R

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1 Science Park Drive, #02-01
Singapore 118221
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RESULTS:

Sample: Nitrile Disposable Exam Gloves, Lot No. 20200428, Blue, Size L

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	3	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 L: 110 ± 10	13	104	Passed
5	Strength a) Force at break (N)	For nitrile examination gloves: ≥ 6.0	13	7.5	Passed
	b) Force at break after challenge testing (N) 7 days at (70±2)°C	For nitrile examination gloves: ≥ 6.0	13	8.1	Passed

Table 3: Results for EN 455-2:2015 Clause 7

Clause	Tests	Requirements	Results	Inferred results
7	Labelling	Manufacturers shall label the glove and/or the packaging with the date of manufacture in accordance with EN ISO 15223-1:2012 and EN 1041:2008+A1:2013. Date of manufacture is defined as the packaging date.	Observed	Passed

RESULTS (cont'd):

Sample: Nitrile Disposable Exam Gloves, Lot No. 20200428, Blue, Size L

Table 4: 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.	0.96 mg per glove	Passed

Table 5: Results for EN 455-3:2015 Clause 4.6

Clause	Tests	Requirements	Results
4.6	Labelling	In addition to the labelling specified in EN 1041:2008+A1:2013 and the relevant symbols given in EN ISO 15223-1:2012, the following requirements apply:	
		a) medical gloves containing natural rubber latex shall be labelled on the packaging of at least the smallest packaging unit with the EN ISO 15223-1:2012 symbol for latex;	NA
		The labelling shall include the following or equivalent warning statement together with the symbol: '(Product) contains natural rubber latex which may cause allergic reactions, including anaphylactic responses';	NA
		b) the labelling shall include a prominent indication of whether the glove is powdered or powder-free;	Comply
		c) sterile powdered gloves shall be labelled with the following or equivalent: 'CAUTION: Surface powder shall be removed aseptically prior to undertaking operative procedures in order to minimize the risk of adverse tissue reactions';	NA
		d) for any medical glove containing natural rubber latex the product labelling shall not include: - any term suggesting relative safety, such as low allergenicity, hypoallergenicity or low protein; - any unjustified indication of the presence of allergens;	NA
		e) if the manufacturer labels the gloves with the protein content, the process limit, measured as specified in 5.3 shall be given.	NA
		Inferred results	Passed

REMARKS:

1. Labelling requirements are assessed based on submitted packaging artwork by client on 20 Oct 2020.
2. NA: Not applicable for the submitted sample.

Yeo Poh Kwang
Associate Engineer

Lee Dai Yi
Engineer
Medical Health Services (NAM)

APPENDIX:

Photo 1: Nitrile Disposable Exam Gloves, Lot No. 20200428, Blue

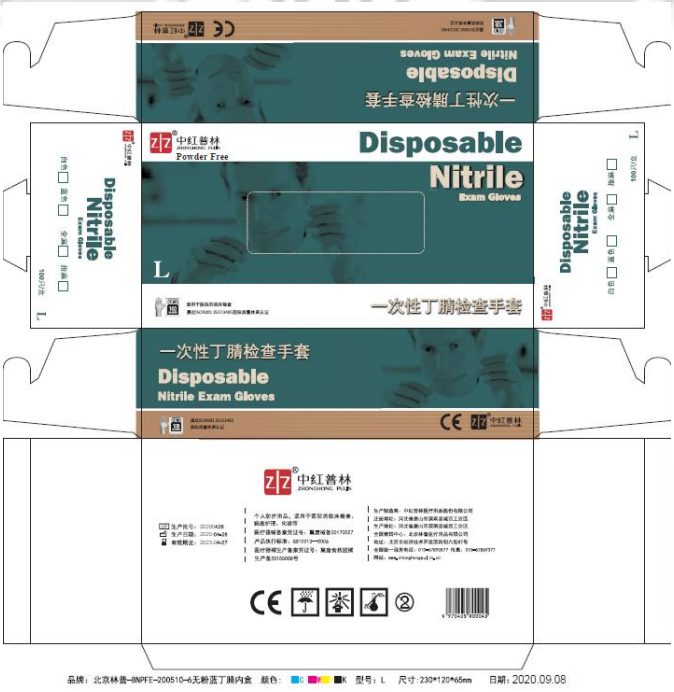

Photo 2: Packaging Artwork for Nitrile Disposable Exam Gloves, Lot No. 20200428, Blue

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SUBJECT:

Testing of Gloves submitted by Zhonghong Pulin Medical Products Co.,Ltd. on 21 Jul 2020.

TESTED FOR:

Zhonghong Pulin Medical Products Co.,Ltd.
West Industrial Park,
Luannan County,
Tangshan City, China

TEST DATE:

22 Jul 2020 to 14 Aug 2020, 20 Oct 2020

DESCRIPTION OF SAMPLES:

S/N	Product Description	Colour	Lot No.	Size	Sample received (pieces)	Manufacturer
1	Nitrile Disposable Exam Gloves	Blue	20200428	XL	401	Zhonghong Pulin Medical Products Co.,Ltd.

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

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

3. EN 455-3:2015 Medical glove for single use
   Part 3: Requirements and testing for biological evaluation
   - Clause 4.4 Powder-free gloves
   - Clause 4.6 Labelling

RESULTS:

Sample: Nitrile Disposable Exam Gloves, Lot No. 20200428, Blue, 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	2	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	249	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	6.8	Passed
	b) Force at break after challenge testing (N) 7 days at (70±2)°C	For nitrile examination gloves: ≥ 6.0	13	7.0	Passed

Table 3: Results for EN 455-2:2015 Clause 7

Clause	Tests	Requirements	Results	Inferred results
7	Labelling	Manufacturers shall label the glove and/or the packaging with the date of manufacture in accordance with EN ISO 15223-1:2012 and EN 1041:2008+A1:2013. Date of manufacture is defined as the packaging date.	Observed	Passed

RESULTS (cont'd):

Sample: Nitrile Disposable Exam Gloves, Lot No. 20200428, Blue, Size XL

Table 4: 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.	0.64 mg per glove	Passed

Table 5: Results for EN 455-3:2015 Clause 4.6

Clause	Tests	Requirements	Results
4.6	Labelling	In addition to the labelling specified in EN 1041:2008+A1:2013 and the relevant symbols given in EN ISO 15223-1:2012, the following requirements apply:	
		a) medical gloves containing natural rubber latex shall be labelled on the packaging of at least the smallest packaging unit with the EN ISO 15223-1:2012 symbol for latex;	NA
		The labelling shall include the following or equivalent warning statement together with the symbol: '(Product) contains natural rubber latex which may cause allergic reactions, including anaphylactic responses';	NA
		b) the labelling shall include a prominent indication of whether the glove is powdered or powder-free;	Comply
		c) sterile powdered gloves shall be labelled with the following or equivalent: 'CAUTION: Surface powder shall be removed aseptically prior to undertaking operative procedures in order to minimize the risk of adverse tissue reactions';	NA
		d) for any medical glove containing natural rubber latex the product labelling shall not include: - any term suggesting relative safety, such as low allergenicity, hypoallergenicity or low protein; - any unjustified indication of the presence of allergens;	NA
		e) if the manufacturer labels the gloves with the protein content, the process limit, measured as specified in 5.3 shall be given.	NA
		Inferred results	Passed

REMARKS:

1. Labelling requirements are assessed based on submitted packaging artwork by client on 20 Oct 2020.
2. NA: Not applicable for the submitted sample.

Yeo Poh Kwang
Associate Engineer

Lee Dai Yi
Engineer
Medical Health Services (NAM)

APPENDIX:

Photo 1: Nitrile Disposable Exam Gloves, Lot No. 20200428, Blue

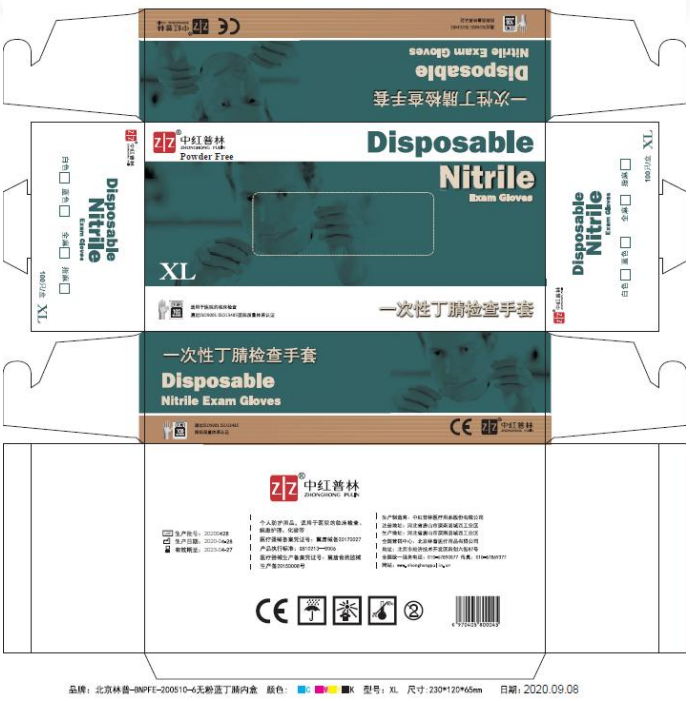

Photo 2: Packaging Artwork for Nitrile Disposable Exam Gloves, Lot No. 20200428, Blue

PSB Singapore

Please note that this Report is issued under the following terms :

1. This report applies to the sample of the specific product/equipment given at the time of its testing/calibration. The results are not used to indicate or imply that they are applicable to other similar items. In addition, such results must not be used to indicate or imply that TÜV SÜD PSB approves, recommends or endorses the manufacturer, supplier or user of such product/equipment, or that TÜV SÜD PSB in any way "guarantees" the later performance of the product/equipment. Unless otherwise stated in this report, no tests were conducted to determine long term effects of using the specific product/equipment.

2. The sample/s mentioned in this report is/are submitted/supplied/manufactured by the Client. TÜV SÜD PSB therefore assumes no responsibility for the accuracy of information on the brand name, model number, origin of manufacture, consignment or any information supplied.

3. Nothing in this report shall be interpreted to mean that TÜV SÜD PSB has verified or ascertained any endorsement or marks from any other testing authority or bodies that may be found on that sample.

4. This report shall not be reproduced wholly or in parts and no reference shall be made by the Client to TÜV SÜD PSB or to the report or results furnished by TÜV SÜD PSB in any advertisements or sales promotion.

5. Unless otherwise stated, the tests were carried out in TÜV SÜD PSB Pte Ltd, No.1 Science Park Drive Singapore 118221.

6. The tests carried out by TÜV SÜD PSB and this report are subject to TÜV SÜD PSB's General Terms and Conditions of Business and the Testing and Certification Regulations of the TÜV SÜD Group.

Effective 01 September 2020

Business Stream Products
Certification Department

TÜVRheinland®
LGA
Precisely Right.

TÜV Rheinland LGA Products GmbH · 90431 Nürnberg

Jinge Li
Zhonghong Pulin Medical
Products Co., Ltd.
West Industrial Park
Luannan County
063500 Tangshan City HEBEI
CHINA

Contact

Tel. +49 911 655-5225
Mail service@de.tuv.com

Date March 08, 2019

Application for	**: EU type-examination certificate PPE**
Certificate No.	: BP 60137453 Sheet 0001
Device	: Protective gloves against chemicals and micro-organisms according to EN ISO 374-1+A1:2018 and EN ISO 374-5:2016
Type	: ZHPFN02
Test requirement	: UEReg 425/2016 EN ISO 374-1:2016+A1 EN ISO 374-5:2016

Dear Madame or Sir,

A specimen of above mentioned product has been tested and found to be technically in compliance with § 20 and § 21 of the ProdSG (= German Product Safety Law).

The certificate is issued with the reservation that the licence holder applies all information required in § 6 of the ProdSG related to name of the manufacturer and, if need be, his authorized representative / the importer including their respective addresses on the product, its packing and/or the user's manual prior to marketing the product in the European Economic Area.

Enclosed please find the certificate of approval No. BP 60137453 0001.

