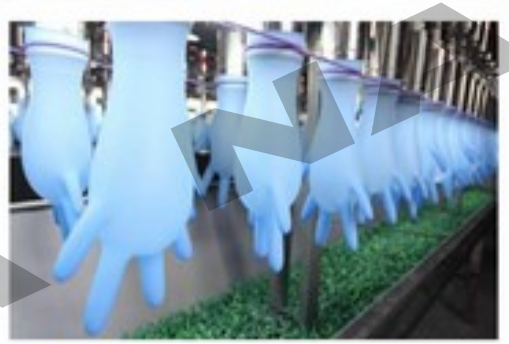

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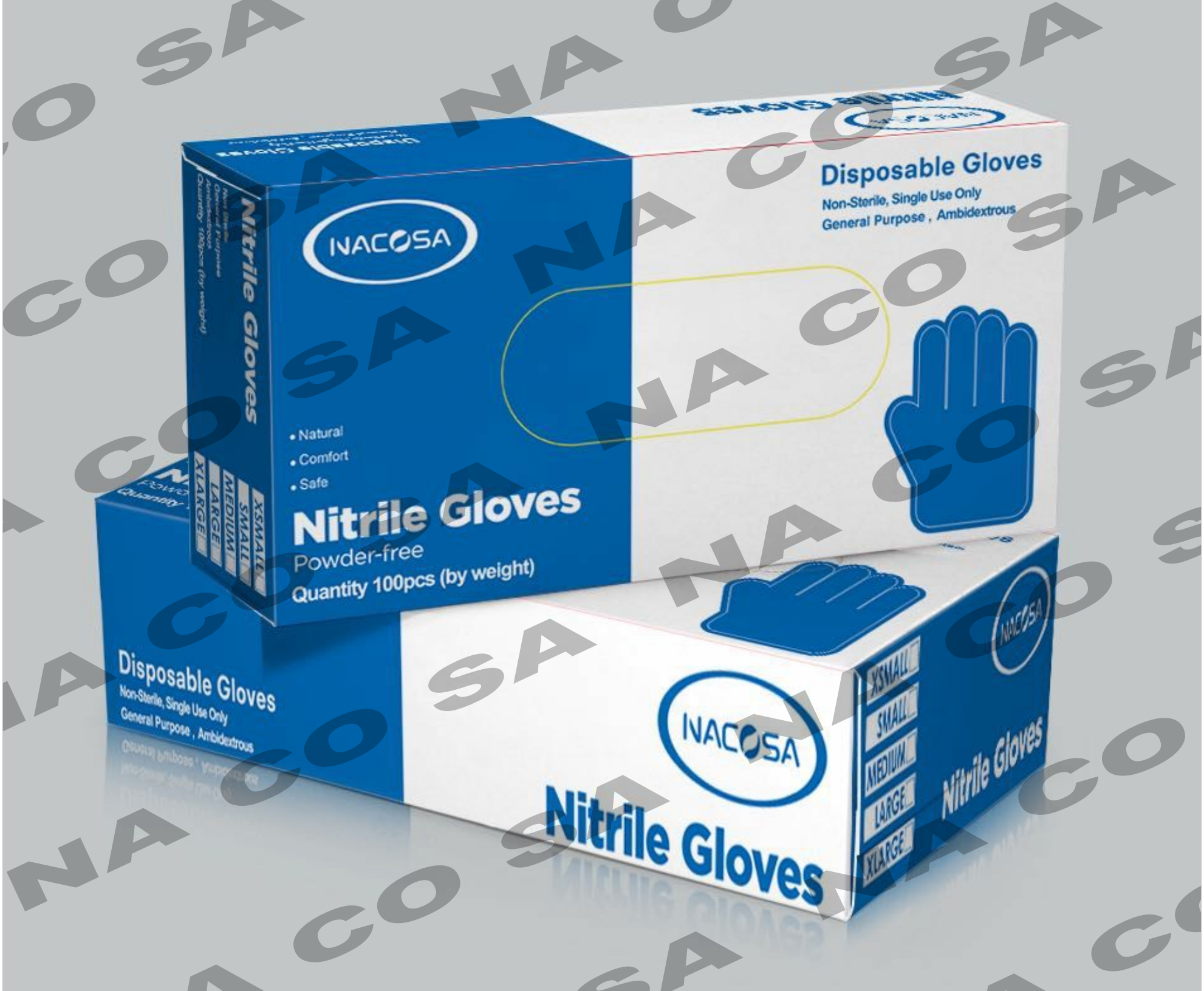
