

Disposable Nitrile Gloves

Material	Nitrile (≥95%)			
Model	Powder-free			
Color	Blue			
Size	S/M/L/XL			
Width	Median≥240mm			
Packing	100 pcs/box, 10 boxes/carton			
Description	Latex-free, Non-sterile			
Executive	CE	MDR Class I	(EU) 2017/745	EN455
Standard	CE2777	PPE CAT III	(EU) 2016/425	EN374
Res AP (2004) 4 For Food Contact				



Issued to:

Med-Hand GmbH
Industriehof 6
D-77933 Lahr/Schwarzwald
Germany

Notified Body: 2777

SATRA customer number: P21146

EU Type-Examination Certificate

Certificate number: 2777/17336-01/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:

MH-001

Description:

Disposable Powder Free Nitrile Gloves
Colour: Blue

Sizes:

6-9(S-XL)

Classification:

EN ISO 374-1:2016+A1:2018/Type B

Level

**EN ISO 374-4:2019
Degradation %**

(K) Sodium hydroxide 40%
(P) Hydrogen peroxide 30%
(T) Formaldehyde 37%

6
2
5

-15.7
-23.1
-14.7

EN ISO 374-5:2016

Level

Protection against Bacterial and Fungi
Protection against Viruses

Pass
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: CHM0311310/2114/JH/A, CHM0311310/2114/JH/B, CHT0309598/2109

Signed on behalf of SATRA:

Quincey Brown

Date first issued: 07/07/2021

Date of issue: 07/07/2021

Expiry date: 07/07/2026

TERMS AND CONDITIONS

The following conditions apply in addition to SATRA's standard terms and conditions of business and those given in the current certification agreement. This certificate has been issued in accordance with Annex V (Module B) of the applicable legislation (see note 11).

Please note:

1. Where the product is classified as category III then CE or UKCA Marking of production is reliant on current compliance with module C2 or Module D of the applicable legislation (See note 11). (Except that specifically produced to fit an individual user).
2. Full details of the scope of the certification and product(s) certified are contained within the manufacturer's technical documentation.
3. Where a translation of this certificate exists, the English language version shall be considered as the authoritative text.
4. Certification is limited to production undertaken at the sites listed in the manufacturer's technical documentation.
5. Ongoing manufactured product shall be consistent with the product(s) certified and listed on this certificate and an EU declaration of product conformity shall be made available in accordance with the applicable legislation (See note 11)
6. The Manufacturer shall inform SATRA of any changes to the certified product or technical documentation.
7. Where results obtained during type testing are within the budget of uncertainty when compared to the pass requirement, classification or performance level, then it is the responsibility of the manufacturer to ensure that the factory production control and manufacturing tolerances are such that the product placed on the market meets with the stated requirements, classifications or performance levels.
8. This certificate shall be kept together with the relevant technical documentation in a safe place by the client named on this certificate. Production of this certificate and other documentation may be required by a representative of the EC member state, or UK government.
9. This certificate relates only to the condition of the testable items at the time of the certification procedure and is subject to the expiry date shown.
10. SATRA reserves the right to withdraw this certificate if it is found that a condition of manufacture, design, materials or packaging have been changed and therefore no longer comply with the requirements of the applicable legislation (See note 11).
11. These terms and conditions shall apply to the requirements set out in Regulation (EU) 2016/425 of the European Parliament and of the council of 9th March 2016 on personal protective equipment or to UK legislation relating to UKCA Marking as defined within the issued certificate.



European
Commission

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CURRENT ACTOR: Importer DE-IM-
000005770, Med-Hand GMBH [Germany] 
[Notifications](#)

Importer, DE-IM- 000005770, Med-Hand GMBH [Germany]

My Actor data

Version	[Current]	Last update date:  2021-05-	n006t2s4
1		28	

[Create new version](#)

Actor identification

Role:	Importer
SRN:	DE-IM-000005770
Country:	Germany
Actor / organisation	Med-Hand GMBH [EN]
name:	
Abbreviated name:	-
VAT	Yes

[Skip to main content](#)



information:

VAT number: DE326214724

EORI number (Economic Operators Registration and Identification number)

-

National trade register: -

Organisation identification document: -

Actor address

Street information, if applicable: Yes

Street: Industriebhof

Street number: 6

Address line 2: -

PO box: -

Latitude: -

Longitude: -

City name: Lahr

Postal code: 77933

Country: Germany

[Skip to main content](#)

Actor contact details

Non-public contact details



First name: April
Last name: Yao
Email: kontakt@med-hand.com
Telephone: -

Public contact details

Email: kontakt@med-hand.com
Telephone: -
Web site: -

Competent Authority

Name: DE/CA39, Regierungspäsidium Freiburg
Referat 25
Address: Kaiser-Joseph-Straße, 167, Freiburg,
Germany
Country: Germany
Email: poststelle@rpf.bwl.de
Telephone number: +49 761 208 0

Actor notification email addresses

Manage your email notifications

Actor Data: kontakt@med-hand.com

Linked non-EU manufacturers

No data available



Customer details: SATRA Technology Services (Dongguan) Ltd SATRA reference: CHM0311310/2114/JH
Unit 110, Xinzhongyin Garden /A
Hongwei Road Your reference: CHT0309598
Xiping, Nancheng District
DONGGUAN CITY
Guangdong Province
China
523079
Date of report: 28th May 2021
Samples received: 6th April 2021
Date(s) work carried out: 4th to 28th May 2021

TECHNICAL REPORT

SATRA Technology Services (Dongguan) Ltd:

Customer: Med-Hand GmbH
Industriehof 6, 77933 Lahr
Schwarzwald
Germany

Subject: EN 16523-1:2015+A1:2018 resistance to permeation by chemicals on gloves described as Disposable Powder Free Nitrile Gloves, Color: Blue, Reference number: MH-001

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: Jade Hurley
Position: Technologist
Department: Chemical & Analytical Technology

WORK REQUESTED:

Samples of gloves described as Disposable Powder Free Nitrile Gloves, Color: Blue, Reference number: MH-001 were received on the 6th April 2021 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 Powder Free Nitrile Gloves, Color: Blue, Reference number: MH-001

CONCLUSION:

When assessed in accordance with the requirements of EN ISO 374-1:2016+A1:2018 the samples of gloves described as Disposable Powder Free Nitrile Gloves, Color: Blue, Reference number: MH-001 achieved the following performance levels:

Chemical	Performance level
40% Sodium hydroxide (CAS: 1310-73-2)	6
30% Hydrogen peroxide (CAS: 7722-84-1)	2
37% Formaldehyde (CAS: 50-00-0)	5

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.

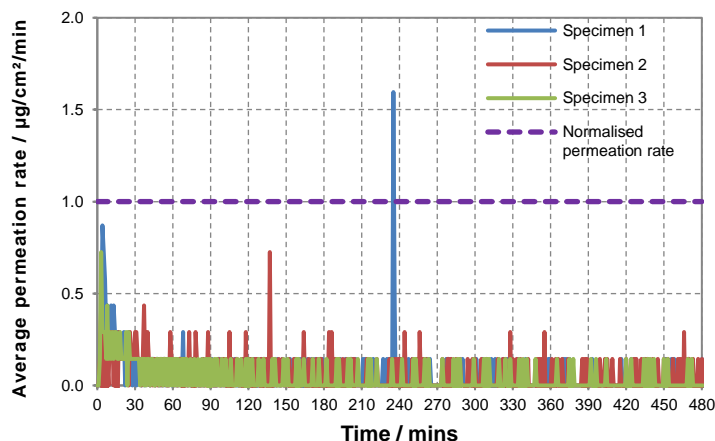
Permeation performance level	Measured breakthrough time (minutes)
1	>10
2	>30
3	>60
4	>120
5	>240
6	>480

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

Test/Property	Sample reference:	Disposable Powder Free Nitrile Gloves, Color: Blue, Reference number: MH-001		Performance	
EN 16523-1:2015 +A1:2018 in accordance with SATRA SOP CAT-009 Using PTFE permeation cells with standardised dimensions	Test information:	Chemical: 40% Sodium hydroxide		Level 6	
		Normalised permeation rate (NPR): 1 µg/cm²/min			
		Detection technique: Conductimetry (continuous 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			
	Specimen	Thickness (mm)△	Breakthrough time (mins)		
	1	0.09	>480		
	2	0.09	>480		
	3	0.09	>480		
		Test result:	>480		
		UoM:	<1		
Visual appearance of specimens after testing:		Swollen			

PERMEATION RATE GRAPHS

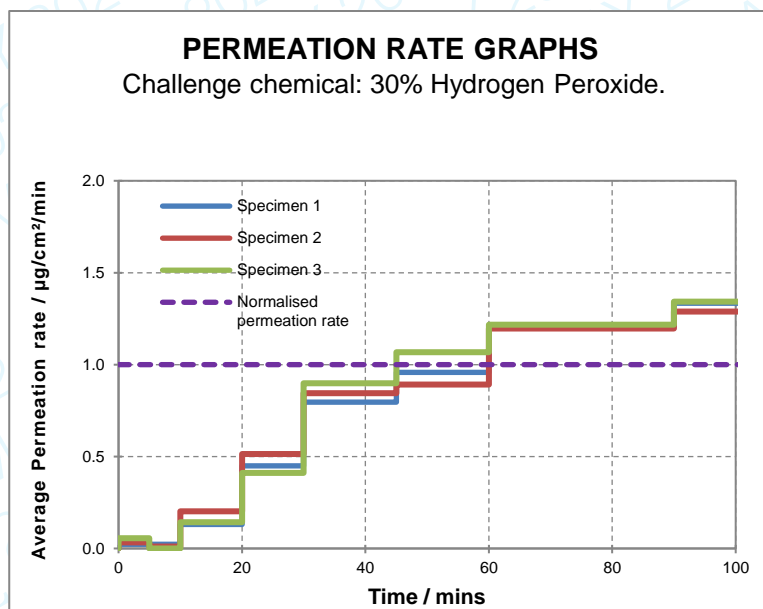
Challenge chemical: 40% Sodium Hydroxide .