Kind regards

Certification body

C. Albrecht

Dipl.-Ing. C. Albrecht

Test sample: no, documentation available

TÜV Rheinland
LGA Products GmbH

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90431 Nürnberg

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Fax +49 911 655-5226
Mail service@de.tuv.com
Web www.tuv.com/safety

C E R T I F I C A T E

EU Type-Examination Certificate
Regulation 2016/425/EU
Personal Protective Equipment

TÜVRheinland®

Registration No.: BP 60137453 0001

Report No.: 60221944 001

Holder:

Zhonghong Pulin Medical
Products Co., Ltd.
West Industrial Park
Luannan County
Tangshan City
063500 Hebei
China

Product:

Protective gloves against chemicals and micro-organisms
according to EN ISO 374-1+A1:2018 and EN ISO 374-5:2016

Identification:

ZHPFN02 disposable gloves
Colour: blue
Material: nitrile, wall thickness 0,05 mm
Sizes: S (6,5) - XL (9)
Performance parameter: Type C, class 6, K: NaOH 40%

- PPE Category III - obligatory monitoring module C2 -

The EU type-examination certificate refers to the above mentioned product. This is to certify that the product complies with the essential requirements of Annex II of the regulation 2016/425/EU. This certificate does not imply assessment of the production of the product and does not permit the use of a TÜV Rheinland mark of conformity. The holder is entitled to use this certificate in connection with the declaration of conformity in accordance with Annex IX.

Valid till: 07.03.2024

Notified Body

Date 08.03.2019

Dipl.-Ing. C. Albrecht

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Notified by Zentralstelle der Länder für Sicherheitstechnik (ZLS).

Notified under No. 0197 to the EC Commission.

CE The CE marking may be used if all relevant and effective EC Directives are complied with. CE

Z E R T I F I K A T

EU-Baumusterprüfbescheinigung
Verordnung 2016/425/EU
Persönliche Schutzausrüstung

TÜVRheinland®

Registrier Nr.: BP 60137453 0001

Bericht Nr.: 60221944 001

Inhaber:
Zhonghong Pulin Medical
Products Co., Ltd.
West Industrial Park
Luannan County
Tangshan City
063500 Hebei
China

Produkt:
Schutzhandschuhe gegen Chemikalien und Mikroorganismen
gemäß EN ISO 374-1+A1:2018 und EN ISO 374-5:2016

Identifikation:

ZHPFN02 Einmalhandschuhe
Farbe: blau
Material: Nitril, Wanddicke 0,05 mm
Größen: S (6,5) - XL (9)
Leistungsparameter: Typ C, Klasse 6, K: NaOH 40%

- PSA Kategorie III - überwachungspflichtig Modul C2 -

Die EU-Baumusterbescheinigung bezieht sich auf das o.g. Produkt. Es wird bescheinigt, dass das Produkt den grundlegenden Anforderungen nach Anhang II der Verordnung 2016/425/EU entspricht. Das Zertifikat stellt kein allgemein gültiges Urteil über die Serienfertigung des Produktes dar und berechtigt nicht zur Nutzung eines TÜV Rheinland Prüfzeichens. Der Inhaber ist berechtigt, diese Bescheinigung im Rahmen seiner EU-Konformitätserklärung gemäß Anhang IX zu verwenden.

Gültig bis: 07.03.2024

Datum 08.03.2019

Benannte Stelle

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Dipl.-Ing. C. Albrecht

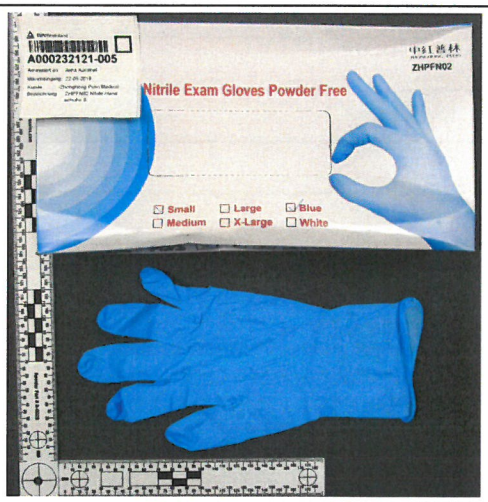
TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Benannt durch die Zentralstelle der Länder für Sicherheitstechnik (ZLS).

Notifiziert unter Nr. 0197 bei der Kommission der Europäischen Gemeinschaft.

CE Die CE-Kennzeichnung darf bei Einhaltung aller zutreffenden EU-Richtlinien angebracht werden. CE

Prüfbericht-Nr.: *Test Report No.:*	**60221944-002**	**Auftrags-Nr.:** *Order No.:*	3290084	Seite 1 von 24 *Page 1 of 24*
Kunden-Referenz-Nr.: *Client Reference No.:*	N/A	**Auftragsdatum:** *Order date:*	14.05.2019	
Auftraggeber: *Client:*	Zhonghong Pulin Medical Products Co. Ltd. Industrial Zone, West of Luannan County, Tangshan City, Hebei Province, China			
Prüfgegenstand: *Test item:*	Schutzhandschuhe / Protective gloves			
Bezeichnung / Typ-Nr.: *Identification / Type No.:*	Nitrilhandschuhe Nitrile gloves	ZHPFN02 ZHPFN02		
Auftrags-Inhalt: *Order content:*	Produktüberwachung PSA Kategorie III / Product surveillance PPE category III			
Prüfgrundlage: *Test specification:*	EN ISO 374-1:2016 + A1:2018 Schutzhandschuhe gegen gefährliche Chemikalien und Mikroorganismen *Protective gloves against dangerous chemicals and micro-organisms*			

Wareneingangsdatum: *Date of receipt:*	22.05.2019
Prüfmuster-Nr.: *Test sample No.:*	A000232121-005-008
Prüfzeitraum: *Testing period:*	11.07.2019 – 19.07.2019
Ort der Prüfung: *Place of testing:*	Prüfstelle für Textilien und PSA Leipzig
Prüflaboratorium: *Testing laboratory:*	TÜV Rheinland LGA Products GmbH
Prüfergebnis*: *Test result*:*	Pass



geprüft von / *tested by:*

23.07.2019	J. Voigt/ Sachverständige/ Expert	
Datum *Date*	**Name / Stellung** *Name / Position*	**Unterschrift** *Signature*

kontrolliert von / *reviewed by:*

23.07.2019	L. Gargulla / Sachverständige/ Expert	
Datum *Date*	**Name / Stellung** *Name / Position*	**Unterschrift** *Signature*

Sonstiges / *Other:* Factory: The Sixth Branch Company of Zhonghong Pulin Medical Products Co., Ltd. Industrial Zone, West of Luannan County, Tangshan City, Hebei Province, China
Sample Pick: 14.05.2019

Zustand des Prüfgegenstandes bei Anlieferung: Prüfmuster vollständig und unbeschädigt
Condition of the test item at delivery: *Test item complete and undamaged*

* Legende:	1 = sehr gut	2 = gut	3 = befriedigend	4 = ausreichend	5 = mangelhaft
	P(ass) = entspricht o.g. Prüfgrundlage(n)		F(ail) = entspricht nicht o.g. Prüfgrundlage(n)	N/A = nicht anwendbar	N/T = nicht getestet
Legend:	*1 = very good*	*2 = good*	*3 = satisfactory*	*4 = sufficient*	*5 = poor*
	P(ass) = passed a.m. test specification(s)		*F(ail) = failed a.m. test specification(s)*	*N/A = not applicable*	*N/T = not tested*

V04

Prüfbericht-Nr.: 60221944-002
Test Report No.:

Liste der verwendeten Prüfmittel
List of used test equipment

Prüfmittel *Test equipment*	**Prüfmittel-Nr. / ID-Nr.** *Equipment No. / ID-No.*	**Nächste Kalibrierung** *Next calibration*
siehe Anlage zu diesem Prüfbericht		
see attachment to this test report		

Produktbeschreibung
Product description

1	**Produktdetails** *Product details*	5-Finger-Handschuh *5 finger gloves*
2	**Artikel / Modell** *Article / Model*	Nitrilhandschuhe ZHPFN02 *Nitrile gloves ZHPFN02*
3	**Größe / Länge** *Size / Length*	S (6,5), M (7,5), L(8,5), XL(9)
4	**Leistungsstufen** *Performance levels*	Chemikalie K NaOH 40% Permeation: Klasse/ *level* 6 Degradation: -4,3 % Typ /*Type* C
5	**Verwendete Materialien** *Used materials*	Nitril Farbe blau ≥ 0,05 mm *Nitrile colour blue ≥ 0,05 mm*
6	**Chargennr.** *Charge no.*	---
7	**Sonstiges** *Other*	Vorhersehbare Verwendung wurde betrachtet. Zurzeit liegen für das/die Produkt/e weder Schutzklauselverfahren an, noch ist ein erhöhtes Unfallaufkommen bekannt. / *Foreseeable use was considered. Currently neither a safeguard clause procedure has been invoked nor is an increase in accidents known for this / these product (s).*
8	**Mitgeltende Dokumente / Prüfberichte** *Further aplicable documents / test reports*	/*1 Prüfbericht Permeation, / *Test report permeation,* Bericht-Nr. / *report nr.*: AZ 347519 (19.07.2019) TÜV Rheinland LGA /*2 Prüfbericht Permeation, Degradation / *Test report permeation, degradation* Bericht-Nr. / *report nr.*: AZ 275838 (10.08.2017) TÜV Rheinland LGA /*3 Prüfbericht / *Test report* Bericht-Nr. / *report nr.*: 60221944-001 (29.01.2019) TÜV Rheinland LGA

A000232121-005-008	---
	

Absatz *Clause*	**EN ISO 374-1:2016 + A1:2018** Anforderungen - Prüfungen / *Requirements - Tests*	Messergebnisse - Bemerkungen *Measuring results - Remarks*	Bewertung *Evaluation*
	Der Originaltext wird nur auszugsweise wieder gegeben. Details sind dem Original-Dokument zu entnehmen. ***The original text is reproduced only in part. For details, be reffered to the original document.***		
	Schutzhandschuhe gegen gefährliche Chemikalien und Mikroorganismen ***Protective gloves against dangerous chemicals and micro-organisms***		
1	**Anwendungsbereich** ***Scope***		
2	**Normative Verweisungen** ***Normative references***		
3	**Begriffe** ***Terms and definition***		
4	**Probenahme** ***Sampling***		
5	**Leistungsanforderung** ***Performance requirements***		
5.1	**Allgemeine Anforderungen** ***General requirements***		
	Schutzhandschuhe gegen gefährliche Chemikalien müssen die Anforderungen in EN 420:2009, Abschnitt 4, Abschnitt 5 und Abschnitt 7, erfüllen. *Protective gloves against dangerous chemicals shall comply with the requirements given in EN 420:2009, Clause 4, Clause 5 and Clause 7.*		
EN 420, 4.1	Gestaltungsgrundsätze und Handschuhkonfektionierung — Allgemeines *Glove design and construction — General*		
	- bei normalen Tätigkeiten Schutz auf der höchstmöglichen Leistungsstufe - minimale Zeit zum An-/ Ausziehen - gesamte Leistung nicht wesentlich herabgesetzt durch Nähte *- in foreseeable conditions of use, protection at highest possible level* *- minimal time for put on/take off* *- overall not significantly decreased by seams*	/*3 gegeben *given*	P ☒ F ☐ N/A ☐ N/T ☐
EN 420, 4.2	Widerstand des Handschuhmaterials gegen Wasserdurchdringung *Resistance of glove materials to water penetration*		
	wenn gefordert, muss der Widerstand des Handschuhmaterials gegen Wasserdurchdringung nach folgenden Prüfvorschriften geprüft werden: - Lederhandschuhe nach EN 344-1 - Textile Erzeugnisse nach EN 20811 *if required, the gloves materials where resistance to water penetration have to tested according follow test methode:* *- leather gloves according to EN 344-1* *- textile products according to EN 20811*	---	P ☐ F ☐ N/A ☒ N/T ☐