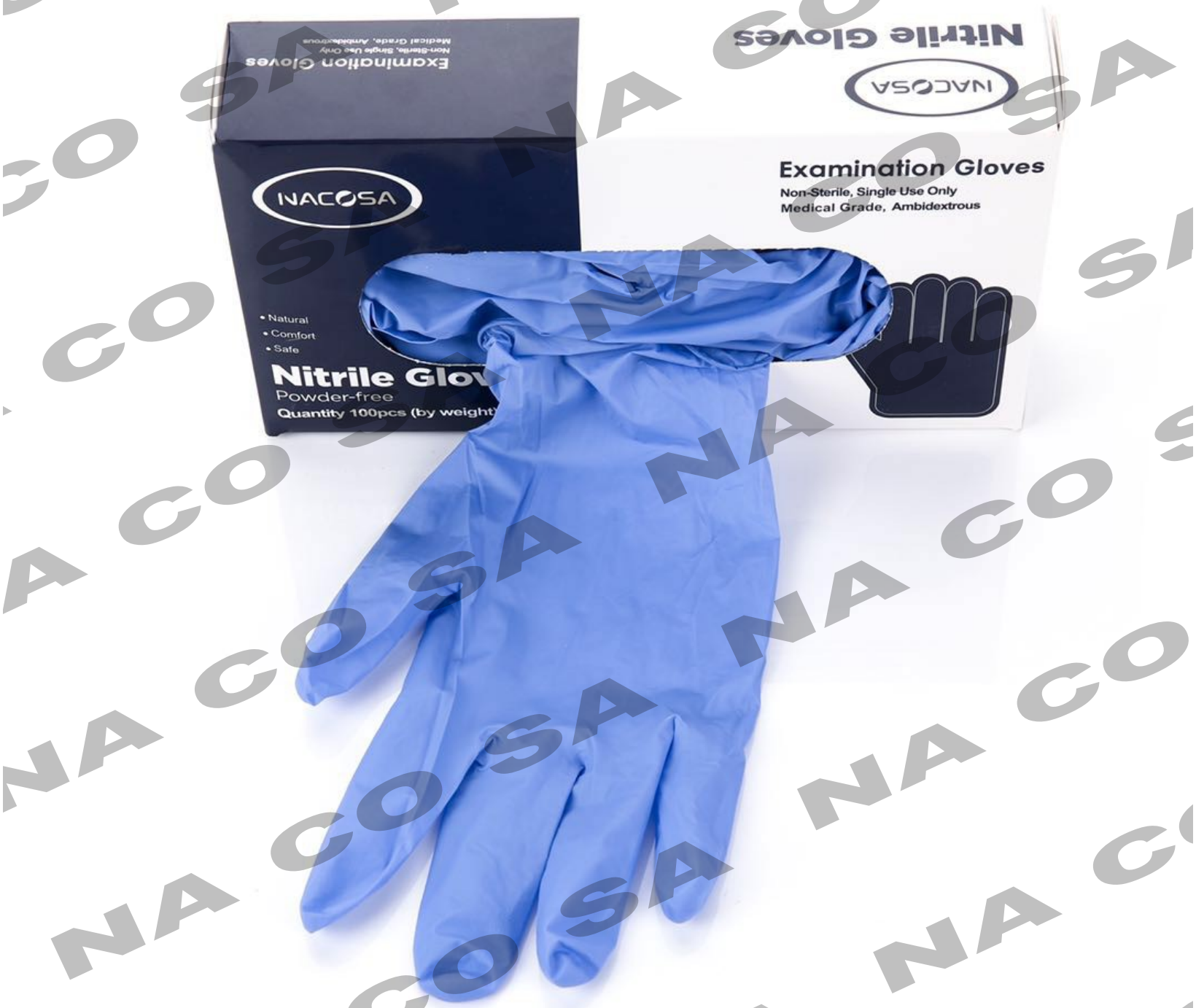
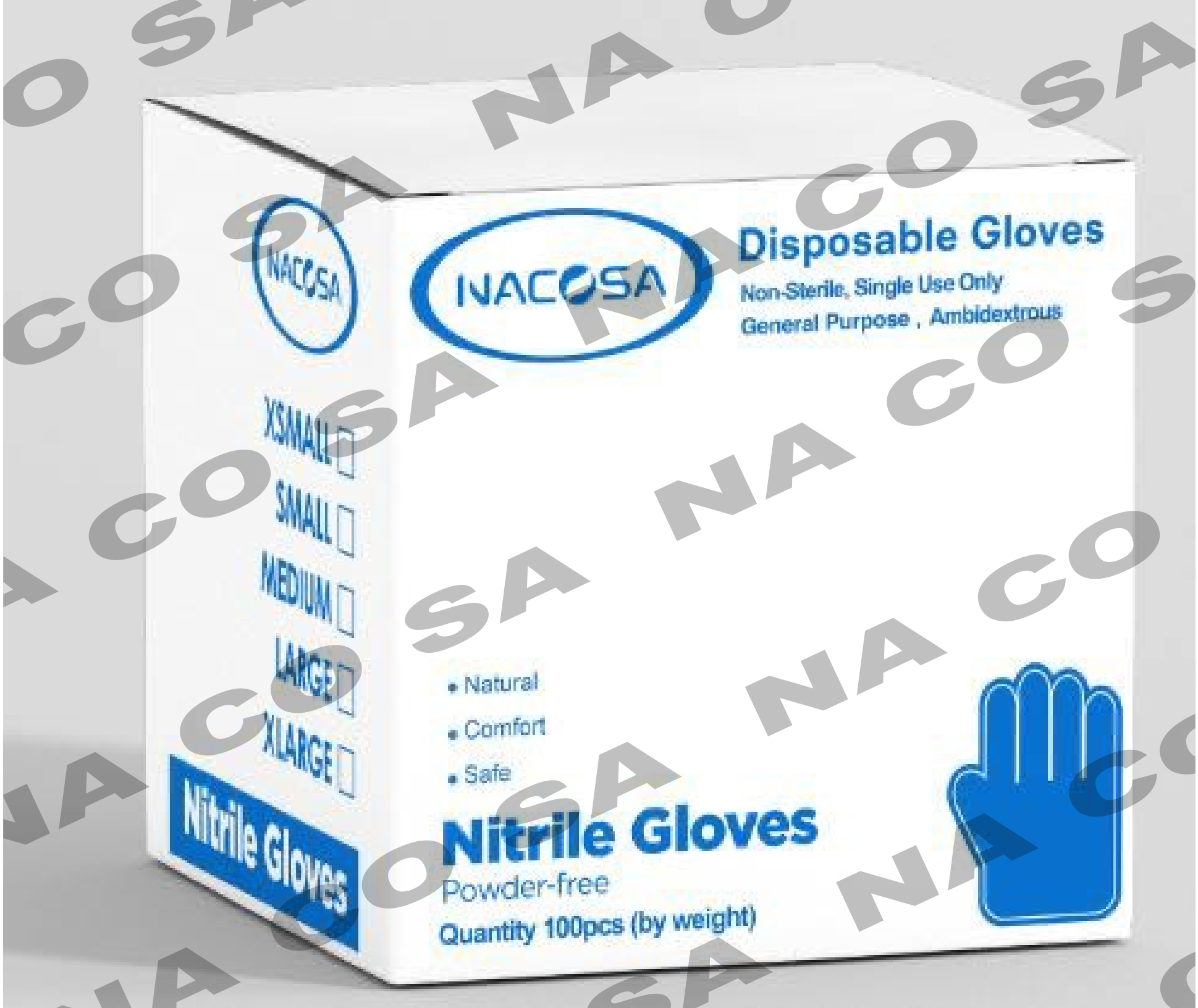
Standard Operation and Professional Manufacture


