

Issued to:



Notified Body: 2777

SATRA customer number: P20282

EU Type-Examination Certificate

Certificate number: 2777/15953-01/E00-00

This EU Type-Examination Certificate covers the following product group(s) supported by testing to the relevant standards/technical specifications and examination of the technical file documentation:

Following the EU Type-Examination this product group has been shown to satisfy the applicable essential health and safety requirements of Annex II of the PPE Regulation (EU) 2016/425 as a Category III product.

Product reference:

HQ316

Description:

Disposable Hybrid Poly Powder-Free Glove

Colour: Clear

Sizes:

8/L

Classification:

EN ISO 374-1:2016+A1:2018 /Type C	Level	EN ISO 374-4:2019 Degradation %
30% Hydrogen Peroxide (P)	6	-3.0

EN ISO 374-5:2016

Protection against Bacteria and Fungi

Pass

Protection against Viruses

Pass

Standards/Technical specifications applied:

EN ISO 21420:2020; EN ISO 374-1:2016+A1:2018; EN ISO 374-5:2016

Technical reports/Approval documents:

SATRA: CHT0305959/2050, CHM0306199/2050/LH/A, CHM0306199/2050/LH/B

Signed on behalf of SATRA:

A handwritten signature in black ink, appearing to be 'Quincey Brown'.

Quincey Brown

Date first issued: 10/03/2021

Date of issue: 10/03/2021

Expiry date: 10/03/2026

German Food, Articles of Daily Use and Feed Code of September 1, 2005 (LFGB), Section 30 and 31 with amendments, European Commission Regulation (EU) No 10/2011 with amendments and BfR recommendations-Specific migration of heavy metal

Test Method : With reference to EN13130-1:2004, analysis was performed by ICP-OES.

Sample 001

Simulant Used : 3% Acetic Acid (W/V) Aqueous Solution

Test Condition : 40 °C 2.0 hr(s)

<u>Test Item(s)</u>	<u>Max. Permissible Limit</u>	<u>Unit</u>	<u>MDL</u>	<u>Test result</u>
Migration times	-	-	-	1st
Area/volume	-	dm ² /kg	-	6.0
Aluminium (Al)	1	mg/kg	0.1	ND
Barium (Ba)	1	mg/kg	0.25	ND
Cobalt (Co)	0.05	mg/kg	0.01	ND
Copper (Cu)	5	mg/kg	0.25	ND
Iron(Fe)	48	mg/kg	0.25	ND
Lithium (Li)	0.6	mg/kg	0.5	ND
Manganese(Mn)	0.6	mg/kg	0.25	ND
Zinc(Zn)	5	mg/kg	0.5	ND
Nickel (Ni)	0.02	mg/kg	0.02	ND

Notes :

(1) Test condition & simulant were specified by client.



Unless otherwise agreed in writing, this document is issued by the Company subject to its General Conditions of Service printed overleaf, available on request or accessible at <http://www.sgs.com/en/Terms-and-Conditions.aspx> and, for electronic format documents, subject to Terms and Conditions for Electronic Documents at <http://www.sgs.com/en/Terms-and-Conditions/Terms-e-Documents.aspx>. Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein. Any holder of this document is advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. This document cannot be reproduced except in full, without prior written approval of the Company. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law. Unless otherwise stated the results shown in this test report refer only to the sample(s) tested.

Attention: To check the authenticity of testing/inspection report & certificate, please contact us at telephone: (86-755) 8307 1443, or email: CN.Doccheck@sgs.com

No. 1177, Lingyun Road, Hi-Tech Zone, Ningbo, Zhejiang, China 315040 t E&E (86-574)89070249 www.sgs.com.cn
 中国·浙江·宁波高新区凌云路1177号 邮编: 315040 t HL (86-574)89070271 t ML (86-574)89070242 sgs.china@sgs.com



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

Customer details:



SATRA reference: CHT0305959 /2050

Your reference: HQ316

Date of report: 22 December 2020

Samples received: 7 December 2020

Date(s) work carried out: 18 December 2020

TECHNICAL REPORT

Subject:

EN ISO 21420: 2020 size & dexterity & innocuousness test, EN ISO 374-2: 2019 air leak and water leak, EN ISO 374-5: 2016 viruses test on Disposable Hybrid Poly Gloves, Powder free, referenced as HQ316, colour: clear, size: L/8

Conditions of Issue:

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

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

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

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

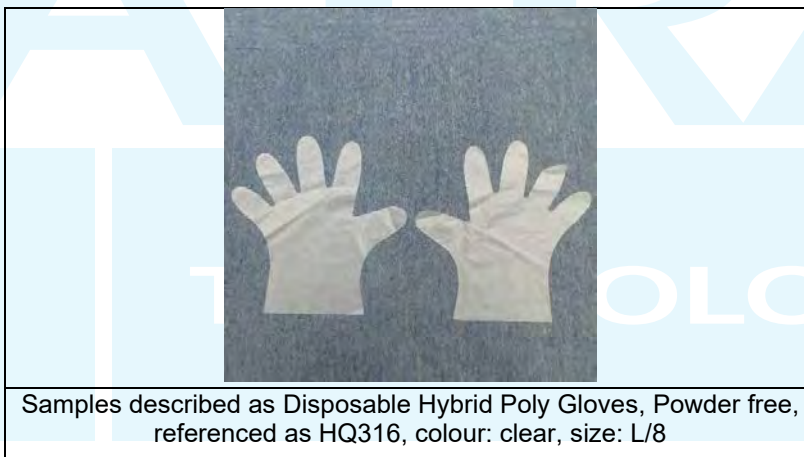
Report signed by: Anthony Mak
Position: General Manager
Department: China Testing

(Page 1 of 11)

WORK REQUESTED

Samples described as Disposable Hybrid Poly Gloves, Powder free, referenced as HQ316, colour: clear, size: L/8 were received by SATRA on 7 December 2020 for testing in accordance with EN ISO 21420: 2020, EN ISO 374-2: 2019 and EN ISO 374-5: 2016.

SAMPLE SUBMITTED



TESTING REQUESTED

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

CONCLUSION

The samples described Disposable Hybrid Poly Gloves, Powder free, referenced as HQ316, colour: clear, size: L/8 were found to achieve the following results:

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

Samples for testing were conditioned for at least 24 hours in a conditioned environment maintained at $(23\pm 2)^\circ\text{C}$ and $(50\pm 5)\%$ 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	Length /mm			± 1.10 mm	N/A
		Size	1	2		
		8	255	256	257	
		Comfortable on fit				
5.2 Dexterity	See table 1	Minimum pin diameter / mm			N/A	Level 5
		Size				
		8	5.0			
		8	5.0			
		8	5.0			
		8	5.0			

Additional Information / Notes

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

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

Clause / Test	Test Results	UoM	Result	
7.2 Air leak test	Total air pressure used	3.1 kPa	NA	Pass
	Sample size	Leaks		
	8	No leaks detected		
	8	No leaks detected		
	8	No leaks detected		
7.3 Water leak test	Sample size	Leaks	NA	Pass
	8	No leaks detected		
	8	No leaks detected		
	8	No leaks detected		
	8	No leaks detected		

Protection Against Viruses Test Results

Testing was conducted at a third-party laboratory and reported under their reference 20R007222. 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 Hybrid Poly Glove, Powder free, referenced as HQ316, colour: clear, size: L/8				
Test method	Specimen	Step 1 (0 kPa, 5 min)	Step 2 (14 kPa, 1min)	Step 3 (0kPa, 4min)	Assay titer (PFU /mL)	Comment
ISO 16604: 2004 Procedure B Using retaining screen	+ control	seen	seen	seen	seen	Acceptable
	- control	None seen	None seen	None seen	< 1	Acceptable
	1	None seen	None seen	None seen	< 1	Pass
	2	None seen	None seen	None seen	< 1	Pass
	3	None seen	None seen	None seen	< 1	Pass

Innocuousness Testing

Testing was conducted at a third-party laboratory and reported under their reference A201210022001. The laboratory is CNAS accredited to ISO 17025: 2017.

Sample Item	Sample Description	Location	Style
I001	Disposable Hybrid Poly Glove, Powder free, referenced as HQ316, colour: clear	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	-	5.43
Temp. of Aqueous Extract	deg. C	25.1
pH Value of Aqueous Extract	-	6.2
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 hydrocarbons 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

Phthalates Content in Toys and Childcare Articles - European Regulation (EC) No. 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Annex XVII, Entry 51 with Amendments up to (EU) No. 2018/2005

Test Method : With reference to ISO 14389:2014, and then analyzed by Gas Chromatograph Mass Spectrometer.

Analyte	Requirement (%w/w)	Result(%w/w)
		Test Item(s)
		I001
Di-(2-ethylhexyl) phthalate (DEHP)	-	ND
Dibutyl phthalate (DBP)	-	ND
Benzylbutyl phthalate (BBP)	-	ND
Diisobutyl phthalate (DIBP)	-	ND
Sum of DEHP+DBP+BBP+DIBP	0.1	ND
Conclusion	-	PASS

Note / Key : ND = Not detected Detection Limit(%w/w) : 0.005
 mg/kg = milligram per kilogram = ppm = part per million
 10 000 mg/kg = 1 % % = percent

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 *****



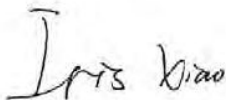
The following sample(s) was/were submitted and identified on behalf of the clients as : Disposable Power Free Gloves

SGS Job No. : NP20-004310 - NB
 Date of Sample Received : 23 Oct 2020
 Testing Period : 23 Oct 2020 - 29 Oct 2020
 Test Requested : Selected test(s) as requested by client.
 Test Method : Please refer to next page(s).
 Test Results : Please refer to next page(s).