Absatz *Clause*	**EN ISO 374-1:2016 + A1:2018** Anforderungen - Prüfungen / *Requirements - Tests*	Messergebnisse - Bemerkungen *Measuring results - Remarks*	Bewertung *Evaluation*
EN 420, 4.3	Unschädlichkeit von Schutzhandschuhen *Innocuousness of protective gloves*		
EN 420, 4.3.1	Allgemeines *General*		
	- beim Gebrauch Schutz ohne gesundheitliche Schädigung - alle enthaltenen Substanzen, die bekannt sind, Allergien zu verursachen, sind anzugeben *- protection at use without harm to user* *- all substances contained which are known to cause allergies are named*	/*3 gegeben *given*	P ☒ F ☐ N/A ☐ N/T ☐
	Azo-Farbstoffe *Azo dye stuff*		
	< 30 mg/kg nach / *according to*: 1907/2006/EU	---	P ☐ F ☐ N/A ☒ N/T ☐
EN 420, 4.3.2	Bestimmung des pH-Wertes *Determination of pH-value*		
	Der pH-Wert für Handschuhe muss größer als 3,5 und kleiner als 9,5 sein. *The pH value for all gloves shall be greater than 3,5 and less than 9,5.*	/*3 Innenhand / *Palm*: pH-Wert / *pH- value*: 6,9	P ☒ F ☐ N/A ☐ N/T ☐
EN 420, 4.3.3	Bestimmung des Chrom(VI)-Gehaltes *Determination of chromium (VI) content*		
	Der Chrom(VI)-Gehalt von Handschuhen, die Leder enthalten, darf bei der Bestimmung nach dem Prüfverfahren nach EN ISO 17075:2007 3,0 mg/kg nicht überschreiten. Enthält der Handschuh verschiedene Arten von Leder, muss jede Leder Art, unabhängig davon, ob sie mit der Haut in Berührung kommt oder nicht, separat geprüft werden und die vorgenannte Anforderung erfüllen. *The quantity of Chromium VI in gloves containing leather shall not exceed 3,0 mg/kg when determined according to the test method described in EN ISO 17075:2007. If the glove includes different types of leather, whether in contact with the skin or not, each leather type shall be tested separately and comply with the above requirement.*	---	P ☐ F ☐ N/A ☒ N/T ☐

Absatz *Clause*	**EN ISO 374-1:2016 + A1:2018** Anforderungen - Prüfungen / *Requirements - Tests*	Messergebnisse - Bemerkungen *Measuring results - Remarks*	Bewertung *Evaluation*
EN 420, 4.3.4	Bestimmung des Protein Gehaltes *Determination of extractable protein content*		
	Schutzhandschuhe aus Naturkautschuk müssen hinsichtlich ihres extrahierbaren Proteingehalts die in DIN EN 16523-1 festgelegten Anforderungen erfüllen. Naturkautschuk: *Lowry- Prüfmethode* so gering wie vernünftigerweise praktikabel (ALARP) *Natural rubber gloves shall be submitted to requirements stated in DIN EN 16523-1 on extractable protein content.* *natural rubber: latex Lowry- test method* *as low as reasonably practicable (ALARP)*	---	P ☐ F ☐ N/A ☒ N/T ☐
EN 420, 4.4	Reinigung *Cleaning*		
	Sofern Pflegeanweisungen angegeben sind, sind die in den spezifischen Normen aufgeführten relevanten Prüfungen an den Handschuhen durchzuführen, bevor und nachdem sie der höchsten empfohlenen Anzahl von Reinigungen unterzogen worden sind. Die Leistungs-stufen dürfen durch die empfohlene Anzahl der Reinigungen nicht negativ beeinflusst werden. *If care instructions are provided, the relevant tests of the specific standards shall be performed on the gloves, before and after they have been subjected to the maximum recommended number of cleaning cycles. The levels of performance shall not be negatively affected throughout the recommended number of cycles.*	---	P ☐ F ☐ N/A ☒ N/T ☐
EN 420, 4.5	Elektrostatische Eigenschaften *Electrostatic properties*		
	wenn erforderlich/ *if required:* Das Prüfergebnis muss in den Herstellerinformationen angegeben werden zusammen mit den Informationen nach 7.3.11. Es dürfen keine Piktogramme für elektrostatische Eigenschaften verwendet werden. *The test result shall be reported in the information supplied by the manufacturer accompanied by the information stated in 7.3.11. Electrostatic pictograms shall not be used for this property.*	---	P ☐ F ☐ N/A ☒ N/T ☐

Absatz *Clause*	**EN ISO 374-1:2016 + A1:2018** Anforderungen - Prüfungen / *Requirements - Tests*	Messergebnisse - Bemerkungen *Measuring results - Remarks*	Bewertung *Evaluation*

EN 420, 5 **Komfort und Leistungsfähigkeit**
Comfort and efficiency

EN 420, 5.1 Größen
Sizing

EN 420, 5.1.2 Größen und Maße der Handschuhe
Sizes and measurements of glove

Tab. 2, Tab. 3

Handschuhgröße *Glove size*	Handumfang *Hand circumference* [mm]	Handlänge *Hand length* [mm]	Mindestlänge des Handschuhs *Minimum length of glove* [mm]
6	152	160	220
7	178	171	230
8	203	182	240
9	229	192	250
10	254	204	260
11	279	215	270

Größe *Size*	Handschuhlänge *Glove length* [mm]
6	---
S/ 6,5	253
M/ 7,5	248
L/ 8,5	251
XL/ 9	251
11	---

P ☒
F ☐
N/A ☐
N/T ☐

EN 420, 5.1.3 Handschuhe für besondere Anwendungen
Gloves for special applications

für den speziellen Zweck passend
(eindeutig angegeben in der Gebrauchanweisung)

fit for special purpose
(clearly stated in instruction for use)

P ☐
F ☐
N/A ☒
N/T ☐

EN 420, 5.2 Beweglichkeit
Dexterity

Tab. 4

Leistungsstufe *Performance level*	geringster Durchmesser des Stiftes *smallest diameter of pin* [mm]
1	11
2	9,5
3	8
4	6,5
5	5

Prüfstift / *pin*: 5 mm

P ☒
F ☐
N/A ☐
N/T ☐

Stufe /
Level 5

Absatz *Clause*	**EN ISO 374-1:2016 + A1:2018** Anforderungen - Prüfungen / *Requirements - Tests*	Messergebnisse - Bemerkungen *Measuring results - Remarks*	Bewertung *Evaluation*
EN 420 5.3	Wasserdampfdurchlässigkeit (WDD) und Wasserdampfaufnahme (WDA) *Water vapour transmission (WVT) and Water vapour absorption (WVA)*		
	sofern durchführbar, müssen Schutzhandschuhe wasserdampfdurchlässig sein sofern gefordert: WDD: ≥ 5 mg/ (cm²h) wenn die Schutzstufe eine Wasserdampfdurchlässigkeit verhindert oder ausschließt, sollte dennoch der Effekt des Schwitzens so viel wie möglich reduziert sein falls gefordert: WDA: ≥ 8 mg/cm² für 8 h *protective gloves shall allow water vapour transmission.* *if required: WVT: ≥ 5 mg/ (cm².h)* *where protection level inhibits or excludes water vapour transmission, effect of perspiration has to be reduced* *if required: WVA: ≥ 8 mg/cm² for 8 h*	---	P ☐ F ☐ N/A ☒ N/T ☐
5.2	**Penetration** ***Penetration***		
	Schutzhandschuhe dürfen bei der Prüfung nach EN 374-2:2014, 7.2 und 7.3, nicht undicht werden. *Protective gloves shall not leak when tested according to EN 374-2:2014, 7.2 and 7.3.*		
EN 374-2	Teil 2: Bestimmung des Widerstandes gegen Penetration *Part 2: Determination of resistance to penetration*		
4.3	Bemerkungen Remarks		
	Das Luft-Leck-Verfahren ist nicht für alle Handschuhe geeignet. Beispielsweise können die Teile einiger Handschuhe zu stark aufgeblasen sein, während andere Teile derselben Handschuhe nur teilweise aufgeblasen sein können. Wenn sich die Luft-Leck-Prüfung als ungeeignet erweist, dann wird nur die Prüfung auf Penetration von Wasser durchgeführt. Bei beiden Verfahren werden keine Undichtheiten berücksichtigt, die bis zu 40 mm vom Rand des flüssigkeitsundurchdringlichen Bereichs des Handschuhes entfernt liegen. *The air leak procedure is not suitable for all gloves. For example parts of some gloves may be overinflated while other parts of the same gloves can only be partially inflated. If the air leak test proves unsuitable, then only the water penetration test is carried out.* *For both methods disregard leaks within the area of 40 mm from the edge of the liquid proof area.*		

Absatz *Clause*	**EN ISO 374-1:2016 + A1:2018** Anforderungen - Prüfungen / *Requirements - Tests*	Messergebnisse - Bemerkungen *Measuring results - Remarks*	Bewertung *Evaluation*
7	Durchführung *Procedure*		
7.1	Allgemeines *General*		
	Der Handschuh wird vorsichtig der Hülle, Schachtel oder seiner Verpackung entnommen. Identifizierungscode, Nummer des Loses, Größe und Marke der Proben werden aufgezeichnet. Eine Sichtprüfung auf Risse, Schlitze und Löcher wird durchgeführt. Sind diese vorhanden, ist anzugeben, dass die Handschuhe die Prüfung nicht bestanden haben. *Carefully remove the glove from the wrapper, box or its packaging. Record the identity code, lot number, size and brand of samples. Visually examine for tears, rips and holes. If these are present, the gloves shall be reported as having failed.*	keine Risse, Schlitze und Löcher vorhanden / *no tears, rips and holes are present*	P ☒ F ☐ N/A ☐ N/T ☐
7.2	Luft-Leck- Prüfung *Air leak test*		
4.1	Ein Handschuh wird in Wasser getaucht und sein Innenvolumen mit Luft aufgeblasen. Eine Undichtheit (Leck) wird als Strom aus Luftblasen sichtbar, der sich an der Oberfläche des Handschuhes bildet. *A glove is immersed in water, and its interior is pressurised with air. A leak is detected by a stream of air bubbles from the surface of the glove.*	Größe/ size — Luft-Leck-Prüfung/ *Air leakage* S/ 6,5 — keine/ *no Leakage* M/ 7,5 — keine/ *no Leakage* L/ 8,5 — keine/ *no Leakage* XL/ 9 — keine/ *no Leakage* Verwendeter Luftdruck / *air pressure used:* 0,5 kPa	P ☒ F ☐ N/A ☐ N/T ☐
Tab. 1	Nenndicke der Handschuhe (e) nach Angaben des Herstellers mm *Nominal glove thickness (e) mm As provided by the manufacturer* — Luftdruck (X) *Air pressure (X) kPa* e < 0,3 — 0,5 0,3 < e < 0,5 — 2,0 0,5 < e < 1,0 — 5,0 e > 1,0 — 6,0		

Absatz *Clause*	**EN ISO 374-1:2016 + A1:2018** Anforderungen - Prüfungen / *Requirements - Tests*	Messergebnisse - Bemerkungen *Measuring results - Remarks*	Bewertung *Evaluation*
7.3	Wasser-Leck-Prüfung *Water leak test*		
4.2	Ein Handschuh wird mit Wasser gefüllt. Eine Undichtheit wird durch das Auftreten von Wassertröpfchen an der Außenseite des Handschuhes festgestellt. *A glove is filled with water. A leak is detected by the appearance of water droplets on the outside of the glove.*	Größe/ size — Luft-Leck-Prüfung/ *Air leakage* S/ 6,5 — keine/ *no Leakage* M/ 7,5 — keine/ *no Leakage* L/ 8,5 — keine/ *no Leakage* XL/ 9 — keine/ *no Leakage*	P ☒ F ☐ N/A ☐ N/T ☐
5.3	**Degradation** ***Degradation***		
	Die Degradation (DR) ist nach EN 374-4 für jede Chemikalie, die in der Kennzeichnung angegeben und in der Benutzerinformation aufgeführt wird, zu bestimmen. Für den Handschuh, der länger als 400 mm ist, muss die zu dem geringsten Permeationsergebnis gehörende Degradation zumindest angegeben werden. *The degradation (DR) shall be determined according to EN 374-4 for each chemical claimed in the marking and reported in the user instruction.* *For the glove longer than 400 mm, the degradation corresponding to the lowest permeation results shall at least be reported.*		
EN 374-4	Teil 4: Bestimmung des Widerstandes gegen Degradation durch Chemikalien *Part 4: Determination of resistance to degradation by chemicals*		
4	Prüfprinzip *Test principles*		
	Der Widerstand eines Werkstoffes für Schutzhandschuhe gegen Degradation durch eine flüssige Chemikalie wird bestimmt, indem die Veränderung der Durchstichfestigkeit des Werkstoffes für Handschuhe nach ständigem Kontakt der Außenfläche mit der beanspruchenden Prüfchemikalie gemessen wird. Die Prüfung gilt für Handschuhe aus natürlichem oder synthetischem Polymer. Gefütterte Handschuhe können unbrauchbare Messergebnisse liefern. *The resistance of a protective glove material to degradation by a liquid chemical is determined by measuring the puncture resistance change of the glove material after a continuous contact with the external surface with the challenge test chemical. The test is applicable to gloves made of natural or synthetic polymer. Lined gloves may produce unusable measurement results.*		