The reading from specimen 1 after 235 minutes was considered to be an outlier and not a breakthrough.

Test/Property	Sample reference:	Disposable Powder Free Nitrile Gloves, Color: Blue, Reference number: MH-001		Performance
EN 16523-1:2015 +A1:2018 in accordance with SATRA SOP CAT-025 Using PTFE permeation cells with standardised dimensions	Test information:	Chemical: 30% Hydrogen peroxide		Level 2
		Normalised permeation rate (NPR): 1 µg/cm²/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		
	Specimen	Thickness (mm)△	Breakthrough time (mins)▽	
	1	0.08	Between 61 to 90	
	2	0.09	Between 61 to 90	
	3	0.08	Between 46 to 60	
	Test result:	Between 46 to 60		
	UoM:	See note below		
Visual appearance of specimens after testing:		Swollen and discoloured		

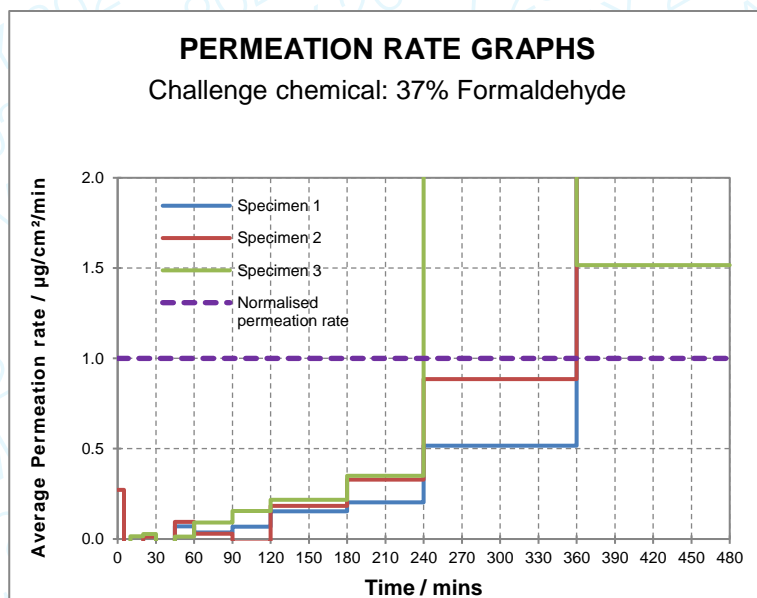
For SOP CAT-025, where both the P1 and Pu are observed in the same sampling range, uncertainty is expressed as the time difference between the mid-point of the range and the previous sampling time. This uncertainty is included in the reported result.



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

Test/Property	Sample reference:	Disposable Powder Free Nitrile Gloves, Color: Blue, Reference number: MH-001		Performance	
EN 16523-1:2015 +A1:2018 in accordance with SATRA SOP CAT-025 Using PTFE permeation cells with standardised dimensions	Test information:	Chemical: 37% Formaldehyde		Level 5	
		Normalised permeation rate (NPR): 1 µg/cm²/min			
		Detection technique: HPLC-DAD (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			
	Specimen	Thickness (mm)△	Breakthrough time (mins)▼		
	1	0.08	Between 361 to 480		
	2	0.08	Between 361 to 480		
	3	0.08	Between 241 to 360		
		Test result:	Between 241 to 360		
		UoM:	See note below		
Visual appearance of specimens after testing:		Swollen and discoloured			

For SOP CAT-025, where both the P1 and Pu are observed in the same sampling range, uncertainty is expressed as the time difference between the mid-point of the range and the previous sampling time. This uncertainty is included in the reported result.



Formaldehyde 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.

A large, light blue rectangular block containing the word "TECHNOLOGY" in a white, bold, sans-serif font. To the left of this block are three vertical bars of increasing height, colored in shades of blue and grey, which are part of the SATRA Technology logo.

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 hereby excluded.
- 1.2 SATRA Technology Centre Limited, 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 the 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 dealing
- 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:
 - (a) the "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
 - (b) "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
 - (c) "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).
- 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 and 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. 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.
- 3.6 SATRA shall observe all statutory provisions with regard to data protection including but not limited to the provisions of the Data Protection Act 2018 and the EU General Data Protection Regulation (GDPR) Regulation (EU) 2016/6798. 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 Client's 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:
 - (a) death or personal injury caused by its negligence or the negligence of its employees or agents;
 - (b) fraud or fraudulent misrepresentation;
 - (c) breach of the terms implied by Section 12 of the Sale of Goods Act 1979;
 - (d) defective products under the Consumer Protection Act 1987; or
 - (e) 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 £100,000 whichever is the lower figure.

6. MISCELLANEOUS

- 6.1 If any one or more provisions of these 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 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

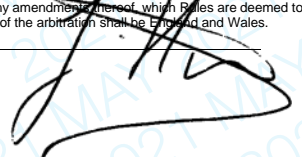
- 7.1 Unless specifically excluded in the terms of an individual contract between SATRA and the Client, the following shall apply to all deliverables including, reports, advice, drawings, photographs, specifications, data or other forms of media.
- 7.2 Deliverables referred to in clause 7.1 shall not 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 of business 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 this Contract shall be effective unless it is in writing, expressly stated to amend this Contract and signed by an authorised signatory of both Parties.

9. DISPUTE RESOLUTION

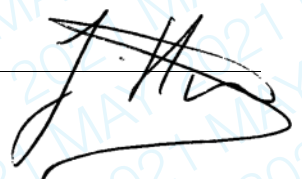
- 9.1 If there should be a dispute between the parties to this Agreement they undertake to act with goodwill and to use all reasonable endeavours to resolve that dispute.
- 9.2 Failure to resolve any dispute by discussions between the parties shall, in the first instance, be referred to a mediator for 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, either party, upon giving written notice, may apply to the President or the Vice President, for the time being, of the Chartered Institute of Arbitrators, for the appointment of a mediator.
- 9.3 Should the mediation fail, in whole or in part, either party may, upon giving written notice, and within twenty-eight days thereof, apply to the President or the Vice President, for the time being, of the Chartered Institute of Arbitrators, for the appointment of a single arbitrator, for final resolution. The arbitrator shall have no connection with the mediator or the mediation proceedings, unless both parties have consented in writing. The arbitration shall be governed by both the Arbitration Act 1996 and the Controlled Cost Rules of the Chartered Institute of Arbitrators (2000 Edition), or any amendments thereof, which Rules are deemed to be incorporated by reference into this clause. The seat of the arbitration shall be England and Wales.



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

- 9.4 The laws of England shall govern the interpretation of this Contract. Subject to clauses 9.1, 9.2 and 9.3 any dispute arising out of or in connection with the Contract shall be subject to the exclusive jurisdiction of the courts of England. However, the Party obtaining a judgement in such courts shall be entitled to enforce it in any court it chooses.
- 10. PROVISION OF SERVICES**
- 10.1 SATRA shall provide Services using reasonable care and skill and in accordance with the Clients 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 accept 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:
- a) In the case of sales where delivery of Goods is made in the United Kingdom 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
- b) 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: -
- a) 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
- b) 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:
- a) hold the Goods as SATRA's bailee;
- b) 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);
- c) not destroy, deface or obscure any identifying mark or packaging on or relating to the Goods; and
- d) 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:
- a) the Client's right to resell the Goods or use them in the ordinary course of its business ceases immediately; and
- b) 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
- c) 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 the Contract, howsoever caused, SATRA's (but not the Client's) rights contained in this clause 13 shall remain in effect.
- 14. PATENTS**
- 14.1 SATRA gives no indemnity against any claim of infringement of Letters 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 Letters Patent, Registered Design, Trade Mark or Copyright published at the date of the 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 Letters 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:
- a) 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
- b) SATRA is given a reasonable opportunity of examining such Goods; and
- c) 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:
- a) 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
- b) 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
- c) the Client has breached any of the terms of the Contract under which the Goods were supplied; or
- d) 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:
- a) 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;
- b) 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 – September 2019



Customer details: SATRA Technology Services (Dongguan) Ltd SATRA reference: CHM0311310/2114/JH
Unit 110, Xinzhongyin Garden /B
Hongwei Road Your reference: CHT0309598
Xiping, Nancheng District
DONGGUAN CITY
Guangdong Province
China
523079
Date of report: 28th May 2021
Samples received: 6th April 2021
Date(s) work carried out: 19th to 21st May 2021

TECHNICAL REPORT

SATRA Technology Services (Dongguan) Ltd:

Customer: Med-Hand GmbH
Industriehof 6, 77933 Lahr
Schwarzwald
Germany

Subject: EN ISO 374-4:2019 determination of resistance to degradation by dangerous chemicals on gloves described as Disposable Powder Free Nitrile Gloves, Color: Blue, Reference number: MH-001

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: Jade Hurley
Position: Technologist
Department: Chemical & Analytical Technology

WORK REQUESTED:

Samples of gloves described as Disposable Powder Free Nitrile Gloves, Color: Blue, Reference number: MH-001 were received on the 6th April 2021 for testing in accordance with EN ISO 374-4:2019.