NACOSA
Disposable Gloves
Non-Sterile, Single Use Only
General Purpose , Ambidextrous
Nitrile Gloves
• Natural
• Comfort
• Safe
Nitrile Gloves
Powder-free
Quantity 100pcs (by weight)
XSMALL
SMALL
MEDIUM
LARGE
XLARGE
Disposable Gloves
Non-Sterile, Single Use Only
General Purpose , Ambidextrous
NACOSA
Nitrile Gloves
XSMALL
SMALL
MEDIUM
LARGE
XLARGE
Nitrile Gloves


NACOSA
Examination Gloves
Non-Sterile, Single Use Only
Medical Grade, Ambidextrous
• Natural
• Comfort
• Safe
Powder-free
NACOSA
Nitrile Gloves


INACOSA
Disposable Gloves
Non-Sterile, Single Use Only
General Purpose , Ambidextrous
XSMALL
SMALL
MEDIUM
LARGE
XLARGE
Nitrile Gloves
• Natural
• Comfort
• Safe
Nitrile Gloves
Powder-free
Quantity 100pcs (by weight)

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Fax +44 (0) 1536 410626
email: info@satra.com
www.satra.com

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Kawasan Perusahaan
Bandar Baru Salak Tinggi
43900 SEPANG
Selangor Darul Ehsan
Malaysia

For the attention of: Sarala Devi Jayaraman

SATRA reference: CHM0258458 /1723 /2 /SPT

Your reference:

Date of report: 21 July 2017

Samples received: 30 June 2017

Date(s) work carried out: 14 – 18 July 2017

TECHNICAL REPORT

Subject: Testing of gloves identified as NBR 3549 in accordance with EN 420: 2003 + A1: 2009 size and dexterity and EN 374-2: 2014