Absatz *Clause*	**EN ISO 374-1:2016 + A1:2018** Anforderungen - Prüfungen / *Requirements - Tests*	Messergebnisse - Bemerkungen *Measuring results - Remarks*	Bewertung *Evaluation*
5	Prüfverfahren für die Prüfung der Durchstichfestigkeit *Test methods, Puncture resistance test*		
5.3.4	Darstellung der Ergebnisse *Expression of results*		
	Die Degradation ist an jedem der drei Handschuhprüfmuster gegen jede spezifische Chemikalie oder jedes Chemikaliengemisch zu bestimmen. Die Degradation des Prüfmusters durch die beanspruchende Chemikalie ist zu ermitteln. Die Standardabweichung (SD) der Degradation der drei Handschuhe ist zu bestimmen. Veränderungen wie Aufquellen, Schrumpfen, Versprödung, Verhärtung, Erweichung, Schuppenbildung, Auflösung, Farbveränderung/ Ausbleichen, Delaminieren sind anzugeben. *Determine the degradation for each of the three glove specimens against each specific chemical or chemical mixture.* *Determine the degradation of the sample against the challenge chemical.* *Determine the standard deviation (SD) of the degradation for the three gloves.* *Any changes such as swelling, shrinking, brittleness, hardening, softening, flaking, disintegration, colour change/bleeding, delaminating shall be noted and described for information*.	/*2 Chemikalie/ *chemical*: NaOH Reinheit/ *purity* : 40% DR1 -12,5 DR2 -11,9 DR3 11,6 **DR** **-4,3** SD 14,6 Veränderungen / *changes:* keine / *none* Prüfdatum / *date of the test*: 10.08.2017	P ☒ F ☐ N/A ☐ N/T ☐ **DR = - 4%**

Absatz	**EN ISO 374-1:2016 + A1:2018**	Messergebnisse - Bemerkungen	Bewertung
Clause	Anforderungen - Prüfungen / *Requirements - Tests*	*Measuring results - Remarks*	*Evaluation*

5.4	**Permeation** ***Permeation***
5.4.1	Allgemeines *General*
	Für den Handschuh, der länger als 400 mm ist, und bei dem die Handinnenfläche und die Stulpe unterschiedliche Leistungsstufen erreichen, muss für jede Chemikalie die geringere Leistungsstufe in der Kennzeichnung angegeben werden. Alle Ergebnisse sollten in der Benutzeranleitung angegeben sein. Jede Kombination von Schutzhandschuh/Prüfchemikalie ist nach Tabelle 1 zu klassifizieren, wobei die in EN 16523-1:2015, 8.5.1.1 oder 8.5.1.3, angegebene Ergebnisse für die normalisierte Durchbruchszeit anzuwenden sind. *For the glove longer than 400 mm, where the palm and cuff achieve different performance levels, the lowest performance level shall be claimed in the marking for each chemical. All the results should be reported in the user instruction.* *Each combination of protective glove/test chemical shall be classified according to Table 1, using the results as given in EN 16523-1:2015, 8.5.1.1 or 8.5.1.3 for the normalized breakthrough time.*
5.4.2	Typ A: Die Permeationsleistung muss mindestens Stufe 2 gegen wenigstens sechs Prüfchemikalien entsprechen, die in Tabelle 2 gelistet sind. *Type A: The permeation performance shall be at least level 2 against a minimum of six test chemicals listed in Table 2.*
5.4.3	Typ B: Die Permeationsleistung muss mindestens Stufe 2 gegen wenigstens drei Prüfchemikalien entsprechen, die in Tabelle 2 gelistet sind. *Type B: The permeation performance shall be at least level 2 against minimum of three test chemicals listed in Table 2.*
5.4.3	Typ C: Die Permeationsleistung muss mindestens Stufe 1 gegen wenigstens eine Prüfchemikalie entsprechen, die in Tabelle 2 gelistet ist. *Type C: The permeation performance shall be at least level 1 against minimum of one test chemical listed in Table 2.*

Tab. 2

Kennbuchstabe ***Code Letter***	**Prüfchemikalie** ***Chemical***	**CAS-RN** ***CAS Number***
A	Methanol / *Methanol*	67-56-1
B	Aceton / *Acetone*	67-64-1
C	Acetonitril / Acetonitrile	75-05-8
D	Dichloromethan / *Dichloromethane*	75-09-2
E	Kohlenstoffdisulfid / *Carbon disulphide*	75-15-0
F	Toluol / *Toluene*	108-88-3
G	Diethylamin / *Diethylamine*	109-89-7
H	Tetrahydrofuran / *Tetrahydrofuran*	109-99-9
I	Ethylacetat / *Ethyl acetate*	141-78-6
J	n-Heptan / *n-Heptane*	142-82-5
K	Natriumhydroxid 40 % / *Sodium hydroxide 40 %*	1310-73-2
L	Schwefelsäure 96 % / *Sulphuric acid 96 %*	7664-93-9
M	Salpetersäure 65 % / *Nitric acid 65 %*	7697-37-2
N	Essigsäure 99 % / *Acetic acid 99 %*	64-19-7
O	Ammoniakwasser 25 % / *Ammonium hydroxide 25 %*	1336-21-6
P	Wasserstoffperoxid 30 % / *Hydrogen peroxide 30 %*	7722-84-1
S	Flusssäure 40 % / *Hydrofluoric acid 40 %*	7664-39-3
T	Formaldehyd 37 % / *Formaldehyde 37 %*	50-00-0

Absatz *Clause*	**EN ISO 374-1:2016 + A1:2018** Anforderungen - Prüfungen / *Requirements - Tests*	Messergebnisse - Bemerkungen *Measuring results - Remarks*	Bewertung *Evaluation*

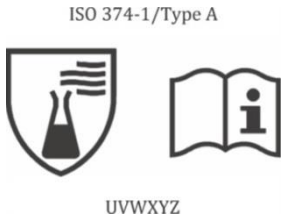
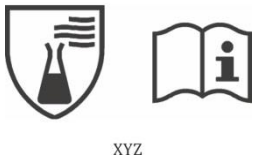
	Leistungsstufen gegen Permeation *Permeation performance levels*		
Tab. 1	<table><tr><th>Gemessene Durchbruchzeit/ *Measured breakthroug time* [min]</th><th>Schutzindex / *Permeation perfomance level*</th></tr><tr><td>> 10</td><td>Klasse / *class* 1</td></tr><tr><td>> 30</td><td>Klasse / *class* 2</td></tr><tr><td>> 60</td><td>Klasse / *class* 3</td></tr><tr><td>> 120</td><td>Klasse / *class* 4</td></tr><tr><td>> 240</td><td>Klasse / *class* 5</td></tr><tr><td>> 480</td><td>Klasse / *class* 6</td></tr></table> Die Prüfchemikalie(n) muss / (müssen) aus der Liste der Prüfchemikalien in Tabelle 2 genommen werden. Abhängig von der Anwendung der Handschuhe könnten andere Prüfchemikalien verwendet werden. *The test chemical(s) shall be taken from the list of test chemicals in Table 2. Other test chemicals could be used depending on the application of the gloves.*	/*1 <table><tr><th>Prüf-chemikalie / *Chemical*</th><th>Durchbruchzeit / *Measured breakthrough time* [min]</th></tr><tr><td>Natriumhydroxid 40 % / *Sodium hydroxide 40 %*</td><td>> 480</td></tr></table>	P ☒ F ☐ N/A ☐ N/T ☐ Level 6 Typ/ *type C*
5.5	**Anforderungen an Handschuh-Typen A, B und C** ***Requirements for gloves types A, B and C***		
Tab. 3	Anforderungen an verschiedene Schutztypen von Handschuhen *Requirements for different protection types of gloves* <table><tr><th></th><th>5.1</th><th>5.2</th><th>5.4.2</th><th>5.4.3</th><th>5.4.4</th></tr><tr><td>Typ A / *Type A*</td><td>X</td><td>X</td><td>X</td><td></td><td></td></tr><tr><td>Typ B / *Type B*</td><td>X</td><td>X</td><td></td><td>X</td><td></td></tr><tr><td>Typ C / *Type C*</td><td>X</td><td>X</td><td></td><td></td><td>X</td></tr><tr><td colspan="6">X = erforderlich / *required*</td></tr></table>		
EN ISO 374-5	Teil 5: Terminologie und Leistungsanforderungen für Risiken durch Mikroorganismen *Part 5:Terminology and performance requirements for micro-organisms risks*		
5	Leistungsanforderung *Performance requirement*		
5.1	Allgemeine Anforderungen *General requirements*		
	Schutzhandschuhe gegen Mikroorganismen sollten der EN 420: 2009, Absatz 4, Abs. 5 und Abs. 7 entsprechen. *Protective gloves against micro-organism risks shall comply with the requirements given in EN 420:2009, Clause 4, Clause 5 and Clause 7.*	gegeben *given*	P ☒ F ☐ N/A ☐ N/T ☐

Absatz *Clause*	**EN ISO 374-1:2016 + A1:2018** Anforderungen - Prüfungen / *Requirements - Tests*	Messergebnisse - Bemerkungen *Measuring results - Remarks*	Bewertung *Evaluation*
5.2	Penetration *Penetration*		
	Schutzhandschuhe gegen Viren, Bakterien und Pilze dürfen bei der Prüfung nach EN 374-2: 2014, 7.2 und 7.3 nicht undicht werden. *Protective gloves against virus, bacteria and fungi shall not leak when tested according to EN 374-2:2014, 7.2 and 7.3.*	gegeben *given*	P ☒ F ☐ N/A ☐ N/T ☐
5.3	Schutz vor Viren *Protection against viruses*		
	Schutzhandschuhe gegen Viren sind nach ISO 16604 Verfahren B zu testen und dürfen im Testtiter keinen nachweisbaren Transfer (<1 PFU / ml) des Phi-X174-Bakteriophagen aufweisen. *Protective gloves against virus shall be tested according to ISO 16604 Procedure B and shall exhibit no detectable transfer (<1 PFU/ml) of the Phi-X174 bacteriophage in the assay titre.*	---	P ☐ F ☐ N/A ☒ N/T ☐
5.4	Anforderungen an verschiedene Schutzarten von Handschuhen *Requirements for different protection types of gloves*		
Tab. 1	Die Anforderungen sind in der Tabelle 1 aufgeführt. *The requirements are mentioned in the Table 1.*		

	5.1	5.2	5.3
Handschuh gegen Bakterien und Pilze *Glove protecting against bacteria and fungi*	X	X	
Handschuh gegen Viren, Bakterien und Pilze *Glove protecting against virus, bacteria and fungi*	X	X	X
X = erforderlich / *required*			

6	**Kennzeichnung** ***Marking***	
	Die Kennzeichnung von Schutzhandschuhen gegen gefährliche Chemikalien muss mit der Anforderung an Schutzhandschuhe in EN 420 und mit folgenden Punkten übereinstimmen. *All information shall be precise and comprehensive, and provided at least in the official language(s) of the country of destination.*	