SAMPLE SUBMITTED:



Sample described as Disposable Powder Free Nitrile Gloves, Color: Blue, Reference number: MH-001.

CONCLUSION:

When assessed in accordance with EN ISO 374-4:2019 the samples of gloves described as Disposable Powder Free Nitrile Gloves, Color: Blue, Reference number: MH-001 achieved the following degradation results:

Chemical	Mean degradation / %
40% Sodium hydroxide (CAS: 1310-73-2)	-15.7
30% Hydrogen peroxide (CAS: 7722-84-1)	-23.1
37% Formaldehyde (CAS: 50-00-0)	-14.7

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 Powder Free Nitrile Gloves, Color: Blue, Reference number: MH-001.		
Challenge chemical:	40% Sodium hydroxide (CAS: 1310-73-2)		
Test temperature / °C:	(23 ± 1)		
Degradation / %:	Glove 1	Glove 2	Glove 3
	-28.7	-5.2	-13.1
Mean degradation (DR) / %:	-15.7		
Standard deviation (σ_{DR}) / %:	12.0		
UoM / ± %:	12.7		
Appearance of samples after testing:	No change		

Sample description:	Disposable Powder Free Nitrile Gloves, Color: Blue, Reference number: MH-001.		
Challenge chemical:	30% Hydrogen peroxide (CAS: 7722-84-1)		
Test temperature / °C:	(23 ± 1)		
Degradation / %:	Glove 1	Glove 2	Glove 3
	-46.1	-26.1	3.1
Mean degradation (DR) / %:	-23.1		
Standard deviation (σ_{DR}) / %:	24.7		
UoM / ± %:	12.5		
Appearance of samples after testing:	No change		

Sample description:	Disposable Powder Free Nitrile Gloves, Color: Blue, Reference number: MH-001.		
Challenge chemical:	37% Formaldehyde (CAS: 50-00-0)		
Test temperature / °C:	(23 ± 1)		
Degradation / %:	Glove 1	Glove 2	Glove 3
	-2.8	-13.7	-27.5
Mean degradation (DR) / %:	-14.7		
Standard deviation (σ_{DR}) / %:	12.4		
UoM / ± %:	12.7		
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.

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 hereby excluded.
- 1.2 SATRA Technology Centre Limited, 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 the 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 dealing
- 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:
 - (a) the "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
 - (b) "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
 - (c) "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).
- 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 and 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. 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.
- 3.6 SATRA shall observe all statutory provisions with regard to data protection including but not limited to the provisions of the Data Protection Act 2018 and the EU General Data Protection Regulation (GDPR) Regulation (EU) 2016/6798. 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 Client's 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:
 - (a) death or personal injury caused by its negligence or the negligence of its employees or agents;
 - (b) fraud or fraudulent misrepresentation;
 - (c) breach of the terms implied by Section 12 of the Sale of Goods Act 1979;
 - (d) defective products under the Consumer Protection Act 1987; or
 - (e) 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 £100,000 whichever is the lower figure.

6. MISCELLANEOUS

- 6.1 If any one or more provisions of these 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 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

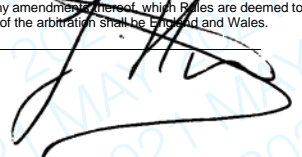
- 7.1 Unless specifically excluded in the terms of an individual contract between SATRA and the Client, the following shall apply to all deliverables including, reports, advice, drawings, photographs, specifications, data or other forms of media.
- 7.2 Deliverables referred to in clause 7.1 shall not 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 of business 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 this Contract shall be effective unless it is in writing, expressly stated to amend this Contract and signed by an authorised signatory of both Parties.

9. DISPUTE RESOLUTION

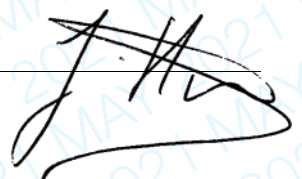
- 9.1 If there should be a dispute between the parties to this Agreement they undertake to act with goodwill and to use all reasonable endeavours to resolve that dispute.
- 9.2 Failure to resolve any dispute by discussions between the parties shall, in the first instance, be referred to a mediator for 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, either party, upon giving written notice, may apply to the President or the Vice President, for the time being, of the Chartered Institute of Arbitrators, for the appointment of a mediator.
- 9.3 Should the mediation fail, in whole or in part, either party may, upon giving written notice, and within twenty-eight days thereof, apply to the President or the Vice President, for the time being, of the Chartered Institute of Arbitrators, for the appointment of a single arbitrator, for final resolution. The arbitrator shall have no connection with the mediator or the mediation proceedings, unless both parties have consented in writing. The arbitration shall be governed by both the Arbitration Act 1996 and the Controlled Cost Rules of the Chartered Institute of Arbitrators (2000 Edition), or any amendments thereto, which Rules are deemed to be incorporated by reference into this clause. The seat of the arbitration shall be England and Wales.



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

- 9.4 The laws of England shall govern the interpretation of this Contract. Subject to clauses 9.1, 9.2 and 9.3 any dispute arising out of or in connection with the Contract shall be subject to the exclusive jurisdiction of the courts of England. However, the Party obtaining a judgement in such courts shall be entitled to enforce it in any court it chooses.
- 10. PROVISION OF SERVICES**
- 10.1 SATRA shall provide Services using reasonable care and skill and in accordance with the Clients 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 accept 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:
- a) In the case of sales where delivery of Goods is made in the United Kingdom 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
- b) 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: -
- a) 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
- b) 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:
- a) hold the Goods as SATRA's bailee;
- b) 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);
- c) not destroy, deface or obscure any identifying mark or packaging on or relating to the Goods; and
- d) 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:
- a) the Client's right to resell the Goods or use them in the ordinary course of its business ceases immediately; and
- b) 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
- c) 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 the Contract, howsoever caused, SATRA's (but not the Client's) rights contained in this clause 13 shall remain in effect.
- 14. PATENTS**
- 14.1 SATRA gives no indemnity against any claim of infringement of Letters 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 Letters Patent, Registered Design, Trade Mark or Copyright published at the date of the 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 Letters 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:
- a) 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
- b) SATRA is given a reasonable opportunity of examining such Goods; and
- c) 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:
- a) 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
- b) 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
- c) the Client has breached any of the terms of the Contract under which the Goods were supplied; or
- d) 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:
- a) 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;
- b) 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 – September 2019



Test Report No. 7191255897-EEC21-WBH
dated 13 Apr 2021



PSB Singapore

Add value.
Inspire trust.

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

SUBJECT:

Testing of Gloves submitted by Med-Hand GmbH on 15 Mar 2021.

TESTED FOR:

Med-Hand GmbH
Industriehof 6, 77933 Lahr,
Schwarzwald, Germany

TEST DATE:

17 Mar 2021 to 13 Apr 2021

DESCRIPTION OF SAMPLES:

S/N	Product Description	Brand/ Model	Colour	Lot No.	Expiry Date	Size	Sample Received (pieces)	Manufacturer
1	Disposable Medical Nitrile Examination Gloves (non-sterile)	MED-HAND/ ML-001	Blue	CH20210301	2024-03	M	300	Med-Hand GmbH

Lot size as specified by client: 35,001 to 150,000 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



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TUV®

RESULTS:

Sample: Disposable Medical Nitrile Examination Gloves (non-sterile), MED-HAND/ ML-001, 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	7	200	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	250	Passed
	b) Width (mm)	For Size M: 95 ± 10	13	95	Passed
5	Strength a) Force at break (N)	For nitrile examination gloves: ≥ 6.0	13	7.1	Passed
	b) Force at break after challenge testing (N) 7 days at (70±2)°C	For nitrile examination gloves: ≥ 6.0	13	7.6	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.	Comply	Passed

RESULTS (cont'd):

Sample: Disposable Medical Nitrile Examination Gloves (non-sterile), MED-HAND/ ML-001, Blue, Size M

Table 4: Results for EN 455-3:2015 Clauses 4.2-4.5


Clause	Tests	Requirements	Results / Remarks	Inferred results
4.2	Chemicals	Gloves shall not be dressed with talcum powder (magnesium silicate).	Glove is not dressed with talcum powder, based on client's declaration letter	Passed
		Other chemicals	Manufacturer shall disclose upon request a list of chemical ingredients	NA
4.3 5.1	Endotoxins	< 20 EU/pair for gloves labelled with 'low endotoxin content'.	Not labelled with 'low endotoxin content'	NA
4.4 5.2	Powder-free gloves	For powder-free gloves: The total quantity of powder residues shall not exceed 2 mg per glove.	0.72 mg per glove	Passed
4.5 5.3	Proteins, leachable	The manufacturer shall strive to minimize the leachable protein level for gloves containing natural rubber latex.	Not natural rubber latex glove	NA


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 the submitted packaging artwork by client.
2. NA: Not applicable for the submitted sample.