Result Summary :

Test Requested	Conclusion
FDA 21 CFR 177.2600- Total Extractives	PASS

Signed for and on behalf of
 SGS-CSTC Standards Technical Services Co., Ltd. Ningbo Branch



Iris Xiao
 Approved Signatory



Unless otherwise agreed in writing, this document is issued by the Company subject to its General Conditions of Service printed overleaf, available on request or accessible at <http://www.sgs.com/en/Terms-and-Conditions.aspx> and, for electronic format documents, subject to Terms and Conditions for Electronic Documents at <http://www.sgs.com/en/Terms-and-Conditions/Terms-e-Documents.aspx>. Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein. Any holder of this document is advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. This document cannot be reproduced except in full, without prior written approval of the Company. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law. Unless otherwise stated the results shown in this test report refer only to the sample(s) tested.

Attention: To check the authenticity of testing/inspection report & certificate, please contact us at telephone: (86-755) 8307 1443, or email: CN.Doccheck@sgs.com

No.1177, Lingyun Road, Hi-Tech Zone, Ningbo, Zhejiang, China 315040 TEL (86-574)89070249 www.sgs.com.cn
 中国·浙江·宁波高新区凌云路1177号 邮编: 315040 TEL (86-574)89070271 TML (86-574)89070242 sgs.china@sgs.com

Test Report

No. NGBEC2006200501

Date: 30 Dec 2020

Page 2 of 4

Test Results :

Test Part Description :

Specimen No.	SGS Sample ID	Description
SN1	NGB20-062005.001	blue gloves

Remarks :

- (1) 1 mg/kg = 0.0001%
- (2) MDL = Method Detection Limit
- (3) ND = Not Detected (< MDL)
- (4) "-" = Not Regulated

American Society for Testing and Materials -ASTM F 963-11 - total Lead in Substrate Materials

Test Method : With reference to CPSC Test Method: CPSC-CH-E1002-08.1. Analysis was performed by ICP-OES.

<u>Test Item(s)</u>	<u>Limit</u>	<u>Unit</u>	<u>MDL</u>	<u>001</u>
Total Lead (Pb)	100	mg/kg	20	ND

American Society for Testing and Materials –ASTM F 963-11 – soluble heavy metal in Substrate Materials/paint and similar surface-coating materials

Test Method : Soluble Heavy Metal contents (Clause 4.3.5) - Sample was extracted by dilute hydrochloric acid in accordance with ASTM F 963-11(Claue 8.3), analysis was performed by ICP-OES.

<u>Test Item(s)</u>	<u>Limit</u>	<u>Unit</u>	<u>MDL</u>	<u>001</u>
Soluble Lead (Pb)	90	mg/kg	5	ND
Soluble Antimony (Sb)	60	mg/kg	5	ND
Soluble Arsenic (As)	25	mg/kg	2.5	ND
Soluble Barium (Ba)	1000	mg/kg	10	ND
Soluble Cadmium (Cd)	75	mg/kg	5	ND
Soluble Chromium (Cr)	60	mg/kg	5	ND
Soluble Mercury (Hg)	60	mg/kg	5	ND
Soluble Selenium (Se)	500	mg/kg	10	ND

Notes :



Unless otherwise agreed in writing, this document is issued by the Company subject to its General Conditions of Service printed overleaf, available on request or accessible at <http://www.sgs.com/en/Terms-and-Conditions.aspx> and, for electronic formal documents, subject to Terms and Conditions for Electronic Documents at <http://www.sgs.com/en/Terms-and-Conditions/Terms-a-Document.aspx>. Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein. Any holder of this document is advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. This document cannot be reproduced except in full, without prior written approval of the Company. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law. Unless otherwise stated the results shown in this test report refer only to the sample(s) tested.