Absatz *Clause*	**EN ISO 374-1:2016 + A1:2018** Anforderungen - Prüfungen / *Requirements - Tests*	Messergebnisse - Bemerkungen *Measuring results - Remarks*	Bewertung *Evaluation*
EN 420	Kennzeichnung und Information – Allgemeines *Marking and Information – General*		
EN 420/ 7.1	Allgemeines *General*		
	Alle Informationen müssen präzise und umfassend sein. Sie sind mindestens in der (den) offiziellen Sprache(n) des Bestimmungslandes anzugeben. *All details have to be precise and in official language of country of destination.*	/*3 gegeben, in Englisch *given, in english*	P ☒ F ☐ N/A ☐ N/T ☐
EN 420/ 7.2	Kennzeichnung *Marking*		
7.2.1	Jeder Schutzhandschuh muss mit folgenden Angaben gekennzeichnet sein: - Name, Handelsmarke oder andere Erkennungsmerkmale des Herstellers oder seines Repräsentanten - Handschuhbezeichnung (Handelsname oder Code, der dem Anwender die eindeutige Identifizierung des Produkts innerhalb des Sortiments des Herstellers oder bevollmächtigten Repräsentanten erlaubt) - Größenbezeichnung - Kennzeichnung mit Verfallsdatum - das Piktogramm mit der Nummer der Norm und die Leistungsstufen *Each protective glove shall be marked with the following information:* *- Name, trade mark or other means of identification of manufacturer or his authorized representative* *- Glove designation (commercial name or code allowing the user to identify clearly the product within the manufacturer's/authorized representative's range)* *- Size designation* *- Marking with date of obsolescence* *- Pictogram with number of standard and performance levels* 	/*3 Zhonghong Pulin Medical Products Co. Ltd. ZHPFN02 gegeben, z.B.: S (6,5) gegeben gegeben *Zhonghong Pulin Medical Products Co. Ltd.* *ZHPFN02* *given, e.g.: S (6,5)* *given* *given*	P ☒ F ☐ N/A ☐ N/T ☐

Absatz *Clause*	**EN ISO 374-1:2016 + A1:2018** Anforderungen - Prüfungen / *Requirements - Tests*	Messergebnisse - Bemerkungen *Measuring results - Remarks*	Bewertung *Evaluation*
6	**Kennzeichnung Permeation** ***Marking permeation***		
6.1	**Kennzeichnung von Handschuhen des Typ A** ***Marking of Type A gloves***		
Bild / ***Fig.* 2**	 Für Schutzhandschuhe, die die in 5.5 angegebenen Typ-A-Anforderungen erfüllen, ist das Piktogramm in Bild 2 mit Verweisung auf diesen Teil von ISO 374-1 zu verwenden. Die sechs geprüften Chemikalien müssen durch ihren Kennbuchstaben identifiziert werden, die unterhalb des Piktogramms angegeben werden müssen, wie in Bild 2 dargestellt. Wurden weitere Chemikalien geprüft, die nicht in der Liste angegeben sind, müssen die Informationen über die Leistungsstufen in der Benutzeranleitung zur Verfügung gestellt werden. *For protective gloves complying with the type A requirements stated in 5.5, the pictograms in Figure 2 shall be used with reference to this part of ISO 374-1. The six tested chemicals shall be identified by their code letter which shall be marked under the pictogram as shown in Figure 2. If other chemicals not present in the list have been tested, information about the performance levels shall be provided in the user instructions.*	---	P ☐ F ☐ N/A ☒ N/T ☐
6.2	**Kennzeichnung von Handschuhen des Typ B** ***Marking of Type B gloves***		
Bild / ***Fig.* 3**	 Für Schutzhandschuhe, die die in 5.5 angegebenen Typ-B-Anforderungen erfüllen, ist das Piktogramm in Bild 3 mit Verweisung auf diesen Teil von ISO 374-1 zu verwenden. Die drei geprüften Chemikalien müssen durch ihren Kennbuchstaben identifiziert werden, die unterhalb des Piktogramms angegeben werden müssen, wie in Bild 3 dargestellt. Wurden weitere Chemikalien geprüft, die nicht in der Liste angegeben sind, müssen die Informationen über die Leistungsstufen in der Benutzeranleitung zur Verfügung gestellt werden. *For protective gloves complying with the type B requirements stated in 5.5, the pictograms in Figure 3 shall be used with reference to this part of ISO 374-1. The three tested chemicals shall be identified by their code letter which shall be marked under the pictogram as shown in Figure 3. If other chemicals not present in the list have been tested, information about the performance levels shall be provided in the user instructions.*	---	P ☐ F ☐ N/A ☒ N/T ☐

Absatz *Clause*	**EN ISO 374-1:2016 + A1:2018** Anforderungen - Prüfungen / *Requirements - Tests*	Messergebnisse - Bemerkungen *Measuring results - Remarks*	Bewertung *Evaluation*
6.3	**Kennzeichnung von Handschuhen des Typ C** ***Marking of Type C gloves***		
Bild / *Fig.* 4	Für Schutzhandschuhe, die die in 5.5 angegebenen Typ-C-Anforderungen erfüllen, ist das Piktogramm in Bild 4 mit Verweisung auf diesen Teil von ISO 374-1 zu verwenden. ISO 374-1/Type C  Die getestete Chemikalie muss in der Gebrauchsanweisung mit Angaben zu ihrer Leistungsstufe angegeben werden. Wurden weitere Chemikalien geprüft, die nicht in der Liste angegeben sind, müssen die Informationen über die Leistungsstufen in der Benutzeranleitung zur Verfügung gestellt werden. *For protective gloves complying with the type C requirements stated in 5.5, the pictogram in Figure 4 shall be used and the reference to this part of ISO 374.* *The tested chemical shall be given in the user instructions with information about its performance levels. If other chemicals not present in the list have been tested, information about the performance levels shall be provided in the user instructions.*	/*3 gegeben *given*	P ☒ F ☐ N/A ☐ N/T ☐
EN 374-5	Kennzeichnung Mikroorganismen *Marking microorganisms*		
6.2	Kennzeichnung von Handschuhen, die vor Bakterien und Pilzen schützen *Marking of gloves protecting against bacteria and fungi*		
	Schutzhandschuhe die vor Mikroorganismen schützen, müssen den Anforderungen der EN 420:2009 Absatz 4, 5, und 7 entsprechen. Sie dürfen keine Beschädigung bei der Prüfung auf Wasser-Leck und Luft-Leck gemäß EN 374-2:2014 aufweisen. *Protective gloves against micro-organism risks shall comply with the requirements given in EN 420:2009, Clause 4, Clause 5 and Clause 7.* *Protective gloves against virus, bacteria and fungi shall not leak when tested according to EN 374-2:2014, 7.2 Air leak test and 7.3.wather leak test.* ISO 374-5:2016 	/*3 gegeben *given*	P ☒ F ☐ N/A ☐ N/T ☐

Absatz *Clause*	**EN ISO 374-1:2016 + A1:2018** Anforderungen - Prüfungen / *Requirements - Tests*	Messergebnisse - Bemerkungen *Measuring results - Remarks*	Bewertung *Evaluation*
6.3	Kennzeichnung von Handschuhen, die vor Viren, Bakterien und Pilze schützen *Marking of gloves protecting against viruses, bacteria and fungi*		
	Schutzhandschuhe die vor Viren schützen, müssen den Anforderungen aus EN 374-5 6.2 entsprechen und dürfen gemäß ISO 16604 Verfahren B kein nachweisbarer Transfer (<1 PFU/ml) des Phi-X174 Bakteriophagen bei der Titer Untersuchung aufweisen. *Protective gloves against virus have to comply with the requirements of EN 374-5 6.2 and shall be tested according to ISO 16604 Procedure B and shall exhibit no detectable transfer (<1 PFU/ml) of the Phi-X174 bacteriophage in the assay titre.* ISO 374-5:2016  VIRUS	---	P ☐ F ☐ N/A ☒ N/T ☐
7	**Information des Herstellers** ***Information supplied by the manufacturer***		
	Die Informationen des Herstellers müssen in Übereinstimmung mit den Anforderungen an die Informationen stehen, die in EN 420 festgelegt sind. Sie müssen außerdem die Ergebnisse von 5.2, 5.3, 5.4 enthalten, die Liste sämtlicher Chemikalien, auf die die Schutzhandschuhe geprüft wurden und die Leistungsstufen, die bei der Permeationsprüfung erreicht wurden. *The information supplied by the manufacturer shall be in accordance with the requirements for information as defined in EN 420. It shall also include the results of 5.2, 5.3, 5.4, the list of all the chemicals to which the protective gloves have been tested and the performance levels obtained in permeation testing.*	/*3 gegeben *given*	P ☒ F ☐ N/A ☐ N/T ☐

Absatz *Clause*	**EN ISO 374-1:2016 + A1:2018** Anforderungen - Prüfungen / *Requirements - Tests*	Messergebnisse - Bemerkungen *Measuring results - Remarks*	Bewertung *Evaluation*
EN 420/ 7.2.2	Kennzeichnung der Verpackung *Marking of Packaging*		
	Jede kleinste Verpackungseinheit, welche den Handschuh unmittelbar enthält, muss eindeutig mit den nachfolgenden Angaben gekennzeichnet sein: - Name und volle Anschrift des Herstellers oder seines autorisierten Repräsentanten - Handschuhbezeichnung (Handelsname oder Code, der dem Anwender die eindeutige Identifizierung des Produkts innerhalb des Sortiments des Herstellers oder bevollmächtigten Repräsentanten erlaubt) - Größenbezeichnung - Kennzeichnung mit Verfallsdatum - Hinweis, wo die Information des Herstellers zu erhalten ist - bei einfachen Handschuhen der Hinweis, „Nur bei minimalen Gefahren“ o. ä. - das Piktogramm mit der Nummer der Norm und die Leistungsstufen *Each packaging enclosure that immediately contains the gloves shall be clearly marked with the following:* *- Name, trade mark or other means of identification of manufacturer or his authorized representative* *- Glove designation (commercial name or code allowing the user to identify clearly the product within the manufacturer's/authorized representative's range)* *- Size designation* *- Marking with date of obsolescence* *- Note where the information of the manufacturer is to obtain* *- for simple gloves note “Only for minimal risks” etc.* *- Pictogram with number of standard and performance levels*	/*3 Zhonghong Pulin Medical Products Co.,Ltd., Luannan County, Tangshan City, Hebei, China ZHPFN02 gegeben gegeben gegeben N/A gegeben *Zhonghong Pulin Medical Products Co.,Ltd., Luannan County, Tangshan City, Hebei, China* *ZHPFN02* *given* *given* *given* *N/A* *given*	P ☒ F ☐ N/A ☐ N/T ☐
EN 420/ 7.2.3	Verfallsdatum *Date of obsolescence*		
	Falls die Schutzwirkung eines Handschuhs durch Alterung deutlich beeinträchtigt wird, d. h. die Leistungsstufen werden innerhalb eines Jahres um eine oder mehrere Leistungsstufen reduziert, ist das Verfallsdatum auf dem Handschuh und der Verpackung anzugeben. *If the protective performances of the glove can be significantly affected by ageing, i. e. one or more performance levels are reduced within a year after glove production and before use, a date of obsolescence shall be indicated on gloves and packaging.*	/*3 gegeben *given*	P ☒ F ☐ N/A ☐ N/T ☐

Absatz	**EN ISO 374-1:2016 + A1:2018**	Messergebnisse - Bemerkungen	Bewertung
Clause	Anforderungen - Prüfungen / *Requirements - Tests*	*Measuring results - Remarks*	*Evaluation*
EN 420/ 7.3	Information des Herstellers - Allgemeines *Information supplied by the manufacturer - General*		
	Folgende Mindestinformationen müssen beigefügt werden:	/*3	P ☒ F ☐ N/A ☐ N/T ☐
	- Name und volle Anschrift des Herstellers oder seines autorisierten Repräsentanten	Zhonghong Pulin Medical Products Co.,Ltd., Luannan County, Tangshan City, Hebei, China	
	- Artikelbezeichnung, Code oder Nr.	ZHPFN02	
	- Informationen über verfügbare Größen	gegeben	
	- Verweis auf die relevanten Europäischen Normen, dazu gehöriges Piktogramm und Leistungsstufen	gegeben	
	- falls erfordert, Verfallsdatum bzw. Information zur Haltbarkeit	gegeben, 5 Jahre	
	- Informationen, wenn der Schutz nur für Teile der PSA gewährleistet ist	N/A	
	- mögliche Probleme	gegeben	
	- Gebrauchsanweisung auch beim Gebrauch mit anderen PSA	N/A	
	- Eine Liste solcher Substanzen, die in dem Handschuh enthalten und bekannt dafür sind, Allergien verursachen zu können.	N/A	
	- Pflegekennzeichnung oder entsprechende Erläuterungen	N/A	
	- Hinweise für die Lagerung	gegeben	
	- Art der geeigneten Transportverpackung, sofern erforderlich.	gegeben	
	- Namen und der Adresse der Prüfstelle und/oder der Prüfstellenkennnummer	gegeben auf Label	
	Weiterhin sind grundsätzliche Erklärungen beizufügen, um das Verstehen der wichtigsten Leistungsstufen zu unterstützen. Die Normen, auf die sie sich beziehen, sind anzugeben.	gegeben	