Yeo Poh Kwang
Associate Engineer


Wong Bee Hui
Product Manager
Medical Health Services (NAM)

APPENDIX:



Photo 1: Disposable Medical Nitrile Examination Gloves (non-sterile), MED-HAND/ ML-001, Blue, Size M



Photo 2: Packaging artwork Disposable Medical Nitrile Examination Gloves (non-sterile), MED-HAND/ ML-001, Blue, Size M

Test Report No. 7191255897-EEC21-WBH
dated 13 Apr 2021



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.
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5. Unless otherwise stated, the tests were carried out in TÜV SÜD PSB Pte Ltd, 15 International Business Park TÜV SÜD @ IBP Singapore 609937.
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 26 January 2021





SUBJECT Chemical Test

TEST LOCATION TÜV SÜD China

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

CLIENT NAME Med-Hand GmbH

CLIENT ADDRESS Industriehof 6, 77933 Lahr/ Schwarzwald/ Germany

TEST PERIOD 08-Mar-2021~17-Mar-2021

RESULT SUMMARY The tested items **complied with** German Food & Feed Acts of September 1, 2005 (LFGB), Section 30 and 31.

- Overall migration test (3% Acetic acid; 10% Ethanol, Water)
- Specific migration of Primary Aromatic Amine
- Color release
- Extractable formaldehyde
- Total lead and zinc content
- Sensory test
- Specific Migration of N-nitrosamines and N-nitrosatable substances

PASS
PASS
PASS
PASS
PASS
PASS
PASS

Prepared By

Nance Gao

(Nance Gao)
Report Drafter

Authorized By

Leo Liu

(Leo Liu)
Authorized Signatory

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



RECEIPT DATE / TEST DATE

08-Mar-2021/ 08-Mar-2021

THE FOLLOWING SAMPLE(S) WAS/WERE SUBMITTED

BY/ ON BEHALF OF THE CLIENTS AS

Sample Name: Disposable Powder Free Nitrile Gloves

Sample Specification: /

Batch No./Date: /

Manufactory: /

SAMPLE NO.	DESCRIPTION	PHOTOGRAPH
721662158	Blue glove	

TEST RESULT(S)

Note: The migration results in this report were tested and expressed based on single use articles.

1. Overall Migration Test

- In accordance with BFR Recommendations XXI
- Test method: With reference to EN 1186: Part 5 (Test methods for overall migration into aqueous food stimulants by cell) and BFR Recommendations XXI
- Migration ratio (S/V): 10dm²/L

Simulant(s) Used	Test Condition	Result(s) [mg/dm ²]	Maximum Permissible Limit [mg/dm ²]
3% Acetic acid	40°C for 10 minutes	9.35	10
10% Ethanol	40°C for 10 minutes	2.40	10
Water	40°C for 10 minutes	<0.500	10

2. Specific migration of Primary Aromatic Amine

- Test method: With reference to EN13130-1:2004, followed by Kunststoffe im Lebensmittelverkehr, Book 2, Teil B II, XXI
- Test condition: 3% Acetic acid, 40°C for 10 minutes
- Migration ratio (S/V): 6dm²/L

Test Item(s)	Result(s) [mg/kg]	Maximum Permissible Limit [mg/kg]
Primary Aromatic Amine	<0.01	0.01

3. Color release

- Test method: With reference to Kunststoffe im Lebensmittelverkehr Book II, Teil B II, IX

Simulant(s) Used	Test Condition	Result(s)	Permissible Limit
10% Ethanol	50°C for 5 hours	No bleeding	No bleeding
2% Acetic acid	50°C for 5 hours	No bleeding	No bleeding
Peanut oil	50°C for 5 hours	No bleeding	No bleeding
Water	50°C for 5 hours	No bleeding	No bleeding

Note: 1. No bleeding denotes no difference was found between blank and sample
2. Bleeding denotes staining was found from sample

4. Extractable formaldehyde

- Test method: For compliance with the Recommendation of the BfR "Kunststoffe im Lebensmittelverkehr" Part XXI. Commodities based on Natural and Synthetic Rubber
- With reference to Section 2.7.1 of methods for the "Testing of commodities made of rubber"
- Test condition: 3% Acetic acid, 40°C for 10 minutes
- Migration ratio (S/V): 6dm²/L

Test Item(s)	Result(s) [µg/ml]	Maximum Permissible Limit [µg/ml]
Extractable Formaldehyde	<0.5	3

5. Total lead and zinc content

- Test method: Acid digestion, then followed by ICP-OES

Test Item(s)	Result(s) [%]	Maximum Permissible Limit [%]
Lead content	<0.001	0.003
Zinc content	1.2171	3.0

6. Sensory test

- Test method: With reference to DIN 10955.
- The submitted sample was simulated in distilled water at 40°C for 10 minutes. After this treatment treated water was examined by panels with regard to any divergence in smell and taste.

Sample(s)	Testing Parameter	Grading result(s)	Recommended level
721662158	Transfer of taste	0	<3
	Transfer of smell	0	<3

Note: 1. Available grading are listed as follow:

- Grading 0: No perceptible taste/smell deviation
1: Just perceptible taste/smell deviation
2: Weak taste/smell deviation
3: Clear taste/smell deviation
4: Strong taste/smell deviation



7. Specific Migration of N-nitrosamines and N-nitrosatable substances

- Test method: Sample preparation with reference to EN 12868:2017, followed by analysis using LC-MS-MS
- Test condition: 3% Acetic acid, 40°C for 10 minutes

Test Item(s)	Result(s) [mg/kg]	Detected limit [mg/kg]	Maximum Permissible Limit [mg/kg]
N-nitrosamines	ND	0.01	0.01
N-nitrosatable substances	ND	0.1	0.1

Note: 1. ND denotes not detected and less than Detected limit
2. Tested N-nitrosamines are listed below:

	Compounds name	Abbreviation	CAS#
1	N-Nitrosodimethylamine	NDMA	62-75-9
2	N-nitrosodiethylamine	NDEA	55-18-5
3/4	N-nitrosopyrrolidine or N-nitroso N-methyl N-phenylamine	NPYR or NMPhA	930-55-2 or 614-00-6
5	N-nitrosomorpholine	NMOR	59-89-2
6	N-Nitrosodi-n-propylamine	NDPA	621-64-7
7	N-nitrosopiperidine	NPIP	100-75-4
8	N-nitroso N-ethyl N-phenylamine	NEPhA	612-64-6
9	N-Nitrosodi-n-butylamine	NDBA	924-16-3
10	N-nitrosodibenzylamine	NDBzA	5336-53-8
11	N-Nitrosodiisononylamine	NDiNA	1207995-62
12	N-nitrosomethylethylamine	NMEA	10595-95-6
13	N-nitrosodiisobutylamine	NDiBA	997-95-5

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

-END OF THE TEST REPORT-



Test Report

No.: XMHL21020008800T

Date: Mar 05, 2021

Page 1 of 17

MED-HAND GMBH
INDUSTRIEHOF 6, SCHWARZWALD, LAHR, 77933, Germany

Sample Description : DISPOSABLE POWDER FREE NITRILE GLOVES

As above test item and its relevant information regarding to the submission are provided and confirmed by the applicant. SGS is not liable to either the test item or its relevant information, in terms of the accuracy, suitability, reliability or/and integrity accordingly.

SGS Ref No. : XMNHG2100218101

Sample Receiving Date : Feb 26, 2021

Test Performing Date : Feb 26, 2021 to Mar 05, 2021

Test Performed : Selected test(s) as requested by applicant

Test Result(s) : For further details, please refer to the following page(s)

Test Requested : As requested by client, SVHC screening is performed according to:
(i) Two hundred and eleven (211) substances in the Candidate List of Substances of Very High Concern (SVHC) for authorization published by European Chemicals Agency (ECHA) on and before Jan 19, 2021 regarding Regulation (EC) No 1907/2006 concerning the REACH.

Summary :

According to the specified scope and evaluation screening, the test results of SVHC are PASS

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

Beck



XMHL 21020008800T

Beck Hong
Authorized Signatory



SGS-CSTC Standards Technical Services Co., Ltd.
Xiamen Branch Testing Center Hardlines

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Member of the SGS Group (SGS SA)

Remark :

1. The chemical analysis of specified SVHC is performed by means of currently available analytical techniques against the following SVHC related documents published by ECHA:
<http://echa.europa.eu/web/guest/candidate-list-table>

These lists are under evaluation by ECHA and may subject to change in the future.

2. REACH obligation:

- 2.1 Concerning article(s):

Communication:

Article 33 of Regulation (EC) No 1907/2006 requires supplier of an article containing a substance meeting the criteria in Article 57 and identified in accordance with Article 59(1) in a concentration above 0.1% weight by weight (w/w) shall provide the recipient of the article with sufficient information, available to the supplier, to allow safe use of the article including, as a minimum, the name of that substance in the Candidate List.