Report signed by: Adam Mortiboys
Position: PPE Technologist
Department: Safety Product Testing

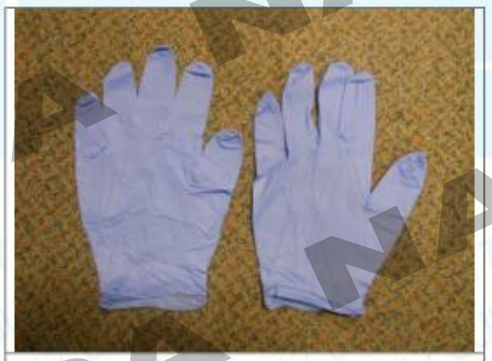
adam mortiboys

Work Requested

Samples of gloves, see Table 1, were received by SATRA, for testing in accordance with EN 420:2003+A1:2009 clauses 5.1 length and fit and 5.2 dexterity and EN 374-2:2014

Table 1 – Samples Received

Sample description as stated by the client	Sizes submitted for testing	Colour of samples submitted	Approximate weight of one glove
NBR 3549	7 – 10	Blue	Size: 10 Weight: 7.2g



NBR 3549

Conclusion

Standard	Clause / Property		Result
EN 420: 2003 + A1: 2009	5.1	Length and fit	See note ■
	5.2	Dexterity	Level 5
EN 374-2: 2014	7.2	Air leak	See note ♦
	7.3	Water leak	Pass

Note ■ – Where gloves do not meet the minimum length requirements specified in Table 1 of EN 420:2003 + A1:2009, the standard therefore requires that the manufacturer shall clearly state in the user instructions the intended application of the gloves and the reason why the gloves do not conform to the minimum length requirements.

Note ♦ - As per clause 4.3 Remarks of EN 374-2: 2014, due to the gloves overinflating the test is deemed not applicable and only the water leak test has been carried out.

Signed:

Adam Mansbridge

Testing

Samples for testing were conditioned for at least 24 hours in a conditioned environment maintained at (23±2) °C and (50±5) % relative humidity. Testing was carried out within the same environment.

Requirements

Table 2 – Requirements for EN 420:2003 + A1:2009 Clause 5 Size and Dexterity

Glove size	6	7	8	9	10	11
Minimum length / mm	220	230	240	250	260	270

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

Table 3 - Requirements for EN 374-2: 2014

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

Test Results

Table 4 - EN 420:2003 + A1:2009 Test Results for gloves identified as NBR 3549

Clause / Test	Test Results	UoM	Result
5.1 Glove length, comfort and fit	Size: Length /mm — Left / Right 7: 256 / 249 Comments on fit: Satisfactory 8: 250 / 251 Comments on fit: Satisfactory 9: 257 / 251 Comments on fit: Satisfactory 10: **255** / **251** Comments on fit: Satisfactory	± 0.3 mm	See note ■
5.2 Dexterity	Size — Minimum pin diameter / mm 7: 5.0 8: 5.0 9: 5.0 10: 5.0	N/A	Level 5

Table 5 - EN 374-2:2014 Test Results of gloves identified as NBR 3549

Clause / Test	Test Results	UoM	Result
7.2 Air leak test	Total Air Pressure Used: 2.44 kPa Sample size — Leaks 7, 8, 9, 10: Not applicable	± 2.8 mmH_20	See note ♦
7.3 Water leak test	Sample size — Leaks 7: No leaks detected 8: No leaks detected 9: No leaks detected 10: No leaks detected	N/A	Pass

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 or arising therefrom 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 property 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 Time no. SATRASUMM and SATRA Microstitch, 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 1998. To the extent that SATRA processes or gets access to personal data in connection with the Services or otherwise in connection with this Contract, it shall take all reasonable technical and organisational measures to ensure the security of such data (and guard against unauthorised or unlawful processing, accidental loss, destruction or damage to such data).

4. SUSPENSION OR TERMINATION OF SERVICES

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

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

5. LIABILITY AND INDEMNIFICATION

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

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

(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 SATRAs 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.

Signed: Adam Mortiboys

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 conduction 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 those 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 where:-

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 prosecuted 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 16.1.

Signed: adam marshall

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

August 7, 2014

WRP Asia Pacific Sdn. Bhd.
Mr. Kirk Penner
Head of Department
Product Management & Regulatory Affairs
Lot 1, Jalan 3, Kawasan Perusahaan
Bandar Baru Salak Tinggi,
43900 Sepang,
Selangor Darul Ehsan,
MALAYSIA 43900

Re: K133168
Trade/Device Name: Dermagrip Powder Free Blue Nitrile Patient Examination Gloves Non-Sterile
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Gloves
Regulatory Class: I
Product Code: LZA
Dated: July 1, 2014
Received: July 3, 2014

Dear Mr. Penner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K133168

Device Name
Dermagrip Powder Free Blue Nitrile Patient Examination Gloves Non-Sterile

Indications for Use *(Describe)*

A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Sreekanth Gutala -S

Digitally signed by Sreekanth Gutala -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=2000540490, cn=Sreekanth Gutala -S
Date: 2014.08.07 13:21:07 -04'00'

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

bsi.