Absatz *Clause*	**EN ISO 374-1:2016 + A1:2018** Anforderungen - Prüfungen / *Requirements - Tests*	Messergebnisse - Bemerkungen *Measuring results - Remarks*	Bewertung *Evaluation*
	The following minimum information shall be supplied: *- Name and full address of manufacturer or his authorized representative*	*Zhonghong Pulin Medical Products Co.,Ltd., Luannan County, Tangshan City, Hebei, China*	
	- Glove designation	*ZHPFN02*	
	- Information on available size range	*given*	
	- Reference to the relevant specific European standard, pictogram with performance levels	*given*	
	- if the expected shelf-life of the gloves is reduced by aging, the expiration date have to be added or information regarding shelf life	*given, 5 years*	
	- if protection is only given, for part of gloves, information have to be added	*N/A*	
	- possible problems	*given*	
	- instruction for use for gloves and also for use with combination of other PPE	*N/A*	
	- A list of the substances contained in the glove which are known to cause allergies.	*N/A*	
	- care symbols or explanations	*N/A*	
	- storage instructions	*given*	
	- Type of packaging suitable for transport, if relevant	*given*	
	- Name and address of the testing laboratory and/or its number	*given at label*	
	Furthermore, a basic explanation shall be given to assist comprehension of the relevant performance levels, and the standard(s) to which they refer shall be indicated.	*given*	

Absatz	**EN ISO 374-1:2016 + A1:2018**	Messergebnisse - Bemerkungen	Bewertung
Clause	Anforderungen - Prüfungen / *Requirements - Tests*	*Measuring results - Remarks*	*Evaluation*
EN 374-1	Folgende Warnhinweise müssen in der Benutzeranleitung hinzugefügt werden:		P ☒ F ☐ N/A ☐ N/T ☐
	„Diese Information macht keine Angaben zur tatsächlichen Schutzdauer am Arbeitsplatz und zur Unterscheidung von Gemischen und reinen Chemikalien.“	gegeben	
	„Der Widerstand gegen Chemikalien wurde unter Laborbedingungen an Proben beurteilt, die lediglich von der Handinnenfläche entnommen wurden (ausgenommen ist der Fall, bei dem der Handschuh 400 mm oder länger ist – in diesem Fall wird ebenfalls die Stulpe getestet) und bezieht sich ausschließlich auf die geprüften Chemikalien. Er kann anders sein, wenn die Chemikalie in einem Gemisch verwendet wird.“	gegeben	
	„Es wird eine Überprüfung empfohlen, ob die Handschuhe für die vorgesehene Verwendung geeignet sind, da die Bedingungen am Arbeitsplatz in Abhängigkeit von Temperatur, Abrieb und Degradation von denen der Typprüfung abweichen können.“	gegeben	
	„Wurden Schutzhandschuhe bereits verwendet, können sie aufgrund von Veränderungen ihrer physikalischen Eigenschaften geringeren Widerstand gegen gefährliche Chemikalien bieten. Durch bei Berührung mit Chemikalien verursachte Degradation, Bewegungen, Fadenziehen, Reibung usw. kann die tatsächliche Anwendungszeit wesentlich reduziert werden. Bei aggressiven Chemikalien kann die Degradation der wichtigste Faktor sein, der bei der Auswahl von gegen Chemikalien beständigen Handschuhen zu berücksichtigen ist.“	gegeben	
	„Vor der Anwendung sind die Handschuhe auf jegliche Fehler oder Mängel zu überprüfen.“	gegeben	
	Bei Handschuhen, die mehrfach verwendet werden können, muss der Hersteller die relevanten Anleitungen für die Dekontamination angeben. Ist keine Information zur Dekontamination vorhanden, sind die Handschuhe nur für die einmalige Verwendung vorgesehen und folgender Warnhinweis ist hinzu zu-fügen: „Nur für die einmalige Verwendung bestimmt“.	N/A	

Absatz *Clause*	**EN ISO 374-1:2016 + A1:2018** Anforderungen - Prüfungen / *Requirements - Tests*	Messergebnisse - Bemerkungen *Measuring results - Remarks*	Bewertung *Evaluation*
	Following Information shall be added in user instructions: *- the results of Penetration, Degradation, Permeation* *- the list of all the chemicals to which the protective gloves have been tested* *- the performance levels obtained in permeation testing.*		
	The following warnings shall be added in the user instructions: *"This information does not reflect the actual duration of protection in the workplace and the differentiation between mixtures and pure chemicals."*	*given*	
	"The chemical resistance has been assessed under laboratory conditions from samples taken from the palm only (except in cases where the glove is equal to or over 400 mm - where the cuff is tested also) and relates only to the chemical tested. It can be different if the chemical is used in a mixture."	*given*	
	"It is recommended to check that the gloves are suitable for the intended use because the conditions at the workplace may differ from the type test depending on temperature, abrasion and degradation."	*given*	
	"When used, protective gloves may provide less resistance to the dangerous chemical due to changes in physical properties. Movements, snagging, rubbing, degradation caused by the chemical contact etc. may reduce the actual use time significantly. For corrosive chemicals, degradation can be the most important factor to consider in selection of chemical resistant gloves"	*given*	
	"Before usage, inspect the gloves for any defect or imperfections."	*given*	
	For reusable gloves, the manufacturer shall provide the relevant instructions for decontamination. *If there is no information about decontamination, then it is intended for single use only and the following warning shall be added: "For single use only".*	*N/A*	

Absatz *Clause*	**EN ISO 374-1:2016 + A1:2018** Anforderungen - Prüfungen / *Requirements - Tests*	Messergebnisse - Bemerkungen *Measuring results - Remarks*	Bewertung *Evaluation*
EN ISO 374-5, 7	Schutzhandschuhe, die gekennzeichnet sind Schutz gegen Micro-Organismen zu bieten und den Anforderungen von 5.4 entsprechen, ist dies in der Informationsbroschüre anzugeben. Die folgende Warnung sollte hinzugefügt werden, dass diese Information nicht die tatsächliche Leistung am Arbeitsplatz wiederspiegelt: „Die Penetration wurde unter Laborbedingen bewertet und bezeiht sich nur auf die geprüften Proben“ Falls nicht gegen Viren geprüft: “Nicht gegen Viren getetstet” *For protective gloves that are marked offering protection against micro-organisms and complying with the requirements in 5.4, this shall be stated in the user instructions.* *The following warning shall be added that this information does not reflect the actual performance in the workplace: „The penetration resistance has been assessed under laboratory conditions and relates only to the tested specimen.”* *If not tested against viruses, the following warning shall be added: “Not tested against viruses”.*	/*3 gegeben *given*	P ☒ F ☐ N/A ☐ N/T ☐

Equipment - Liste

Prüfdatum von	11.07.2019
Prüfdatum bis	19.07.2019
Projektleiter	Julia Voigt
Kostenstelle	556
Prüfberichtsnummer	60221944-002
Projektnummer	0003290084A00160
Kunde	TUV Rheinland (Shanghai) Co., Ltd.
Produktname	Nitrilhandschuhe ZHPFN02
Bemerkung	PRODUKTÜBERWACHUNG PSA KATEGORIE III

Alte ID	GTEM-ID	Beschreibung	Typbezeichnung	Hersteller	Inte. (mon)	Fälligkeit TT.MM.JJJJ
01802	2733340	Maßstab	Arbeitsmaßstab zur B	EMW Herkner	60	21.02.2022
01833	2733371	Stifte für Fingerfertigkeit - SET			60	14.12.2021
01832	2733370	Luft-Leck-Prüfgerät	Manometer Kl 1,6 0	EMW Herkner	24	02.10.2020
	2911461	Manometer Kl. 1,6	0 bis 40 kPa	Afriso	12	02.10.2019
01753	2733291	Dickenmessgerät	DM 2000	Wolf Messtechnik	24	01.03.2021
01829	2733367	Penetrationsprüfgerät (D-PM)		Eigenbau	NA*	NA*

* Keine Eintragung bei Geräten, für die keine Kalibrierung vorgesehen wurde oder die nur eine Erstkalibrierung benötigen.

ggf. Unterschrift: _____

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Nancheng District, Dongguan City
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Tel: +86 (0) 769 22888020
email: info@satrafe.com

Customer details: Zhonghong Pulin Medical Products Co., Ltd.
West Industrial Park, Luannan County
Tangshan City
Hebei
China
063500

SATRA reference: CHT0309328 /2109

Your reference: ZHPFN02

Date of report: 23 March 2021

Samples received: 1 March 2021

Date(s) work carried out: 4-22 March 2021

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 on Disposable Powder Free Nitrile Gloves referenced as ZHPFN02, colour: blue, size: XS(5-6), S(6-7), M(7-8), L(8-9), XL(9-10).

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

TECHNICAL REPORT

WORK REQUESTED

Samples described as Disposable Powder Free Nitrile Gloves referenced as ZHPFN02, colour: blue, size: XS(5-6), S(6-7), M(7-8), L(8-9), XL(9-10) were received by SATRA on 1 March 2021 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 ZHPFN02, colour: blue

TESTING REQUESTED

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

CONCLUSION

The samples described as Disposable Powder Free Nitrile Gloves referenced as ZHPFN02, colour: blue, size: XS(5-6), S(6-7), M(7-8), L(8-9), XL(9-10) 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 ISO 374-2: 2019 Clause 7.2 – Pass
EN ISO 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)

Testing

Testing was carried out in accordance with EN ISO 21420:2020 and EN ISO 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

Test Results

Table 3 – EN ISO 21420:2020 Test Results

Clause / Test	Requirement	Test Results	UoM (See note ♣)	Result
5.1 Glove length, comfort and fit	N/A	Size / Length /mm: 1 / 2 / 3 5-6: 237 / 234 / 240 — Comfortable on fit 6-7: 230 / 235 / 236 — Comfortable on fit 7-8: 246 / 245 / 240 — Comfortable on fit 8-9: 237 / 235 / 240 — Comfortable on fit 9-10: 254 / 256 / 260 — Comfortable on fit	± 1.10 mm	N/A
5.2 Dexterity	See table 1	Size / Minimum pin diameter / mm 5-6: 5.0 6-7: 5.0 7-8: 5.0 8-9: 5.0	N/A	Level 5

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

Clause / Test	Test Results		UoM (See note ♣)	Result
7.2 Air leak test	Total air pressure used	3.1 kPa	N/A	Pass
	Sample size	Leaks		
	5-6	No leaks detected		
	6-7	No leaks detected		
	7-8	No leaks detected		
	8-9	No leaks detected		
	9-10	No leaks detected		
7.3 Water leak test	Sample size	Leaks	N/A	Pass
	5-6	No leaks detected		
	6-7	No leaks detected		
	7-8	No leaks detected		
	8-9	No leaks detected		
	9-10	No leaks detected		

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

Protection Against Viruses Test Results

Testing was conducted at a third-party laboratory and reported under their reference 21R000882. 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 ZHPFN02, colour: blue					
Test method	**Specimen**	**Step 1 (0 kPa, 5 min)**	**Step 2 (14 kPa, 1min)**	**Step 3 (0kPa, 4min)**	**Titre of phage Phi-X174 (PFU /mL)**	**Comment**
ISO 16604: 2004 Procedure B Using retaining screen	+ control	Penetration	Penetration	Penetration	Penetration	Acceptable
	- control	No penetration	No penetration	No penetration	< 1	Acceptable
	1	Invisible penetrate	Invisible penetrate	Invisible penetrate	< 1	Pass
	2	Invisible penetrate	Invisible penetrate	Invisible penetrate	< 1	Pass
	3	Invisible penetrate	Invisible penetrate	Invisible penetrate	< 1	Pass

Innocuousness Test Results

Testing was conducted at a third-party laboratory and reported under their reference A210304071001. The laboratory is CNAS accredited to ISO 17025: 2017.