Notification:

In accordance with Regulation (EC) No 1907/2006, any EU producer or importer of articles shall notify ECHA, in accordance with paragraph 4 of Article 7, if a substance meets the criteria in Article 57 and is identified in accordance with Article 59(1) of the Regulation, if (a) the substance in the Candidate List is present in those articles in quantities totaling over one tonne per producer or importer per year; and (b) the substance in the Candidate List is present in those articles above a concentration of 0.1% weight by weight (w/w).

SGS adopts the ruling of the Court of Justice of the European Union on the definition of an article under REACH unless indicated otherwise. Detail explanation is available at the following link:

<http://www.sgs.com/-/media/global/documents/technical-documents/technical-bulletins/sgs-crs-position-statement-on-svhc-in-articles-a4-en-16-06.pdf?la=en>

- 2.2 Concerning material(s):

Test results in this report are based on the tested sample. This report refers to testing result of tested sample submitted as homogenous material(s). In case such material is being used to compose an article, the results indicated in this report may not represent SVHC concentration in such article. If this report refers to testing result of composite material group by equal weight proportion, the material in each composite test group may come from more than one article.

If the sample is a substance or mixture, and it directly exports to EU, client has the obligation to comply with the supply chain communication obligation under Article 31 of Regulation (EC) No. 1907/2006 and the conditions of Authorization of substance of very high concern included in the Annex XIV of the Regulation (EC) No. 1907/2006.

- 2.3 Concerning substance and preparation:

If a SVHC is found over 0.1% (w/w) and/or the specific concentration limit which is set in



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Regulation (EC) No 1272/2008 and its amendments, client is suggested to prepare a Safety Data Sheet (SDS) against the SVHC to comply with the supply chain communication obligation under Regulation (EC) No 1907/2006, in which:

- a substance that is classified as hazardous under the CLP Regulation (EC) No 1272/2008.
- a mixture that is classified as hazardous under the CLP Regulation (EC) No 1272/2008, when it contains a substance with concentration equal to, or greater than the classification limit as set in Regulation (EC) No. 1272/2008; or
- a mixture is not classified as hazardous under the CLP Regulation (EC) No 1272/2008, but contains either:
 - (a) a substance posing human health or environmental hazards in an individual concentration of $\geq 1\%$ by weight for mixtures that are solid or liquids (i.e., non-gaseous mixtures) or $\geq 0.2\%$ by volume for gaseous mixtures; or
 - (b) a substance that is PBT, or vPvB in an individual concentration of $\geq 0.1\%$ by weight for mixtures that are solid or liquids (i.e., non-gaseous mixtures); or
 - (c) a substance on the SVHC candidate list (for reasons other than those listed above), in an individual concentration of $\geq 0.1\%$ by weight for non-gaseous mixtures; or
 - (d) a substance for which there are Europe-wide workplace exposure limits.

3. If a SVHC is found over the reporting limit, client is suggested to identify the component which contains the SVHC and the exact concentration of the SVHC by requesting further quantitative analysis from the laboratory.

Test Sample :

Sample Description :

Specimen No.	SGS Sample ID	Description
SN1	XMN21-002181.001	Blue nitrile gloves

Test Method :

SGS In-House method- SGS-CCL-TOP-092-01, SGS-CCL-TOP-092-02, Analyzed by ICP-OES, UV-VIS, GC-MS, HPLC-DAD/MS and Colorimetric Method.

Test Result: (Substances in the Candidate List of SVHC)

Batch	Substance Name	CAS No.	001 Concentration (%)	RL (%)
-	All tested SVHC in candidate list	-	ND	-



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Notes :

1. The table above only shows detected SVHC, and SVHC that below RL are not reported. Please refer to Appendix for the full list of tested SVHC.
2. RL = Reporting Limit (Test data will be shown if it \geq RL. RL is not regulatory limit.) ND = Not detected (lower than RL),
ND is denoted on the SVHC substance.
3. * The test result is based on the calculation of selected element(s) and to the worst-case scenario.
** The test result is based on the calculation of selected marker(s) and to the worst-case scenario.
For detail information, please refer to the SGS REACH website:
<http://www.sgs.com/en/Consumer-Goods-Retail/Toys-and-Juvenile-Products/Toys/REACH/Management-of-SVHC.aspx>
4. RL = 0.005% is evaluated for element (i.e. cobalt, arsenic, lead, chromium (VI), aluminum, zirconium, boron, strontium, zinc, antimony, cadmium, titanium and barium respectively), except molybdenum RL=0.0005%, boron RL=0.0025% (only for Lead bis(tetrafluoroborate)).
5. Calculated concentration of boric compounds are based on the water extractive boron by ICP-OES.
6. § The substance is proposed for the identification as SVHC only where it contains Michler's ketone (CAS Number: 90-94-8) or Michler's base (CAS Number: 101-61-1) $\geq 0.1\%$ (w/w).
7. The test was subcontracted to SGS Guangzhou chemical lab.



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Appendix
Full list of tested SVHC:

Batch	No.	Substance Name	CAS No.	RL (%)
I	1	4,4'-Diaminodiphenylmethane(MDA)	101-77-9	0.050
I	2	5-tert-butyl-2,4,6-trinitro-m-xylene (musk xylene)	81-15-2	0.050
I	3	Alkanes, C10-13, chloro (Short Chain Chlorinated Paraffins)	85535-84-8	0.050
I	4	Anthracene	120-12-7	0.050
I	5	Benzyl butyl phthalate (BBP)	85-68-7	0.050
I	6	Bis (2-ethylhexyl)phthalate (DEHP)	117-81-7	0.050
I	7	Bis(tributyltin)oxide (TBTO)	56-35-9	0.050
I	8	Cobalt dichloride*	7646-79-9	0.005
I	9	Diarsenic pentaoxide*	1303-28-2	0.005
I	10	Diarsenic trioxide*	1327-53-3	0.005
I	11	Dibutyl phthalate (DBP)	84-74-2	0.050
I	12	Hexabromocyclododecane (HBCDD) and all major diastereoisomers identified (α -HBCDD, β -HBCDD, γ -HBCDD)	-	0.050
I	13	Lead hydrogen arsenate*	7784-40-9	0.005
I	14	Sodium dichromate*	7789-12-0, 10588-01-9	0.005
I	15	Triethyl arsenate*	15606-95-8	0.005
II	16	2,4-Dinitrotoluene	121-14-2	0.050
II	17	Acrylamide	79-06-1	0.050
II	18	Anthracene oil**	90640-80-5	0.050
II	19	Anthracene oil, anthracene paste**	90640-81-6	0.050
II	20	Anthracene oil, anthracene paste, anthracene fraction**	91995-15-2	0.050



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Appendix
Full list of tested SVHC:

Batch	No.	Substance Name	CAS No.	RL (%)
II	21	Anthracene oil, anthracene paste, distn. lights**	91995-17-4	0.050
II	22	Anthracene oil, anthracene-low**	90640-82-7	0.050
II	23	Diisobutyl phthalate	84-69-5	0.050
II	24	Lead chromate molybdate sulphate red (C.I. Pigment Red 104)*	12656-85-8	0.005
II	25	Lead chromate*	7758-97-6	0.005
II	26	Lead sulfochromate yellow (C.I. Pigment Yellow 34)*	1344-37-2	0.005
II	27	Pitch, coal tar, high temp.**	65996-93-2	0.050
II	28	Tris(2-chloroethyl)phosphate	115-96-8	0.050
III	29	Ammonium dichromate*	7789-09-05	0.005
III	30	Boric acid*	-	0.005
III	31	Disodium tetraborate, anhydrous*	1303-96-4, 1330-43-4, 12179-04-3	0.005
III	32	Potassium chromate*	7789-00-6	0.005
III	33	Potassium dichromate*	7778-50-9	0.005
III	34	Sodium chromate*	7775-11-03	0.005
III	35	Tetraboron disodium heptaoxide, hydrate*	12267-73-1	0.005
III	36	Trichloroethylene	79-01-6	0.050
IV	37	2-Ethoxyethanol	110-80-5	0.050
IV	38	2-Methoxyethanol	109-86-4	0.050
IV	39	Chromic acid, Oligomers of chromic acid and dichromic acid, Dichromic acid*	-	0.005



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Appendix
Full list of tested SVHC:

Batch	No.	Substance Name	CAS No.	RL (%)
IV	40	Chromium trioxide*	1333-82-0	0.005
IV	41	Cobalt(II) carbonate*	513-79-1	0.005
IV	42	Cobalt(II) diacetate*	71-48-7	0.005
IV	43	Cobalt(II) dinitrate*	10141-05-6	0.005
IV	44	Cobalt(II) sulphate*	10124-43-3	0.005
V	45	1,2,3-trichloropropane	96-18-4	0.050
V	46	1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich	71888-89-6	0.050
V	47	1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters	68515-42-4	0.050
V	48	1-methyl-2-pyrrolidone	872-50-4	0.050
V	49	2-ethoxyethyl acetate	111-15-9	0.050
V	50	Hydrazine	7803-57-8, 302-01-2	0.050
V	51	Strontium chromate*	7789-06-02	0.005
VI	52	1,2-Dichloroethane	107-06-2	0.050
VI	53	2,2'-dichloro-4,4'-methylenedianiline	101-14-4	0.050
VI	54	2-Methoxyaniline; o-Anisidine	90-04-0	0.050
VI	55	4-(1,1,3,3-tetramethylbutyl)phenol	140-66-9	0.050
VI	56	Aluminosilicate Refractory Ceramic Fibres *	-	0.005
VI	57	Arsenic acid*	7778-39-4	0.005
VI	58	Bis(2-methoxyethyl) ether	111-96-6	0.050
VI	59	Bis(2-methoxyethyl) phthalate	117-82-8	0.050