Attention: To check the authenticity of testing/inspection report & certificate, please contact us at telephone: (86-755) 8307 1443, or email: CN.Doccheck@sgs.com

EGS-CSI (Singapore) Technical Services Co., Ltd.
Ningbo Branch Laboratory

No.1177, Lingyun Road, Hi-Tech Zone, Ningbo, Zhejiang, China 315040
中国·浙江·宁波高新区凌云路1177号

T&E (86-574)89070249
IHL (86-574)89070271
www.sgsgroup.com.cn
ML (86-574)89070242
sgs.china@sgs.com

Test Report

No. NGBEC2006200501

Date: 30 Dec 2020

Page 4 of 4

Sample photo:



SGS authenticate the photo on original report only

*** End of Report ***



Unless otherwise agreed in writing, this document is issued by the Company subject to its General Conditions of Service printed overleaf, available on request or accessible at <http://www.sgs.com/en/Terms-and-Conditions.aspx> and, for electronic formal documents, subject to Terms and Conditions for Electronic Documents at <http://www.sgs.com/en/Terms-and-Conditions/Terms-a-Document.aspx>. Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein. Any holder of this document is advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. This document cannot be reproduced except in full, without prior written approval of the Company. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law. Unless otherwise stated the results shown in this test report refer only to the sample(s) tested.

Attention: To check the authenticity of testing/inspection report & certificate, please contact us at telephone: (86-755) 8307 1443, or email: CN.Doccheck@sgs.com

EGS-CS-001
Ningbo Branch
Inspection & Testing Services

No.1177, Lingyun Road, Hi-Tech Zone, Ningbo, Zhejiang, China 315040 TEL (86-574)89070249
中国·浙江·宁波高新区凌云路1177号 邮编: 315040 TEL (86-574)89070271

www.sgsgroup.com.cn
sgs.china@sgs.com



中国认可
国际互认
检测
TESTING
CNAS L0604

scan to see the report



QDHL2102001554MD

Test Report

Report No.: QDHL2102001554MD

Sample Description: DISPOSABLE HYBRID POLY GLOVE,
POWDER FREE

Applicant:

Test Type:

SUBMITTED BY CLIENT

SGS-CSTC Standards Technical Services (Qingdao) Co., Ltd.
Page 1 of 6

Unless otherwise agreed in writing, this document is issued by the Company subject to its General Conditions of Service printed overleaf, available on request or accessible at <http://www.sgs.com/en/Terms-and-Conditions.aspx> and, for electronic format documents, subject to Terms and Conditions for Electronic Documents at <http://www.sgs.com/en/Terms-and-Conditions/Terms-e-Documents.aspx>. Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein. Any holder of this document is advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. This document cannot be reproduced except in full, without prior written approval of the Company. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law.



QD 7442276

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

SGS Center, No.143, Zhuzhou Road, Laoshan District, Qingdao, Shandong, China 266101

t (86-532) 68999888

www.sgs.com

sgs.china@sgs.com



中国认可
国际互认
检测
TESTING
CNAS L0604

Report No.: QDHL2102001554MD

Test Report

Sample information	Sample Description	DISPOSABLE HYBRID POLY GLOVE, POWDER FREE	Color	CLEAR
	Received sample quantity/ Tested sample quantity	200PCS/ 200PCS	Type/ Specifications	SIZE: L
	Lot No.	HQ316	Lot Quantity	NOT PROVIDED
	Manufacture Date	2021.1	Expiration Date	2026.1
	Material/Appearance	RECYCLABLE HYBRID POLY	Storage Condition	NOT PROVIDED
	Manufacturer			
	Others			
Client information	Applicant			
	Applicant address			

Attention: To check the authenticity of testing/inspection report & certificate, please contact us at telephone: (86-755)83071443, or email: C.N.Doccheck@sgs.com

SGS-CSTC Standards Technical Services (Qingdao) Co., Ltd.
Page 2 of 6

Unless otherwise agreed in writing, this document is issued by the Company subject to its General Conditions of Service printed overleaf, available on request or accessible at <http://www.sgs.com/en/Terms-and-Conditions.aspx> and, for electronic format documents, subject to Terms and Conditions for Electronic Documents at <http://www.sgs.com/en/Terms-and-Conditions/Terms-e-Documents.aspx>. Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein. Any holder of this document is advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. This document cannot be reproduced except in full, without prior written approval of the Company. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law.

QD 7442277



SGS Center, No.143, Zhuzhou Road, Laoshan District, Qingdao, Shandong, China 266101 t (86-532) 6899888 www.sgsgroup.com.cn sgs.china@sgs.com

Report No.: QDHL2102001554MD

Attention: To check the authenticity of testing /inspection report & certificate, please contact us at telephone: (86-755)85071443, or email: C.N.Docheck@sgs.com

Test information	Sample Receiving Date	FEB.23,2021	Test Period Date	FEB.23,2021 TO FEB.26,2021
	Sample No.	QDHL2102001554MD	Test environment	Meet requirement
	Test items	Water tightness test		
	Testing Accordance	EN 455-1:2020 Medical Gloves for Single Use – Part 1: Requirements and Testing for Freedom from Holes Clause 5.1		
Test conclusion	This report only provides the test results and individual judgment, conclusion please see follow pages.			
Remark	/			
			Issue date: FEB.26,2021	