Sample Item	Sample Description	Location	Style
I001	Disposable Powder Free Nitrile Gloves referenced as ZHPFN02, 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	25.1
pH Value of Aqueous Extract	-	7.4
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.

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	Client's Requirement
		Test Item(s)	
		I001	
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 *****

TERMS AND CONDITIONS FOR THE SALE OF GOODS AND/OR THE PROVISION OF SERVICES

1. GENERAL

1.1 Work done, Services undertaken or the sale of Goods are subject to the terms and conditions detailed below and (subject to clause 5.2) all other conditions, warranties and representations, expressed or implied by statute relating thereto are, to the maximum extent permitted by law, hereby excluded.

1.2 SATRA Technology Services (Dongguan) Limited (东莞赛卓检测技术服务有限公司), its subsidiaries and associated companies (hereinafter referred to as "SATRA") may perform Services for, or supply Goods to, persons or entities (public, private or governmental) issuing instructions (hereinafter termed the "Client"). Each also known individually as a Party, or jointly as Parties.

1.3 These terms and conditions will apply to any Contract between SATRA and the Client to the exclusion of any other terms which the Client may seek to impose or which may be implied by trade, custom, practice or course of dealings.

1.4 Unless otherwise agreed in writing, no party other than the Client is entitled to provide instructions or information relating to the Goods or Services required or to the delivery of goods, results, reports or certificates.

1.5 All references in these terms and conditions to:

1.5.1 "Contract" is the contract between SATRA and the Client for the supply of Goods or Services which is made subject to these terms and conditions; and

1.5.2 "Services" are the work or services to be supplied or performed under the Contract (including, where relevant the supply of software, components and consumables); and

1.5.3 "Goods" are the equipment, consumables or other physical items sold under the Contract (including documents, drawings or other information required in order to operate the equipment); and

1.5.4 "PRC" means the People's Republic of China.

1.6 All drawings, descriptive matter, specifications and advertising material (including brochures and catalogues) are issued or published with the sole purpose of giving an indication of the Goods or Services being described and shall not form part of the Contract.

1.7 Where SATRA and the Client agree that the sale of Goods shall be governed by Incoterms 2010 (or any subsequent revision thereto) then the sale shall be governed by the relevant Incoterms mode of transport which is agreed by SATRA and the Client.

2 FEES AND PAYMENT

2.1 Where SATRA has agreed to perform the Services or supply the Goods on the basis of credit then payment terms are net 21 days from date of invoice, unless otherwise specified and may require part payment prior to delivery of the Services or Goods. In the event of the Client failing to make payment as agreed SATRA will be entitled to withhold delivery of the Goods or Services or cancel the Contract. SATRA reserves the right to charge interest on any overdue payments at a rate of 1.5% per month accruing on a daily basis from the date the invoice is due until the date payment is received.

2.2 Where the provision of Services or the sale of Goods is subject to a proforma invoice then SATRA shall not be obliged to start working on the provision of the Goods or Services until after payment in full has been made as cleared funds to SATRA.

2.3 SATRA reserves the right to charge for any and all expenses incurred as a result of performing the Services required by the Client. Although SATRA will try to provide an estimate of such expenses these may change as a result of circumstances out of SATRA's control.

2.4 Unless otherwise agreed in writing, the price for the Goods or Services shall be the price set in the order acknowledgement. SATRA shall not be bound by any price quoted which is not in writing. Prices for the sale of Goods include packing cases and materials but not carriage or installation which will be quoted separately and as agreed with the Client.

2.5 Quotations are valid from the date of issue for a period of 90 days unless otherwise specified or agreed in writing.

2.6 Should the Client become insolvent, bankrupt, subject to an administration order, enter into liquidation or receivership, or make arrangements with creditors SATRA reserves the right to cancel the Contract and terminate the supply of the Goods or Services. Where the Contract with SATRA is terminated all outstanding monies due from the Client to SATRA shall be immediately payable, and any materials supplied by SATRA to the Client returned. Termination of the Contract shall be without prejudice to any of SATRA's accrued rights.

2.7 All invoices issued by SATRA are payable in full. The Client is responsible for payment of withholding and any other taxes and all import duties. Payments made to SATRA shall not be reduced by such amounts.

2.8 The Client shall not be entitled to withhold or defer payment due to SATRA as a result of any dispute or counter claim that it may allege against SATRA.

2.9 SATRA reserves the right to bring action against the Client in order to collect unpaid fees, including court action. All fees associated with such actions shall be paid for by the Client including legal fees and related costs.

2.10 Where unforeseen costs arise as a result of provision of the Goods or carrying out the Services SATRA shall inform the Client immediately but reserves the right to charge additional costs to cover said costs and expenses.

3 INTELLECTUAL PROPERTY RIGHTS

3.1 All intellectual property rights belonging to a Party prior to entry into the Contract shall remain with that Party. Nothing in this Contract shall allow transfer of any intellectual property rights from one Party to the other.

3.2 In the event of certification services, the use of certification marks by the Client may be subject to national and international laws and regulations. The responsibility for the use of these certification marks lies solely with the Client.

3.3 All intellectual property rights in reports, drawings, graphs, charts, photographs or any other material (in whatever medium) produced by SATRA pursuant to this Contract shall belong to SATRA. The Client shall have the right to use said material in accordance with the terms of this Contract.

3.4 The Client agrees and acknowledges that SATRA retains any and all propriety rights in concepts, ideas and inventions that may arise during the preparation or provision of any report (including any deliverables provided by SATRA to the Client) and the provision of the Services to the Client.

3.5 All intellectual property rights in any software supplied to the Client shall belong to SATRA or SATRA's licensors.

3.6 With respect to the sale of SATRA Timeline, SATRASUMM and SATRA Visionstitch, provided that the Client is a member of SATRA and has paid its annual Smartcare fee then the Client will be entitled to use the software for its own internal use and will be entitled to receive minor software upgrades and fixes. SATRA may however terminate the supply of software upgrades and fixes for older versions of software which it no longer considers viable to support. The Client's rights to use the software and receive software upgrades and fixes will terminate if the Client has not paid its annual Smartcare fee. Major upgrades are not included within the entitlement to upgrades but may be offered by SATRA from time to time for an additional fee.

3.7 SATRA shall observe all statutory provisions with regard to data protection. To the extent that SATRA processes or gets access to personal data in connection with the Services or otherwise in connection with this Contract, it shall take all reasonable technical and organisational measures to ensure the security of such data (and guard against unauthorised or unlawful processing, accidental loss, destruction or damage to such data).

4 SUSPENSION OR TERMINATION OF SERVICES

4.1 Cancellation by the Client of orders for Goods or Services will only be acceptable by prior agreement with SATRA and a charge will usually be made.

4.2 SATRA shall not be liable for any delay or failure in providing the Goods or Services due to circumstances beyond its reasonable control (including any failure by the Client to comply with its obligations). If any such circumstances arise which prevent SATRA from delivering the Goods or completing the Services, then SATRA will be entitled to cancel or reschedule the delivery of Goods or Services at its discretion. In the event of cancellation SATRA will be entitled to retain all fees paid by the Client for Goods or Services already supplied but will refund to the Client any fees paid by the Client for Goods or Services which have not yet been supplied. The Client will not be liable for any non-refundable expenses already incurred by SATRA in relation to Goods or Services not yet supplied unless the cancellation is due to the Clients failure to comply with its obligations under the Contract.

5 LIABILITY AND INDEMNIFICATION

5.1 Reports are issued on the basis of information, documents and or samples submitted to SATRA by the Client, or on behalf of the Client and are provided solely for the benefit of the Client who is responsible for acting as it sees fit on the basis of such reports and findings. Subject to clause 5.2, neither SATRA nor any of its employees, agents or subcontractors shall be liable to the Client or any third party for any actions taken or not taken on the basis of such findings and reports, nor for any incorrect results arising as a result of unclear, erroneous, incomplete, misleading or false information provided to SATRA.

5.2 Nothing in these terms and conditions shall limit or exclude SATRA's liability for:

5.2.1 death or personal injury caused by its negligence or the negligence of its employees or agents;
5.2.2 fraud or fraudulent misrepresentation; or
5.2.3 any other liability which cannot be limited or excluded by applicable law.

5.3 Subject to clause 5.2 SATRA shall not be liable to the Client whether in contract, tort (including negligence), breach of statutory duty or otherwise arising under or in connection with the Contract for loss of profits, sales, contracts, anticipated savings, loss or damage to goodwill or any indirect or consequential loss.

5.4 Subject to clause 5.2 SATRA's total aggregate liability to the Client, whether in contract, tort (including negligence), breach of statutory duty or otherwise arising under or in connection with the Contract shall be limited to the total amount of fees for the Services or the price of the Goods (excluding any value added tax or other sales tax or expenses) payable by the Client to SATRA under the Contract or RMB500,000 whichever is the lower figure.

6 MISCELLANEOUS

6.1 If any one or more provisions of these terms and conditions are found to be illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions shall not in any way be affected or impaired thereby.

6.2 During the course of providing the Goods or Services and for a period of one year thereafter the Client shall not directly or indirectly entice, encourage or make any offer to SATRA's employees to leave their employment with SATRA.

6.3 The use of SATRA's corporate name or registered marks for advertising purposes is not permitted without SATRA's prior written authorisation.

6.4 All reports and documentation which are supplied to the Client under the Contract remain the property of SATRA until paid in full. Under no circumstances will a Client's purchase order override SATRA's retention of title in accordance with this clause.

6.5 The Client acknowledges that in entering into this Contract it has not relied on any representation, warranty, collateral contract or other assurance (except those set out or referred to in these terms and conditions) made by or on behalf of SATRA or any other party before entering into the Contract. The Client waives all rights and remedies that, but for this clause, might otherwise be available to it in respect of any such representation, warranty, collateral contract or other assurance.

6.6 To the extent permitted by applicable laws and regulations, all provisions of the Contract that limit or exclude the liability of SATRA are intended also to be for the benefit of SATRA's holding company (called SATRA, and being a company limited by guarantee and incorporated in England and Wales with company number 00153475), and shall accordingly be enforceable by such holding company as well as or instead of by SATRA, and on the basis that any limit on the liability of SATRA shall apply to it and to such holding company in the aggregate.

7 CONFIDENTIALITY

7.1 Unless specifically excluded in the terms of an individual contract between SATRA and the Client, the following shall apply to all deliverables including, reports, advice, drawings, photographs, specifications, data or other forms of media.

7.2 Deliverables referred to in clause 7.1 shall not be disclosed to third parties or used in litigation without the consent of SATRA.

7.3 Where SATRA has given consent to disclosure of any service deliverables referred to in clause 7.1, the Client shall draw the attention of the third party to these terms and conditions and the basis on which SATRA undertakes testing, reporting and advising. The Client shall indemnify SATRA for any failure to do so.

7.4 The service deliverables referred to in clause 7.1 are submitted to the Client as confidential documents. Confidentiality shall continue to apply after completion of the business, but shall cease to apply to information or knowledge which has come into the public domain through no breach of this Contract by the Client.

7.5 The Client shall not disassemble, remove parts or carry out any form of analysis on goods or materials sold by SATRA for the purposes of reverse engineering or obtaining information on the construction, content or composition of the item without the consent of SATRA.

8 AMENDMENT

8.1 No amendment to a Contract shall be effective unless it is in writing, expressly stated to amend the Contract and signed by an authorised signatory of both Parties.

9 DISPUTE RESOLUTION

9.1 If there should be a dispute between the parties to this Agreement they undertake to act with goodwill and to use all reasonable endeavours to resolve that dispute.