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Appendix
Full list of tested SVHC:

Batch	No.	Substance Name	CAS No.	RL (%)
VI	60	Calcium arsenate*	7778-44-1	0.005
VI	61	Dichromium tris(chromate) *	24613-89-6	0.005
VI	62	Formaldehyde, oligomeric reaction products with aniline	25214-70-4	0.050
VI	63	Lead diazide, Lead azide*	13424-46-9	0.005
VI	64	Lead dipicrate*	6477-64-1	0.005
VI	65	Lead styphnate*	15245-44-0	0.005
VI	66	N,N-dimethylacetamide	127-19-5	0.050
VI	67	Pentazinc chromate octahydroxide*	49663-84-5	0.005
VI	68	Phenolphthalein	77-09-8	0.050
VI	69	Potassium hydroxyoctaoxodizincatedichromate*	11103-86-9	0.005
VI	70	Trilead diarsenate*	3687-31-8	0.005
VI	71	Zirconia Aluminosilicate Refractory Ceramic Fibres*	-	0.005
VII	72	[4-[[4-anilino-1-naphthyl][4-(dimethylamino)phenyl]methylene]cyclohexa-2,5-dien-1-ylidene] dimethylammonium chloride (C.I. Basic Blue 26)§	2580-56-5	0.050
VII	73	[4-[4,4'-bis(dimethylamino)benzhydrylidene]cyclohexa-2,5-dien-1-ylidene]dimethylammonium chloride (C.I. Basic Violet 3)§	548-62-9	0.050
VII	74	1,2-bis(2-methoxyethoxy)ethane (TEGDME; triglyme)	112-49-2	0.050
VII	75	1,2-dimethoxyethane; ethylene glycol dimethyl ether (EGDME)	110-71-4	0.050
VII	76	4,4'-bis(dimethylamino) benzophenone (Michler's Ketone)	90-94-8	0.050
VII	77	4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol§	561-41-1	0.050
VII	78	Diboron trioxide*	1303-86-2	0.005



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Appendix
Full list of tested SVHC:

Batch	No.	Substance Name	CAS No.	RL (%)
VII	79	Formamide	75-12-7	0.050
VII	80	Lead(II) bis(methanesulfonate)*	17570-76-2	0.005
VII	81	N,N,N',N'-tetramethyl-4,4'-methylenedianiline (Michler's base)	101-61-1	0.050
VII	82	TGIC (1,3,5-tris(oxiranylmethyl)-1,3,5-triazine-2,4,6(1H,3H,5H)-trione)	2451-62-9	0.050
VII	83	α,α -Bis[4-(dimethylamino)phenyl]-4 (phenylamino)naphthalene-1-methanol (C.I. Solvent Blue 4) §	6786-83-0	0.050
VII	84	β -TGIC (1,3,5-tris[(2S and 2R)-2,3-epoxypropyl]-1,3,5-triazine-2,4,6-(1H,3H,5H)-trione)	59653-74-6	0.050
VIII	85	[Phthalato(2-)]dioxotrilead*	69011-06-9	0.005
VIII	86	1,2-Benzenedicarboxylic acid, dipentylester, branched and linear	84777-06-0	0.050
VIII	87	1,2-Diethoxyethane	629-14-1	0.050
VIII	88	1-Bromopropane	106-94-5	0.050
VIII	89	3-Ethyl-2-methyl-2-(3-methylbutyl)-1,3-oxazolidine	143860-04-2	0.050
VIII	90	4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated	-	0.050
VIII	91	4,4'-Methylenedi-o-toluidine	838-88-0	0.050
VIII	92	4,4'-Oxydianiline and its salts	101-80-4	0.050
VIII	93	4-Aminoazobenzene	60-09-3	0.050
VIII	94	4-Methyl-m-phenylenediamine	95-80-7	0.050
VIII	95	4-Nonylphenol, branched and linear	-	0.050
VIII	96	6-Methoxy-m-toluidine	120-71-8	0.050



VIII 97 Acetic acid, lead salt, basic* 51404-69-4 0.005

Appendix
Full list of tested SVHC:

Batch	No.	Substance Name	CAS No.	RL (%)
VIII	98	Biphenyl-4-ylamine	92-67-1	0.050
VIII	99	Bis(pentabromophenyl) ether (DecaBDE)	1163-19-5	0.050
VIII	100	Cyclohexane-1,2-dicarboxylic anhydride, cis-cyclohexane-1,2-dicarboxylic anhydride, trans-cyclohexane-1,2-dicarboxylic anhydride	-	0.050
VIII	101	Diazene-1,2-dicarboxamide (C,C'-azodi(formamide))	123-77-3	0.050
VIII	102	Dibutyltin dichloride (DBTC)	683-18-1	0.050
VIII	103	Diethyl sulphate	64-67-5	0.050
VIII	104	Diisopentylphthalate	605-50-5	0.050
VIII	105	Dimethyl sulphate	77-78-1	0.050
VIII	106	Dinoseb	88-85-7	0.050
VIII	107	Dioxobis(stearato)trilead*	12578-12-0	0.005
VIII	108	Fatty acids, C16-18, lead salts*	91031-62-8	0.005
VIII	109	Furan	110-00-9	0.050
VIII	110	Henicosafuoroundecanoic acid	2058-94-8	0.050
VIII	111	Heptacosafuorotetradecanoic acid	376-06-7	0.050
VIII	112	Hexahydromethylphthalic anhydride, Hexahydro-4-methylphthalic anhydride, Hexahydro-1-methylphthalic anhydride, Hexahydro-3-methylphthalic anhydride	-	0.050
VIII	113	Lead bis(tetrafluoroborate)*	13814-96-5	0.005
VIII	114	Lead cyanamidate*	20837-86-9	0.005
VIII	115	Lead dinitrate*	10099-74-8	0.005



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VIII 116 Lead monoxide* 1317-36-8 0.005

Appendix
Full list of tested SVHC:

Batch	No.	Substance Name	CAS No.	RL (%)
VIII	117	Lead oxide sulfate*	12036-76-9	0.005
VIII	118	Lead tetroxide (orange lead)*	1314-41-6	0.005
VIII	119	Lead titanium trioxide*	12060-00-3	0.005
VIII	120	Lead titanium zirconium oxide*	12626-81-2	0.005
VIII	121	Methoxyacetic acid	625-45-6	0.050
VIII	122	Methyloxirane (Propylene oxide)	75-56-9	0.050
VIII	123	N,N-dimethylformamide	68-12-2	0.050
VIII	124	N-Methylacetamide	79-16-3	0.050
VIII	125	N-Pentyl-isopentylphthalate	776297-69-9	0.050
VIII	126	o-Aminoazotoluene	97-56-3	0.050
VIII	127	o-Toluidine	95-53-4	0.050
VIII	128	Pentacosafuorotridecanoic acid	72629-94-8	0.050
VIII	129	Pentalead tetraoxide sulphate*	12065-90-6	0.005
VIII	130	Pyrochlore, antimony lead yellow*	8012-00-8	0.005
VIII	131	Silicic acid, barium salt, lead-doped*	68784-75-8	0.005
VIII	132	Silicic acid, lead salt*	11120-22-2	0.005
VIII	133	Sulfurous acid, lead salt, dibasic*	62229-08-7	0.005
VIII	134	Tetraethyllead*	78-00-2	0.005
VIII	135	Tetralead trioxide sulphate*	12202-17-4	0.005



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VIII	136	Tricosafuorododecanoic acid	307-55-1	0.050
VIII	137	Trilead bis(carbonate)dihydroxide (basic lead carbonate)*	1319-46-6	0.005

Appendix
Full list of tested SVHC:

Batch	No.	Substance Name	CAS No.	RL (%)
VIII	138	Trilead dioxide phosphonate*	12141-20-7	0.005
IX	139	4-Nonylphenol, branched and linear, ethoxylated	-	0.050
IX	140	Ammonium pentadecafluorooctanoate (APFO)**	3825-26-1	0.050
IX	141	Cadmium oxide*	1306-19-0	0.005
IX	142	Cadmium*	7440-43-9	0.005
IX	143	Dipentyl phthalate (DPP)	131-18-0	0.050
IX	144	Pentadecafluorooctanoic acid (PFOA)	335-67-1	0.050
X	145	Cadmium sulphide*	1306-23-6	0.005
X	146	Dihexyl phthalate	84-75-3	0.050
X	147	Disodium 3,3'-[[1,1'-biphenyl]-4,4'-diylbis(azo)]bis(4-aminonaphthalene-1-sulphonate) (C.I. Direct Red 28)	573-58-0	0.050
X	148	Disodium 4-amino-3-[[4'-[(2,4-diaminophenyl)azo][1,1'-biphenyl]-4-yl]azo]-5-hydroxy-6-(phenylazo)naphthalene-2,7-disulphonate (C.I. Direct Black 38)	1937-37-7	0.050
X	149	Imidazolidine-2-thione; (2-imidazoline-2-thiol)	96-45-7	0.050
X	150	Lead di(acetate)*	301-04-2	0.005
X	151	Trixylyl phosphate	25155-23-1	0.050
XI	152	1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear	68515-50-4	0.050
XI	153	Cadmium chloride*	10108-64-2	0.005