By Royal Charter

EU Type Examination Certificate

This is to certify that:

WRP Asia Pacific Sdn Bhd
Lot 1, Jalan 3
Kawasan Perusahaan
Bandar Baru Salak Tinggi
Sepang
Selangor
43900
Malaysia

Holds Certificate Number: CE 688314

In respect of:

Powder Free Nitrile Gloves

on the basis that BSI carried out the relevant Type Examination procedures under the requirements with the Regulation (EU) 2016/425 of the European Parliament and Council relating to Personal Protective Equipment Regulation (PPE) Annex V (Module B) and meets the relevant health and safety requirements specified in Annex II

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Drs. Dave Hagenaars, Managing Director

Previous Notified Body: BSI 0086

First Issued: 2018-04-26

Latest Issue: 2019-09-12

Effective Date: 2019-09-12

Expiry Date: 2023-04-26

PRODUCTS RvA C 645

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EU Type Examination Certificate

No. CE 688314

Product Specification

Model – Nitrile gloves

Classification: Protective glove for use against chemical and micro-organism hazards.

Description: Powder Free Nitrile Disposable Protective Gloves manufactured from 100% nitrile synthetic rubber latex (Acylonitrile-butadiene) not containing natural rubber latex. Inner surface of gloves is smooth surface that assists in donning the gloves without using lubricant such as powder on the glove surface. The glove is available as either Sterile or Non-Sterile as indicated.

The main features of this protective glove are:
- Beaded cuff
- Micro-organisms penetration resistance
- Chemical permeation resistance
- Diamond embossed of palm/back of hand (Ambidextrous)

Models in range: Nitrile gloves.

Category: Category III – complex

Applicable Standards:
General requirements for gloves to EN 420:2003 +A1:2009
Protective gloves again chemicals & micro-organisms to EN ISO 374-1:2016
Resistance to penetration to EN 374-2:2014
Determination of resistance to permeation by chemicals tested to EN 16523-1:2015
Resistance to penetration by blood borne tested to EN ISO 374-5:2016
Resistance to degradation by chemicals to EN 374-4:2013
Resistance of clothing materials to penetration by blood-borne pathogens to ISO 16604:2014

First Issued: 2018-04-26
Latest Issue: 2019-09-12

Effective Date: 2019-09-12
Expiry Date: 2023-04-26

EU Type Examination Certificate

No. CE 688314

Product Specification (Continued)

Model – Nitrile disposable gloves (WRP NBR 3549)

Performance: **General requirements for gloves to EN 420:2003+A1:2009**

Dexterity: Level 5

Resistance to penetration to EN 374-2:2014
Pass

Resistance to chemical permeation to EN ISO 374-1:2016
Test method EN 16523-1:2015

n-Heptane (J) – level 1
40% Sodium hydroxide (K) – level 6
96% Sulphuric acid (L) – level 0
37% Formaldehyde (T) – level 5
30% Hydrogen peroxide (P) – level 5

Protection against micro-organism risks to EN ISO 374-5:2016

Bacteria and fungi (Test method EN 374-2:2014) Pass
Viruses (Test Method ISO 16604:2004) Pass

Resistance to degradation by chemicals to EN 374-4:2013

n-Heptane (J) 36.7%
40% Sodium hydroxide (K) -9.0%
96% Sulphuric acid (L) 100%
37% Formaldehyde (T) –39.1%
30% Hydrogen peroxide 40.5%

First Issued: 2018-04-26
Latest Issue: 2019-09-12

Effective Date: 2019-09-12
Expiry Date: 2023-04-26

EU Type Examination Certificate

No. CE 688314

Product Specification (Continued)

Model – Nitrile multipurpose gloves (WRP NBR E DUO)

Performance: **General requirements for gloves to EN 420:2003+A1:2009**

PH Value: Pass

Resistance to chemical permeation to EN ISO 374-1:2016
Test method EN 16523-1:2015

n-Heptane (J) – level 1
40% Sodium hydroxide (K) – level 6
37% Formaldehyde (T) – level 5
30% Hydrogen peroxide (P) – level 4
40% Hydrofluoric acid – level 1