9.2 Failure to resolve any dispute by discussions between the parties shall, in the first instance, be referred to a mediator for resolution. The parties shall attempt to agree upon the appointment of a mediator, upon receipt, by either of them, of a written notice to concur in such appointment. Should the parties fail to agree within 21 days, the terms of clause 9.3 shall apply.

9.3 Should the mediation fail, in whole or in part, either party may, upon giving written notice, refer the dispute to the Shenzhen Court of International Arbitration for arbitration in accordance with its rules of arbitration then in force. The place of arbitration shall be Shenzhen. The number of arbitrators shall be one. Unless agreed otherwise, the language used for the arbitration shall be English and Chinese and each Party shall have the right to have its own interpreters and legal advisors present throughout the arbitration. The arbitral award shall be final and binding upon the Parties and the Parties agree to be bound thereby and to act accordingly. Application may be made to any court having jurisdiction for judicial acceptance of the award and an order of enforcement and execution.

9.4 Unless specified otherwise in a Contract, the laws of the PRC shall govern the interpretation of a Contract.

TERMS AND CONDITIONS FOR THE SALE OF GOODS AND/OR THE PROVISION OF SERVICES

10 PROVISION OF SERVICES

10.1 SATRA shall provide Services using reasonable care and skill and in accordance with the Client's specific instructions and as confirmed by SATRA as part of the Contract review process.

10.2 Estimates for completion of the Services are made in good faith and date from receipt of a written order, payment of a proforma invoice if required, full information and samples to enable SATRA to proceed. While SATRA will make every effort to fulfil them, such estimates are subject to unforeseen events and if not achieved, cannot give rise to any claim. Time will not be of the essence in relation to the performance of the Services.

10.3 Results given in test reports or certificates refer only to samples submitted for analysis to SATRA. 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.

10.4 SATRA may delegate all or part of the Services to a subcontractor and the Client authorises SATRA to disclose all information required to undertake the Services.

10.5 Where the Client requests SATRA to witness testing of other services being undertaken by a third party the Client agrees that SATRA's sole responsibility is to be present at the time of the work and to forward the results or confirm that the service has been undertaken. The Client agrees that unless otherwise agreed SATRA is not responsible for the condition or calibration of any equipment unless provided by SATRA.

10.6 Unless otherwise agreed in advance, test samples will be retained for 6 weeks from the date of the final report after which time they will be disposed of and SATRA shall cease to have any responsibility for such samples.

Where the nature of the samples or the Services undertaken results in specialist disposal then SATRA reserves the right to pass the cost of such disposal onto the Client.

Storage for longer periods may be possible only if agreed in advance and may incur a storage charge payable by the Client.

Where practical and agreed in advance, samples may be returned at the Client's expense. However, samples are in most instances partially or fully destroyed as part of the work undertaken and SATRA cannot guarantee that samples will be returned in an "as new" condition.

10.7 Where SATRA receives documents reflecting engagements between the Client and third parties or documents belonging to third parties, such documents shall be considered as being for information only and shall not release the Client from any or all obligations to SATRA.

10.8 SATRA reserves the right to make changes to the Services, provided that such changes do not materially affect the nature or quality of the provision of these Services or where they are necessary in order to ensure that any applicable laws or safety requirements are complied with.

10.9 The Client acknowledges that SATRA by providing the Services, neither takes the place of the Client or any third party or releases them from any of their obligations.

11 CLIENT RESPONSIBILITIES RELATING TO THE PROVISION OF SERVICES

11.1 The Client shall provide sufficient samples, information, instructions and documents as required to enable SATRA to carry out the Services in accordance with the methods, standards or other specifications as agreed.

11.2 Where applicable the Client shall allow access by members of SATRA staff to such premises where the Services are to be performed and provide any specialist equipment and personnel.

11.3 The Client shall inform SATRA in advance of any known hazards, dangers or other safety matters relating to samples submitted to SATRA or on site visits made by SATRA.

11.4 Where the Client fails to comply with any of its responsibilities SATRA reserves the right to suspend any Services until such time as the Client has complied and may require the Client to reimburse SATRA the amount of any additional costs arising from the suspension.

12 DELIVERY AND NON-DELIVERY OF GOODS

12.1 Delivery dates for the supply of the Goods are approximate only and not guaranteed. Time of delivery is not of the essence of the Contract and SATRA shall not be liable for any delay in delivery of Goods.

12.2 Should expedited delivery be requested and agreed, SATRA shall be entitled to make additional charges to cover overtime or any other additional costs.

12.3 Delivery of the Goods shall take place at such location as SATRA and the Client agree. If the Client agrees to collect the Goods from SATRA's premises, then delivery will take place at those premises in which case the consignment of Goods as recorded by SATRA upon dispatch shall be evidence of the Goods received by the Client unless the Client can provide conclusive evidence to the contrary.

12.4 SATRA shall not be liable for the non-delivery of Goods (even if caused by SATRA) unless the Client provides written notice of non-delivery in accordance with clause 13.2. Liability for non-delivery of Goods shall in any event be limited to replacing the Goods within a reasonable time frame or the issue of a credit note to the value of the Goods not delivered.

12.5 Should delivery of the Goods be suspended or delayed by the Client for any reason SATRA reserves the right to charge for storage and for all expenses incurred, including loss of or wastage of resources that cannot otherwise be used. If the delay extends beyond 30 days SATRA shall be entitled to immediate payment for any Goods that are ready for delivery, and any other additional costs.

12.6 If for any reason the Client fails to take delivery of any of the Goods when they are ready for delivery, or SATRA is unable to deliver the Goods on time because the Client has not provided appropriate instructions, documents, licenses or authorisations then risk in the Goods shall pass to the Client, the Goods and/or Services shall be deemed to have been delivered; and SATRA may store the Goods until delivery, whereupon the Client shall be liable for all related costs and expenses (including, without limitation, storage and insurance).

13 RISK/TITLE OF GOODS

13.1 Subject to clause 12.6 the risk in the Goods will transfer to the Client on delivery of the Goods unless SATRA and the Client have agreed that the sale of the Goods will be governed by Incoterms 2010 (or any subsequent revision thereto) in which case risk will transfer to the Client in accordance with the Incoterms mode of transport which is agreed by SATRA and the Client.

13.2 The Company shall not accept responsibility for loss or damage in transit unless:

13.2.1 In the case of sales where delivery of Goods is made in the PRC, SATRA is notified by the Client within 10 days of the invoice date of non-arrival of Goods and within 3 days of the invoice date of receipt of Goods damaged in transit; or

13.2.2 in all other cases the Client notifies SATRA on the non-arrival or damage in transit within a reasonable period of time as determined by SATRA.

13.3 Title to the Goods shall not pass to the Client until the earlier of when: -

13.3.1 SATRA receives payment in full (in cash or cleared funds) for the Goods and any other Goods that SATRA has supplied to the Client in which case title to the Goods shall pass at the time of payment of all such sums; and

13.3.2 the Client resells the Goods in accordance with clause 13.5 in which case title shall pass to the Client immediately before the time at which the resale by the Client occurs.

13.4 Until ownership of Goods has passed to the Client, the Client shall:

13.4.1 hold the Goods as SATRA's bailee;

13.4.2 store the Goods (at no cost to SATRA) separately from all other goods belonging to the Client or any third party in such a way that they remain readily identifiable as SATRA's property (including where the Goods have been sold to a 3rd party);

13.4.3 not destroy, deface or obscure any identifying mark or packaging on or relating to the Goods; and

13.4.4 maintain the Goods in satisfactory condition and keep them insured on SATRA's behalf for their full price against all risks to the reasonable satisfaction of SATRA. The Client shall obtain an endorsement of SATRA's interest in the goods on its insurance policy. On request the Client shall allow SATRA to inspect such Goods and shall produce the policy of insurance.

13.5 The Client may resell the Goods before ownership has passed to it solely on condition that sale shall be effected in the ordinary course of the Client's business at full market value.

13.6 If before title to the Goods passes to the Client, the Client becomes subject to any of the events referred to in clause 2.6 then without limiting any other right or remedy SATRA may have:

13.6.1 the Client's right to resell the Goods or use them in the ordinary course of its business ceases immediately; and

13.6.2 SATRA may at any time require the Client to deliver up all Goods in its possession that have not been resold or irrevocably incorporated into another product; and

13.6.3 if the Client fails to do so promptly SATRA may exercise its rights under clause 13.7.

13.7 The Client grants SATRA, its agents and employees an irrevocable licence at any time to enter any premises where the Goods are or may be stored in order to inspect them, or, where the Client's right to possession has terminated, to recover them.

13.8 On termination of a Contract, howsoever caused, SATRA's (but not the Client's) rights contained in this clause13 shall remain in effect.

14 PATENTS

14.1 SATRA gives no indemnity against any claim of infringement of any Patent, Registered Design, Trade Mark or Copyright by the use of or sale of any article or material supplied to the Client. If its use is impossible without infringement of a Patent, Registered Design, Trade Mark or Copyright published at the date of a Contract, SATRA will refund to the Client the purchase price of the said article or material provided that it is returned to SATRA free of charge. The Client warrants that any design or instruction furnished or given by the Client shall not be such as will cause SATRA to infringe any Patent, Registered Design, Trade Mark or Copyright in the execution of the Client's order.

15 WARRANTY OF GOODS

15.1 SATRA warrants that on delivery and for a period of 12 months from the date of delivery or within the shelf life of the Goods (whichever is the shorter period) the Goods shall be free from defects in design, material and workmanship.

16 DEFECTIVE GOODS

16.1 Subject to clauses 16.6 and 16.7 if:

16.1.1 the Client gives notice in writing to SATRA in accordance with clause 16.3 and during the period referred to in clause 15.1 that the Goods do not comply with the warranty in that clause; and

16.1.2 SATRA is given a reasonable opportunity of examining such Goods; and

16.1.3 the Client (if asked to do so by SATRA) returns such Goods to SATRA's place of business,

then SATRA will, at its option, repair or replace the defective Goods or refund the price of the defective Goods in full. SATRA reserves the right to repair the Goods at the Client's premises.

16.2 The Client must inspect all Goods upon delivery. Failure to do so may result in further charges being applied in the event of a return.

16.3 If Goods are found to be faulty, defective or damaged the Client must inform SATRA in writing as soon as reasonably possible and in any event within 10 working days of the fault, damage or defect being discovered.

16.4 Without prejudice to clause 16.1 if no notice of rejection has been received by SATRA within 3 months of delivery, the Client shall be deemed to have accepted the Goods.

16.5 SATRA will pay the reasonable costs of carriage, packaging and insurance for any defective Goods which are returned by the Client provided that SATRA is liable under clause 16.1 to repair or replace the defective Goods. If SATRA determines that the Goods are not defective or if SATRA is not liable to repair or replace the Goods due to the circumstances under clauses 16.6 or 16.7 then the Client will be responsible for the payment of such costs.

16.6 SATRA shall not be under any liability to repair or at its option replace or pay for the repair or replacement of any Goods which are found to be defective if:

16.6.1 the defect is caused or substantially caused by wear and tear, overloading, misuse, neglect, modification or attempted modification carried out by any organisation other than by SATRA or their approved agents, or use with ancillary equipment not approved in writing by SATRA, or default in proper maintenance or cleaning; or

16.6.2 the Client authorises or carries out any repair or replacement of any Goods without first affording SATRA a reasonable opportunity to replace or repair them; or

16.6.3 the Client has breached any of the terms of the Contract under which the Goods were supplied; or

16.6.4 the Goods have been manufactured to a design or specification or in compliance with other information provided by the Client and the defect has arisen as a result of that design, specification or information;

16.7 Where Goods or parts of Goods are not manufactured by SATRA then SATRA shall be liable for defects only to the extent that SATRA obtains redress from the manufacturer or supplier thereof provided that:

16.7.1 SATRA shall not be obliged to take any step to attempt to obtain such redress except at the request and expense of the Client and upon provision by the Client of a full indemnity as to costs for which SATRA may thereby become liable;

16.7.2 nothing in this condition 16.7 shall have effect as to impose upon SATRA any additional liability or obligations other than those referred to in condition 16.1.

16.8 Except as provided in clause 16.1 SATRA shall have no liability to the Client arising from any failure of the Goods to comply with the warranty in clause 15.1.

Terms and conditions – May 2017