Approver: *Jemielaw* Auditor: *Jemielaw* Compiler: *William D'rao*
 Date: *2021.02.26* Date: *2021.02.26* Date: *2021.02.26*

SGS-CSTC Standards Technical Services (Qingdao) Co., Ltd.
Page 3 of 6

Unless otherwise agreed in writing, this document is issued by the Company subject to its General Conditions of Service printed overleaf, available on request or accessible at <http://www.sgs.com/en/Terms-and-Conditions.aspx> and, for electronic format documents, subject to Terms and Conditions for Electronic Documents at <http://www.sgs.com/en/Terms-and-Conditions/Terms-e-Documents.aspx>. Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein. Any holder of this document is advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. This document cannot be reproduced except in full, without prior written approval of the Company. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law.



QD 7442278



中国认可
国际互认
检测
TESTING
CNAS L0604

Report No.: QDHL2102001554MD

Test Results

Test Items	Unit	Test Method	Requirement	Test Result	Assessment
Water tightness test	/	EN 455-1: 2020 Clause 5.1	Sample quantity: 200 pcs AQL: 1.5 Ac: 7 Re: 8	Found: 0	Pass

End of Report

Attention: To check the authenticity of testing /inspection report & certificate, please contact us at telephone: (86-755)85071443, or email: CN.Doccheck@sgs.com

SGS-CSTC Standards Technical Services (Qingdao) Co., Ltd.
Page 5 of 6

Unless otherwise agreed in writing, this document is issued by the Company subject to its General Conditions of Service printed overleaf, available on request or accessible at <http://www.sgs.com/en/Terms-and-Conditions.aspx> and, for electronic format documents, subject to Terms and Conditions for Electronic Documents at <http://www.sgs.com/en/Terms-and-Conditions/Terms-e-Documents.aspx>. Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein. Any holder of this document is advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. This document cannot be reproduced except in full, without prior written approval of the Company. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law.



QD 7442280

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

SGS Center, No.143, Zhuzhou Road, Laoshan District, Qingdao, Shandong, China 266101 t (86-532) 68999888 www.sgsgroup.com.cn sgs.china@sgs.com



SATRA Technology Centre Ltd
Wyndham Way, Telford Way, Kettering,
Northamptonshire, NN16 8SD United Kingdom
Tel: +44 (0) 1536 410000
Fax +44 (0) 1536 410626
email: info@satra.com
www.satra.com



Customer details:

SATRA reference: SPC0306262 /2051 /2

STE/CHT Job No.: CHT0305959

Date of report: 24 February 2021

Samples received: 14 December 2020

Date(s) work carried out: Between 28 January to 8 February 2021

TECHNICAL REPORT

SATRA Technology Services (Dongguan) Ltd:

Customer:

Subject: Testing of gloves identified as HQ316 Disposable Hybrid Poly, powder free glove for testing in accordance with EN 455-2:2015

Conditions of Issue:

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

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

Tests marked # fall outside the UKAS Accreditation Schedule for SATRA.

All opinions and interpretations of results, and the comments based upon them are outside the scope of UKAS accreditation and are based on current SATRA knowledge.

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

Where values for uncertainty of measurement are included within the report then the uncertainty of the corresponding results are based on a standard uncertainty multiplied by a coverage factor $k=2$, which provides a coverage probability of approximately 95%.

When reporting results against a conformance statement (Pass/Fail) then uncertainty of measurement is taken into account based on a non-binary acceptance which itself is based on the guard band being equal to the expanded uncertainty.

Where the result corrected for uncertainty on a worst-case basis falls outside of the requirement or specification then the risk of a pass result being a false accept is up to 50%. We will therefore not provide either a pass or fail statement when this occurs but will include information in the notes in relation to the result obtained.

Please note that where uncertainty of measurement values have not been included then uncertainty has not been applied to these results. SATRA uncertainty of measurement values are however available upon request.

Report signed by: Adam Mortiboys
Position: Team Leader
Department: Safety Product Testing

(Page 1 of 8)

adam mortiboys

Work Requested

Samples of gloves, see Table 1, were received by SATRA, for testing in accordance with EN 455-2:2015

Table 1 – Samples Received

Sample description as stated by the client	Sizes submitted for testing	Colour of samples submitted	Approximate weight of one glove
HQ316 Disposable Hybrid Poly, powder free glove	8 (M)	Translucent	Size: 8 (M) Weight: 2.0g



Conclusion

Standard	Clause / Property	Result
EN 455-2: 2015	4.2 Length	Pass
	4.3 Width	Pass
	5.2 Force at break	Pass requirement c only
	5.3 Force at break after challenge testing	Pass requirement c only

Testing

Samples were tested as received, and were conditioned to the individual requirements of each clause as stated in the standards.