Resistance to penetration by blood borne tested to EN ISO 374-5:2016
Pass

Resistance to degradation by chemicals to EN 374-4:2013

n-Heptane (J) 38.2%
40% Sodium hydroxide (K) –16.3%
37% Formaldehyde (T) 1.3%
30% Hydrogen peroxide (P) 7.1%

First Issued: 2018-04-26
Latest Issue: 2019-09-12

Effective Date: 2019-09-12
Expiry Date: 2023-04-26

EU Type Examination Certificate

No. CE 688314

Certificate Administration Details

Technical File Reference: TF/PPE/002

Certificate Amendment Record

Issue date	Comments	BSI Internal report No.
March 2018	First issue.	0086:18:8888423
December 2018	Addition of models Nitrile Multi-Purpose Gloves	0086:18:9665354
March 2019	Revision to add virus claim.	

Note: The Certificate holder is responsible for keeping the Notified Body advised of changes to any aspect of the overall process used in the manufacture of the product.

Certificate validity

The Certificate holder is responsible for ensuring that the Notified Body is advised of changes to any aspect of the overall process utilised in the manufacture of the product, failure to do so could invalidate the Certificate in respect of product manufactured following the introduction of such changes.

The Conformity to Type Based on Quality Assurance of the Production Process, Annex VIII (Module D), for the product are referenced in BSI issued Certificate number CE 51699

First Issued: 2018-04-26
Latest Issue: 2019-09-12

Effective Date: 2019-09-12
Expiry Date: 2023-04-26

EU Type Examination Certificate

No. CE 688314

Location	Certified Activities
WRP Asia Pacific Sdn Bhd Lot 1, Jalan 3 Kawasan Perusahaan Bandar Baru Salak Tinggi Sepang Selangor 43900 Malaysia	Powder Free Nitrile Gloves

First Issued: 2018-04-26
Latest Issue: 2019-09-12

Effective Date: 2019-09-12
Expiry Date: 2023-04-26

SATRA TECHNOLOGY

Notified Body 0321

Issued to: **WRP Asia Pacific Sdn Bhd**
Lot 1 Jalan 3
Kawasan Perusahaan
Bandar Baru Salak Tinggi
43900 SEPANG
Selangor Darul Ehsan
Malaysia

SATRA Client : P1748

EC Type-Examination Certificate

Number 8987 Issue 2

Date first issued: 25/09/2017

This is to certify that the product group reference "WRP NBR 3549" comprising the following products:

Product Reference	Description
WRP NBR 3549	Nitrile disposable gloves, available in blue, violet and black colour variant.

Sizes:
6/XS – 11/XXL

Classification:

EN ISO 374-1:2016/Type B	Level	EN 374-4:2013 Degradation %
n-Heptane (J)	1	36.7
40% Sodium Hydroxide (K)	6	-9.0
96% Sulphuric Acid (L)	0	100
37% Formaldehyde (T)	5	-39.1
30% Hydrogen peroxide (P)	5	40.5

EN ISO 374-5:2016	Level
Protection against bacteria and Fungi	Pass
Protection against viruses	Pass

Technical reports:
SATRA: CHM0258458/1723/CL/A/Issue 2, CHM0258458/1723/CL/C/Issue 2, CHM0258458/1723/CL/E/Issue 2, CHM0258458/1723/2/SPT, SPC0262694/1740, CHM0263035/1741/CL/A, CHM0263035/1741/CL/B, CHM0264783/1747/EN/A, CHM0264783/1747/EN/B

has been subject to an EC Type-examination in accordance with Article 10 of the PPE Directive (89/686/EEC) and has been shown to satisfy the relevant provisions of this Directive for the complex category through:

i Testing to the following standard: **EN 420:2003+A1:2009; EN ISO 374-1:2016; EN ISO 374-5:2016**
ii Examination of the relevant technical documentation.

You are therefore licensed to mark the product(s) listed above in accordance with Article 13 of Directive (89/686/EEC) and any relevant amending Directives once you have drawn up an EC declaration of product conformity. Please note that:

1. Full details of the certification and product are contained in the manufacturer's technical file
2. This certificate is issued subject to the conditions on the reverse side of this certificate
3. CE Marking of production is also reliant on current compliance with Directive 89/686/EEC Article 11
4. Where a translation of this certificate exists, the English language version shall be considered as the authoritative text

Signed: (Camille Lu) Date 11/01/2018

Signed:

On behalf of SATRA

Data Sheet

EPIC N

Nitrile Powder Free Non-Latex Surgical Gloves, Sterile

Reorder #		Size: 5½ : EP-13-55 6 : EP-13-60 6½ : EP-13-65 7 : EP-13-70	Size: 7½ : EP-13-75 8 : EP-13-80 8½ : EP-13-85 9 : EP-13-90
Style Number		WRP NBR PF 75-SP	
Product Part #		402xx.10472100	
510K # / MDL #		K000971 / D036529	
Design and Feature		Hand Specific, straight fingers, smooth (SH9) and beaded cuff	
Type		Powder free and Gamma-sterilized surgical gloves	
Material		Nitrile (latex-free)	
Color		White	
Surface Treatment		Single Chlorination	
Powder Free Residue (mg/glove)		<2	
Dimension - Palm Width (mm)		Size: 5½ : 72 ± 4 6 : 77 ± 5 6½ : 83 ± 5 7 : 89 ± 5	Size: 7½ : 95 ± 5 8 : 102 ± 6 8½ : 108 ± 6 9 : 114 ± 6
Dimension - Length (mm)		Size: 5½ : Min 278 6 : Min 280 6½ : Min 280 7 : Min 283	Size: 7½ : Min 287 8 : Min 288 8½ : Min 290 9 : Min 290
Dimension - Weight (g)		Size: 5½ : 11.0 ± 4 6 : 12.0 ± 4 6½ : 13.0 ± 4 7 : 14.0 ± 4	Size: 7½ : 15.0 ± 4 8 : 16.0 ± 4 8½ : 17.0 ± 4 9 : 18.0 ± 4
Single-wall Thickness (mm)	Finger Palm Cuff	0.16 ± 0.02 Min. 0.14 0.13 ± 0.02	
Physical Properties	Before Aging Tensile Strength (MPa) Ultimate Elongation (%) Modulus at 500% (MPa) Force at Break (N)	Before Aging Min. 17 Min. 650 Max. 7.0 Min. 9	After Aging Min. 12 Min. 490 N/A Min. 9
Packing Mode	Inner Wallet Pouch Dispenser Carton	1 Pair Gloves 1 Inner Wallet 50 Pouches 6 Dispensers	
Glove Marking		No marking	
Lot # identification on Finished Goods		Lot Number Structure: **YMMPPPPSS** Y = Year of Packing P = WRP's PWO MM = Month of Packing SS = Size	
Product Shelf Life		5 years upon manufactured date.	
Pre-shipment Inspection	Dimension Physical Properties 1000ml Water Leak Powder Free Residue Major Visual Inspection Minor Visual Inspection	N=13 (EN455-2); S-2, AQL 4.0 (ASTM) N=13 (EN455-2); S-2, AQL 4.0 (ASTM) G-I, AQL 0.65 N=3 pairs G-I, AQL 1.5 G-I, AQL 2.5	
Product Conformance		• EN455 Parts 1, 2, 3 and 4 - In compliance with European Medical Device Directive 93/42/EEC (CE Class IIa) • In compliance with the provisions of Regulation (EU) 2016/425 and type tested to EN420:2003+AI:2009, EN ISO 374-1:2016, EN374-2:2014, EN 16523-1:2015, EN374-4:2013 and EN ISO 374-5:2016; CE2797 • ASTM D3577	
Quality Assurance		• US FDA Quality System Regulation (QSR) • EN ISO9001:2015 • EN ISO13485:2016 & ISO13485:2016 Quality Management Systems	

Note: The above information is a guideline of typical performance values and characteristic of the product; and not to be used as actual product specifications

Your Partner In Protection™

Help (./help/index.html)

DRLM Home (mainMenu.htm)

✔ Facility

✔ Products Listing

Annual Registration Successful

Facility: WRP ASIA PACIFIC SDN. BHD., SALAK TINGGI, SEPANG, Selangor, MALAYSIA

You have successfully updated your registration and listing information for 2020.

Your registration will be valid through Dec 31, 2020.

Be sure to print this page for your records.

The next registration renewal period is October 1 - December 31, 2020.

Registering your facility and listing devices does not, in any way, constitute FDA approval of your facility or devices.

You may contact the FDA with any questions at reglist@cdrh.fda.gov.

The Owner/Operator Number for this Registration is: 8041005.

Facility Information

Registration Number:
8041005

Initial Importer:
N

Facility Name:
WRP ASIA PACIFIC SDN. BHD.

Address:
LOT 1, JALAN 3,, KAWASAN PERUSAHAAN BANDAR BARU
SALAK TINGGI, SEPANG, Selangor, 43900, MALAYSIA

DUNS Number:

Foreign Trade Zone:
N

Facility URL:

Other Business Trade Name(s):

Owner/Operator Information

Owner/Operator Number:
8041005

Contact Name:
Hasnah - Abdul Hamid

Company:
WRP ASIA PACIFIC SDN. BHD.