XI	154	Sodium perborate; perboric acid, sodium salt*	-	0.005
XI	155	Sodium peroxometaborate*	7632-04-04	0.005

Appendix
Full list of tested SVHC:

Batch	No.	Substance Name	CAS No.	RL (%)
XII	156	2-(2H-Benzotriazol-2-yl)-4,6-ditertpentylphenol (UV-328)	25973-55-1	0.050
XII	157	2-benzotriazol-2-yl-4,6-di-tert-butylphenol (UV-320)	3846-71-7	0.050
XII	158	2-Ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradeca noate; DOTE	15571-58-1	0.050
XII	159	Cadmium fluoride*	7790-79-6	0.005
XII	160	Cadmium sulphate*	10124-36-4, 31119-53-6	0.005
XII	161	Reaction mass of 2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradeca noate & 2-ethylhexyl 10-ethyl-4-[[2- [(2-ethylhexyl)oxy]-2-oxoethyl]thio]-4-octyl-7-oxo-8-oxa-3,5-di thia-4-stannatetradecanoate (reaction mass of DOTE & MOTE)	-	0.050
XIII	162	1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters; 1,2-benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters with ≥ 0.3% of dihexyl phthalate	-	0.050
XIII	163	5-sec-butyl-2- (2,4-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [1], 5-sec-butyl-2- (4,6-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [2] [covering any of the individual isomers of [1] and [2] or any combination thereof]	-	0.050
XIV	164	1,3-propanesultone	1120-71-4	0.050
XIV	165	2,4-di-tert-butyl-6-(5-chlorobenzotriazol-2-yl)phenol (UV-327)	3864-99-1	0.050
XIV	166	2-(2H-benzotriazol-2-yl)-4-(tert-butyl)-6-(sec-butyl)phenol (UV-350)	36437-37-3	0.050
XIV	167	Nitrobenzene	98-95-3	0.050



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XIV	168	Perfluorononan-1-ol-acid and its sodium and ammonium salts	-	0.050
XV	169	Benzo[def]chrysene (Benzo[a]pyrene)	50-32-8	0.050

Appendix
Full list of tested SVHC:

Batch	No.	Substance Name	CAS No.	RL (%)
XVI	170	4,4'-isopropylidenediphenol (bisphenol A)	80-05-7	0.050
XVI	171	4-Heptylphenol, branched and linear	-	0.050
XVI	172	Nonadecafluorodecanoic acid (PFDA) and its sodium and ammonium salts	-	0.050
XVI	173	p-(1,1-dimethylpropyl)phenol	80-46-6	0.050
XVII	174	Perfluorohexane-1-sulphonic acid and its salts	-	0.050
XVIII	175	1,6,7,8,9,14,15,16,17,17,18,18-Dodecachloropentacyclo[12.2.1.16,9.02,13.05,10]octadeca-7,15-diene ("Dechlorane Plus"™) [covering any of its individual anti- and syn-isomers or any combination thereof]	-	0.050
XVIII	176	Benz[a]anthracene	56-55-3	0.050
XVIII	177	Cadmium nitrate*	10325-94-7	0.005
XVIII	178	Cadmium carbonate*	513-78-0	0.005
XVIII	179	Cadmium hydroxide*	21041-95-2	0.005
XVIII	180	Chrysene	218-01-9	0.050
XVIII	181	Reaction products of 1,3,4-thiadiazolidine-2,5-dithione, formaldehyde and 4-heptylphenol, branched and linear (RP-HP) [with ≥0.1% w/w 4-heptylphenol, branched and linear]	-	0.050
XIX	182	Benzene-1,2,4-tricarboxylic acid 1,2-anhydride (trimellitic anhydride)	552-30-7	0.050
XIX	183	Benzo[ghi]perylene	191-24-2	0.050
XIX	184	Decamethylcyclopentasiloxane (D5)	541-02-6	0.050



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XIX	185	Dicyclohexyl phthalate (DCHP)	84-61-7	0.050
XIX	186	Disodium octaborate*	12008-41-2	0.005
XIX	187	Dodecamethylcyclotetrasiloxane (D6)	540-97-6	0.050

Appendix
Full list of tested SVHC:

Batch	No.	Substance Name	CAS No.	RL (%)
XIX	188	Ethylenediamine	107-15-3	0.050
XIX	189	Lead*	7439-92-1	0.005
XIX	190	Octamethylcyclotetrasiloxane (D4)	556-67-2	0.050
XIX	191	Terphenyl hydrogenated	61788-32-7	0.050
XX	192	1,7,7-trimethyl-3-(phenylmethylene)bicyclo[2.2.1]heptan-2-one (3-benzylidene camphor)	15087-24-8	0.050
XX	193	2,2-bis(4'-hydroxyphenyl)-4- methylpentane	6807-17-6	0.050
XX	194	Benzo[k]fluoranthene	207-08-9	0.050
XX	195	Fluoranthene	206-44-0	0.050
XX	196	Phenanthrene	85-01-8	0.050
XX	197	Pyrene	129-00-0	0.050
XXI	198	2,3,3,3-tetrafluoro-2-(heptafluoropropoxy)propionic acid, its salts and its acyl halides (covering any of their individual isomers and combinations thereof)	-	0.050
XXI	199	2-methoxyethyl acetate	110-49-6	0.050
XXI	200	4-tert-butylphenol (PTBP)	98-54-4	0.050
XXI	201	Tris(4-nonylphenyl, branched and linear) phosphite (TNPP) with $\geq 0.1\%$ w/w of 4-nonylphenol, branched and linear (4-NP)	-	0.050
XXII	202	2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone	119313-12-1	0.050



XXII	203	2-methyl-1-(4-methylthiophenyl)-2-morpholinopropan-1-one	71868-10-5	0.050
XXII	204	Diisohexyl phthalate	71850-09-4	0.050
XXII	205	Perfluorobutane sulfonic acid (PFBS) and its salts	-	0.050

Appendix
Full list of tested SVHC:

Batch	No.	Substance Name	CAS No.	RL (%)
XXIII	206	1-vinylimidazole	1072-63-5	0.050
XXIII	207	2-methylimidazole	693-98-1	0.050
XXIII	208	Butyl 4-hydroxybenzoate	94-26-8	0.050
XXIII	209	Dibutylbis(pentane-2,4-dionato-O,O')tin**	22673-19-4	0.050
XXIV	210	bis(2-(2-methoxyethoxy)ethyl) ether	143-24-8	0.050
XXIV	211	Dioctyltin dilaurate, stannane, dioctyl-, bis(coco acyloxy) derivs., and any other stannane, dioctyl-, bis(fatty acyloxy) derivs. wherein C12 is the predominant carbon number of the fatty acyloxy moiety**	-	0.050



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Sample photo(s):

XMNHG2100218101



XMN21-002181.001

End of Report



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Customer details: Med-Hand GmbH
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Germany

SATRA reference: CHT0309598 /2109

Your reference: MH-001

Date of report: 20 April 2021

Samples received: 4 March 2021

Date(s) work carried out: 6-14 April 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 test on Disposable Powder Free Nitrile Gloves, Size: S6, M7, L8, XL9, Color: Blue, Reference number: MH-001

Conditions of Issue:

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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: Adam Zhang
Position: Technologist
Department: China Testing

WORK REQUESTED

Samples described as Disposable Powder Free Nitrile Gloves, Size: S6, M7, L8, XL9, Color: Blue, Reference number: MH-001 were received by SATRA on 4 March 2021 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 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, Size: S6, M7, L8, XL9, Color: Blue, Reference number: MH-001 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			± 1.10 mm	N/A
			1	2	3		
		6	240	239	235		
		Comfortable on fit					
		7	238	240	240		
		Comfortable on fit					
		8	238	233	240		
5.2 Dexterity	See table 1	Size	Minimum pin diameter / mm			N/A	Level 5
		6	5.0				
		7	5.0				
		8	5.0				
		9	5.0				

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	2.9 kPa	N/A	Pass
	Sample size	Leaks		
	6	No leaks detected		
	7	No leaks detected		
	8	No leaks detected		
7.3 Water leak test	9	No leaks detected		
	Sample size	Leaks	N/A	Pass
	6	No leaks detected		
	7	No leaks detected		
	8	No leaks detected		
	9	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 21R001192. 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, Color: Blue, Reference number: MH-001						
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 A210406029001. The laboratory is CNAS accredited to ISO 17025: 2017.