Requirements

EN 455-2:2015 Dimensions of examination/procedure gloves

Size	Median length (mm)	Median width (mm)
Extra small	≥ 240	≤ 80
Small		80 ± 10
Medium		95 ± 10
Large		110 ± 10
Extra large		≥ 110
Length measured according to figure 1 of EN 455-2:2015 Width measured according to figure 1 of EN 455-2:2015 The width requirements are for gloves from natural rubber latex and all other elastomeric materials. These dimensions may not be appropriate for gloves made from other materials		

Requirements for EN 455-2:2015 Force at Break

	Median Values of Force at Break (N)		
	Surgical gloves a)	Examination / Procedure Gloves b) c)	
Force at break	≥ 9.0	≥ 6.0	≥ 3.6
After challenge test			
A) Requirements for surgical gloves b) Requirements for all examination gloves, except gloves made from thermoplastic materials (e.g. polyvinylchloride, polyethylene) c) Requirements for gloves made from thermoplastic materials (e.g. polyvinylchloride, polyethylene)			

Test Results

EN 455-2:2015 Test Results of gloves identified as HQ316 Disposable Hybrid Poly, powder free glove

Clause / Test	Test Results				Result
	Sample	Size	Length mm	Width mm	
4.2 Length and 4.3 Width	1	8 (M)	260	141	Pass Length Pass Width
	2	8 (M)	260	141	
	3	8 (M)	260	141	
	4	8 (M)	260	142	
	5	8 (M)	260	141	
	6	8 (M)	260	141	
	7	8 (M)	260	141	
	8	8 (M)	261	141	
	9	8 (M)	260	142	
	10	8 (M)	260	141	
	11	8 (M)	261	141	
	12	8 (M)	260	141	
	13	8 (M)	260	141	
Median	-	260	141		

EN 455-2:2015 Test Results for as received gloves identified as HQ316 Disposable Hybrid Poly, powder free glove

Clause / Test	Test Results					Result
	Sample	Single wall thickness mm (tf)	Thickness of dumbbell pieces mm (tx)	tf/tx	Force at break /N	
5.2 Force at Break	1	0.05	0.05	1.0	4.18	Pass requirement c only
	2	0.05	0.05	1.0	4.03	
	3	0.06	0.05	1.2	4.15	
	4	0.045	0.05	0.9	3.66	
	5	0.055	0.05	1.1	4.02	
	6	0.045	0.05	0.9	3.97	
	7	0.05	0.06	0.8	3.82	
	8	0.05	0.05	1.0	4.50	
	9	0.055	0.05	1.1	4.42	
	10	0.06	0.05	1.2	4.12	
	11	0.045	0.05	0.9	3.48	
	12	0.055	0.06	0.9	4.01	
	13	0.055	0.06	0.9	4.07	
	Median	-	-	-	4.03	
$t_f/t_x \geq 0.9$ No correction is required $t_f/t_x < 0.9$ Correction is required						

EN 455-2:2015 Test Results for after aged gloves identified as HQ316 Disposable Hybrid Poly, powder free glove

Clause / Test	Test Results					Result
	Sample	Single wall thickness mm (tf)	Thickness of dumbbell pieces mm (tx)	tf/tx	Force at break /N	
5.3 Force at break after challenge testing	1	0.05	0.05	1.0	4.47	Pass requirement c only
	2	0.055	0.05	1.1	4.18	
	3	0.05	0.05	1.0	4.08	
	4	0.05	0.06	0.8	3.65	
	5	0.055	0.05	1.1	4.47	
	6	0.055	0.05	1.1	4.40	
	7	0.06	0.06	1.0	4.28	
	8	0.055	0.06	0.9	4.57	
	9	0.065	0.06	1.1	3.05	
	10	0.06	0.05	1.2	3.26	
	11	0.05	0.05	1.0	3.62	
	12	0.055	0.05	1.1	3.37	
	13	0.06	0.05	1.2	4.42	
	Median	-	-	-	4.18	
$t_f/t_x \geq 0.9$ No correction is required $t_f/t_x < 0.9$ Correction is required						

Additional Information / Notes

Additional uncertainty of measurement information

Clause / Test	Property	UoM
4.2 Length and 4.3 Width	Measurement (mm)	± 1.2 mm
5.2 Force at break	Force (N)	± 4.2%



SATRA Technology Centre Ltd
Wyndham Way, Telford Way, Kettering,
Northamptonshire, NN16 8SD United Kingdom
Tel: +44 (0) 1536 410000
Fax +44 (0) 1536 410626
email: info@satra.com
www.satra.com

Customer details:

SATRA reference: SPC0306262/2051/JH

STE Job number: CHT0305959

Date of report: 19th January 2021

Samples received: 14th December 2020

Date(s) work carried out: 14th January 2021

TECHNICAL REPORT

SATRA Technology Services (Dongguan) Ltd:

Customer:

Subject:

Determination of removable surface powder in accordance with EN ISO 21171:2006 on samples described as HQ316 Disposable Hybrid Poly, powder free glove

Conditions of Issue:

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

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

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

Please note uncertainty of measurement has not been applied to the results in this report. SATRA uncertainty of measurement values are available on request.

Report signed by: Jade Hurley
Position: Technologist
Department: Chemical & Analytical Technology

(Page 1 of 5)

WORK REQUESTED:

Samples of gloves described as HQ316 Disposable Hybrid Poly, powder free glove were received on the 14th December 2020 for the determination of removable surface powder in accordance with EN ISO 21171:2006.

SAMPLES SUBMITTED:



Samples described as HQ316 Disposable Hybrid Poly, powder free glove

TESTS REQUIRED:

- EN ISO 21171: 2006 – Medical gloves – Determination of removable surface powder. Method B – Procedure for “powder free” gloves other than surgeon’s gloves

CONCLUSION:

The gloves described as HQ316 Disposable Hybrid Poly, powder free glove were tested in accordance with EN ISO 21171:2006 method B and were found to contain 0.3 mg residual powder per glove and therefore can be classified as powder free gloves

RESULTS:

EN ISO 21171:2006 – Medical gloves – Determination of removable surface powder

Sample	Method	Mass of powder per glove (mg)
HQ316 Disposable Hybrid Poly, powder free glove	B	0.3
Requirement (clause 4.4)	≤ 2.0 mg for a 'powder-free' glove	

Method B – The result is based on one replicate of 5 gloves for each glove type






SATRA Technology Centre Ltd
Wyndham Way, Telford Way, Kettering,
Northamptonshire, NN16 8SD United Kingdom
Tel: +44 (0) 1536 410000
Fax +44 (0) 1536 410626
email: info@satra.com
www.satra.com



Customer details:

SATRA reference: CHM0306199/2050/LH
/A
Your reference: CHT0305959
Date of report: 26th January 2021
Samples received: 10th December 2020
Date(s) work carried out: 14th to 20th January 2021

TECHNICAL REPORT

SATRA Technology Services (Dongguan) Ltd:

China

Subject: EN 16523-1:2015+A1:2018 resistance to permeation by chemicals on gloves described as Disposable Hybrid Poly Glove, Powder free, referenced as HQ316, colour: clear, size: L/8

Conditions of Issue:

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

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

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

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

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

Report signed by: Lorna Harding
Position: Technologist
Department: Chemical & Analytical Technology

(Page 1 of 6)

WORK REQUESTED:

Samples of gloves described as Disposable Hybrid Poly Glove, Powder free, referenced as HQ316, colour: clear, size: L/8 were received on the 10th December 2020 for testing in accordance with EN 16523-1:2015+A1:2018 and assessment in accordance with the requirements of EN ISO 374-1:2016+A1:2018.

SAMPLES SUBMITTED:



Samples described as Disposable Hybrid Poly Glove, Powder free, referenced as HQ316, colour: clear, size: L/8

CONCLUSION:

When assessed in accordance with the requirements of EN ISO 374-1:2016+A1:2018 the samples of gloves described as Disposable Hybrid Poly Glove, Powder free, referenced as HQ316, colour: clear, size: L/8 achieved the following performance levels:

Chemical	Performance level
30% Hydrogen peroxide (CAS: 7722-84-1)	6

Full results are reported in the following tables.

TESTING REQUIRED:

- EN 16523-1:2015+A1:2018 - Determination of material resistance to permeation by chemicals - Part 1: Permeation by liquid chemical under conditions of continuous contact

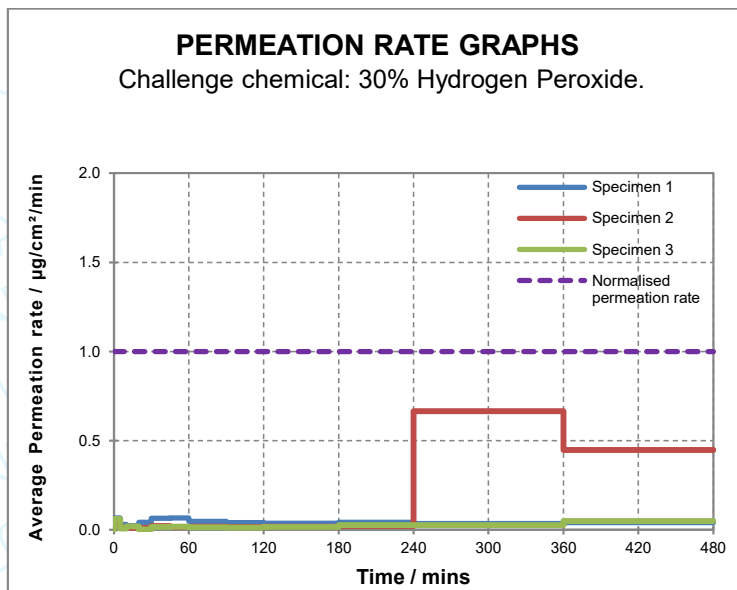
RESULTS AND REQUIREMENTS:

EN ISO 374-1:2016+A1:2018 - Protective gloves against dangerous chemicals and micro-organisms - Part 1: Terminology and performance requirements for chemical risks. Table 1: Permeation performance levels.

Permeation performance level	Measured breakthrough time (minutes)
1	>10
2	>30
3	>60
4	>120
5	>240
6	>480

Performance levels are based on the lowest individual result achieved per chemical.

Test/Property	Sample reference:	Disposable Hybrid Poly Glove, Powder free, referenced as HQ316, colour: clear, size: L/8		Performance
EN 16523-1:2015 +A1:2018 in accordance with SATRA SOP CAT-025	Test information:	Chemical: 30% Hydrogen peroxide		Level 6
		Normalised permeation rate (NPR): 1 µg/cm ² /min		
		Detection technique: Electrochemical detector (periodic measurement)		
		Collection medium: Deionised water (closed loop)		
		Collection medium stirring rate: 45 – 65 ml/min (each cell constant to within ± 10%)		
		Test temperature: (23 ± 1) °C		
Using PTFE permeation cells with standardised dimensions	Specimen	Thickness (mm) [△]	Breakthrough time (mins) [▽]	
	1	0.07	>480	
	2	0.07	>480	
	3	0.06	>480	
	Test result:		>480	
UoM:		<1		
Visual appearance of specimens after testing:		Discoloured		



Hydrogen peroxide is determined by discrete sampling; therefore the permeation rate graph is not a smooth curve.

- △ EN 16523-1:2015+A1:2018 does not require the test specimen thicknesses to be reported, this information is indicative only.
- ▽ Breakthrough expressed as a range between discrete sampling points where the average permeation rate exceeds the NPR. Due to the complexity of the detection technique, the minimum sampling frequency as specified in table 1 of EN 16523-1:2015+A1:2018 is not possible.



SATRA Technology Centre Ltd
Wyndham Way, Telford Way, Kettering,
Northamptonshire, NN16 8SD United Kingdom
Tel: +44 (0) 1536 410000
Fax +44 (0) 1536 410626
email: info@satra.com
www.satra.com



Customer details:

SATRA reference: CHM0306199/2050/LH
/B
Your reference: CHT0305959
Date of report: 26th January 2021
Samples received: 10th December 2020
Date(s) work carried out: 15th to 18th January 2021

TECHNICAL REPORT

SATRA Technology Services (Dongguan) Ltd:

China

Subject: EN ISO 374-4:2019 determination of resistance to degradation by dangerous chemicals on gloves described as Disposable Hybrid Poly Glove, Powder free, referenced as HQ316, colour: clear, size: L/8

Conditions of Issue:

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

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

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

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

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

Report signed by: Lorna Harding
Position: Technologist
Department: Chemical & Analytical Technology

(Page 1 of 5)

WORK REQUESTED:

Samples of gloves described as Disposable Hybrid Poly Glove, Powder free, referenced as HQ316, colour: clear, size: L/8 were received on the 10th December 2020 for testing in accordance with EN ISO 374-4:2019.

SAMPLE SUBMITTED:



Samples described as Disposable Hybrid Poly Glove, Powder free, referenced as HQ316, colour: clear, size: L/8

CONCLUSION:

When assessed in accordance with EN ISO 374-4:2019 the samples of gloves described as Disposable Hybrid Poly Glove, Powder free, referenced as HQ316, colour: clear, size: L/8 achieved the following degradation results:

Chemical	Mean degradation / %
30% Hydrogen peroxide (CAS: 7722-84-1)	-3.0

TESTING REQUIRED:

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

RESULTS:

Sample description:	Disposable Hybrid Poly Glove, Powder free, referenced as HQ316, colour: clear, size: L/8		
Challenge chemical:	30% Hydrogen peroxide (CAS: 7722-84-1)		
Test temperature / °C:	(23 ± 1)		
Degradation / %:	Glove 1	Glove 2	Glove 3
	-17.3	16.0	-7.9
Mean degradation (DR) / %:	-3.0		
Standard deviation (σ_{DR}) / %:	17.2		
UoM / ± %:	69.7		
Appearance of samples after testing:	No change		

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