Sample Item	Sample Description	Location	Style
I001	Blue Nitrile Gloves	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
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-	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	-	7.7
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
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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

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 costs. 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 Client's 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 clause 13 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



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国际互认
检测
TESTING
CNAS L6760

171020340088

Test Report

Report No: HAPTX21030185

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Applicant Med-Hand GmbH

Address Industriehof 6, 77933 Lahr/Achwald/Germany

Sample Information

Sample Name Disposable Powder Free Nitrile Gloves

*The information above is provided and confirmed by the applicant.

Sample Received Date Mar.08,2021

Testing Period Mar.08,2021 to Mar.10,2021

Testing Requested As per client's request, to determine the RoHS 2.0 (Pb, Cd, Hg, Cr⁶⁺, PBBs, PBDEs, DBP, BBP, DEHP, DIBP) in the submitted sample according to RoHS Directive (EU) 2015/863 Annex II.

Testing Results Please refer to next page(s)

Signer:

Authorized signatory

Date: Mar.10,2021

[Website of verification report: CNCA verification platform yz.cnca.cn](http://cnca.cn)

江苏环谱检测技术服务有限公司

JIANGSU HAP TESTING SERVICE CO.,LTD

地址: 扬州市经济技术开发区吴州东路 198 号

Address: NO.198 Wuzhou East Road, economic and technological development zone, YangZhou

URL: www.hap-test.com

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☎: 400-6600-776 ☎: 0514-89711561



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TESTING
CNAS L6760

171020340088

Test Report

Report No: HAPTX21030185

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Determination of RoHS 2.0 (unit: mg/kg)

Testing method

- (1) With reference to IEC 62321-5:2013. By ICP - OES for measuring;
- (2) With reference to IEC 62321-4: 2013+Amd1: 2017. By ICP-OES for measuring;
- (3) With reference to IEC 62321-7-2:2017. By UV-VIS for measuring;
- (4) With reference to IEC 62321-6:2015. By GC-MS for measuring;
- (5) With reference to IEC 62321-8:2017. By GC-MS for measuring.

Testing Item(s)	Method	MDL	Limit	Results
Lead (Pb)	(1)	2	1000	ND
Cadmium (Cd)		2	100	ND
Mercury (Hg)	(2)	2	1000	ND
Chromium(VI) (Cr ⁶⁺)	(3)	8	1000	ND
Polybrominated Biphenyls (PBBs)	(4)	—	1000	ND
Polybrominated Diphenyl Ethers (PBDEs)		—	1000	ND
Dibutyl Phthalate (DBP)	(5)	50	1000	ND
Benzylbutyl Phthalate (BBP)		50	1000	ND
Bis-(2-ethylhexyl) Phthalate (DEHP)		50	1000	ND
Diisobutyl phthalate (DIBP)		50	1000	ND

Note:

- (1) 1 mg/kg=1 ppm=0.0001%
- (2) MDL=Method Detection Limit
- (3) ND=Not Detected (<MDL)
- (4) "—" =Not Regulated
- (5) Polybrominated Biphenyls, Polybrominated Diphenyl Ethers list, and detection limit (MDL)

Polybrominated Biphenyls (PBBs)	MDL	Polybrominated Diphenyl Ethers (PBDEs)	MDL
Bromobiphenyl	5	Bromobiphenyl ether	5
Dibromobiphenyl	5	Dibromobiphenyl ether	5
Tribromobiphenyl	5	Tribromobiphenyl ether	5
Tetrabromobiphenyl	5	Tetrabromodiphenyl ether	5
Pentabromobiphenyl	5	Pentabromodiphenyl ether	5
Hexabromobiphenyl	5	Hexabromodiphenyl ether	5
Heptabromobiphenyl	5	Heptabromodiphenyl ether	5
Octabromobiphenyl	5	Octabromobiphenyl ether	5
Nonabromobiphenyl	5	Nonabromobiphenyl ether	5
Marabromodiphenyl	5	Marabromobiphenyl ether	5

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Test Report

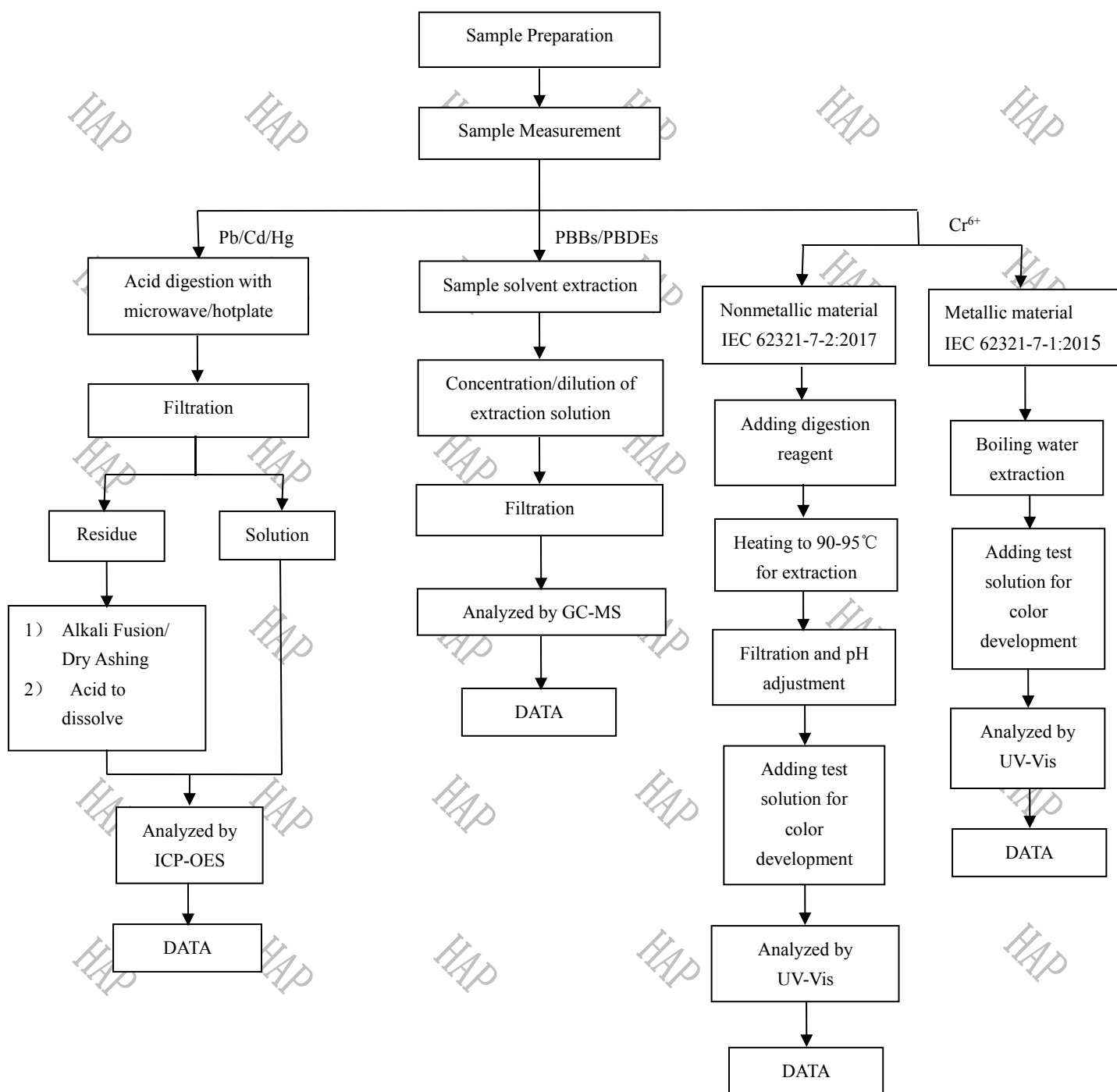
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Annex

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RoHS Testing Flow Chart

The sample was dissolved totally according to the following procedure (except for Hexavalent Chromium (Cr^{6+}), The sum of Polybrominated Biphenyls(PBBs) and The sum of Polybrominated Diphenyl Ethers(PBDEs) tests).

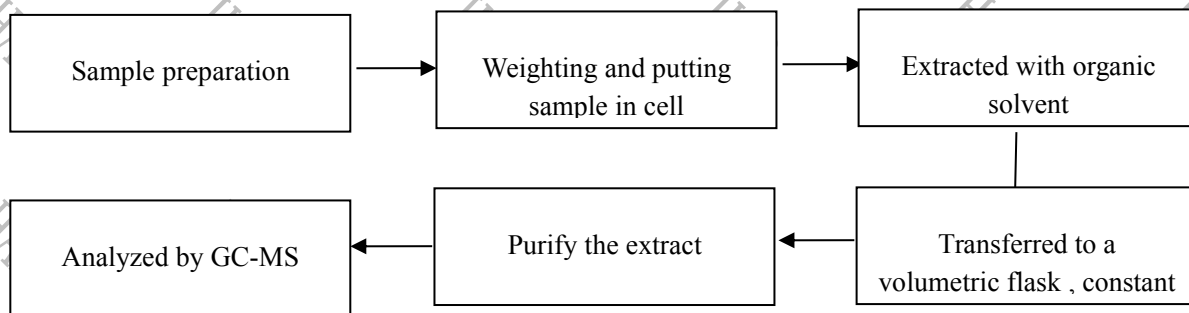


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Phthalate Testing Flow Chart:



Sample photo:



End of report



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