Address: LOT1,JALAN3,KAWASAN PERUSAHAAN , BANDAR BARU SALAK TINGGI SEPANG,SELANGOR, 43900, MALAYSIA

Telephone:
60 - 3 - 87061486

Fax:
-

E-mail: hasnah@wrpworld.com

DUNS Number:

Official Correspondent Information

Contact Name:
Hasnah - Abdul Hamid

Company:
WRP ASIA PACIFIC SDN. BHD.

Address: LOT1,JALAN3,KAWASAN PERUSAHAAN , BANDAR BARU SALAK TINGGI SEPANG,SELANGOR, 43900, MALAYSIA

Telephone:
60 - 3 - 87061486

Fax:
-

E-mail: hasnah@wrpworld.com

DUNS Number:

United States Agent Information

Contact Name:
Micheal Scaglione

Contact Title:
Mr

Business Name:
WRP USA INC

Address: 3700 Massillon rd
Uniontown, Ohio, 44685, UNITED STATES

Phone:
330 - 8961066

Fax:

DUNS Number:

E-mail: mjs@wrp-usa.com

bsi.

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 9001:2015

This is to certify that:

Holds Certificate No: **FM 13934**

and operates a Quality Management System which complies with the requirements of ISO 9001:2015 for the following scope:

Design and manufacture of natural rubber and synthetic rubber sterile surgical gloves, sterile and non-sterile examination gloves and sterile urological balloon catheters.

For and on behalf of BSI:

Chris Cheung, Head of Compliance & Risk - Asia Pacific

Original Registration Date: 1991-12-03
Effective Date: 2019-04-15
Latest Revision Date: 2019-04-15
Expiry Date: 2021-12-20

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bsi.

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Holds Certificate No: **MD 99288**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

Design and manufacture of natural rubber and synthetic rubber sterile surgical gloves, sterile and non-sterile examination gloves and sterile urological balloon catheters.

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2005-10-21
Latest Revision Date: 2019-04-15

Effective Date: 2019-04-15
Expiry Date: 2021-12-20

...making excellence a habit.

DATA SHEET

NITRILE EXAMINATION GLOVES, POWDER FREE, NON-STERILE

Reorder #	Size: :	XS S M L XL	
Product Part #			112xx.112111930
510K # / MDL #			N/A
Design and Feature			Ambidextrous, textured surface at fingers (E1) and beaded cuff
Type			Powder free and non-sterile examination gloves
Material			100% nitrile (Acrylonitrile-butadiene)
Color			Blue (PMS2726)
Surface Treatment			Chlorination on donning side
Powder Free Residue (mg/glove)			≤ 2
Dimension	Size: :	XS S M L XL	Palm Width (mm) / Length (mm) ≤80 / Min. 240 80 ± 10 / Min. 240 95 ± 10 / Min. 240 110 ± 10 / Min. 240 ≥110 / Min. 240
Weight	Size: :	XS S M L XL	2.5 ± 0.3 3.0 ± 0.3 3.5 ± 0.3 4.0 ± 0.3 4.5 ± 0.3
Single-wall Thickness (mm) *All sizes	Finger Palm Cuff		Spec Min. 0.05 Min. 0.05 Min. 0.05
Physical Properties	Before Aging Tensile Strength (MPa) Elongation (%) Force at Break (N)		EN/ASTM Spec Min 14 Min 500 Min 6
Physical Properties	After Aging Tensile Strength (MPa) Elongation (%) Force at Break (N)		EN/ASTM Spec Min 14 Min 400 Min 6
Packing Mode			200 gloves by weight per dispenser and 10 dispensers per carton
Glove Marking			No marking.
Lot # identification on Finished Goods			Lot Number Structure: YMMPPPPSS (9 digits) Y = Year of Packing MM = Month of Packing PPPP = WRP's Packing Work Order # (PWO) SS = Size (00=XS, 01=S, 02=M, 03=L and 04=XL)
Recommended Shelf Life			5 years upon manufactured date.
Pre-shipment Inspection *Single-Normal Sampling Plan	Dimension Physical Properties 1000ml Water Leak Powder Free Residue Major Visual Inspection Minor Visual Inspection		N=13, Median N=13, Median G-I, AQL 1.5 N=5 G-I, AQL 2.5 G-I, AQL 4.0
Product Conformance			• Medical Device: in compliance with European Medical Device Directive 93/42/EEC (CE Class I) • EN455 Parts 1, 2, 3 and 4 • Personal Protective Equipment of Complex Design Category III, in European Regulation (EU) 2016/425, type tested to EN 420:2003+A1:2009, EN ISO 374-1:2016 Type b, EN 374-2:2014, EN 374-4:2013, EN 374-5:2016 & EN 16523-1:2015, CE 2797 • ASTM D6319
Quality Assurance			• US FDA Quality System Regulation (QSR) • ISO9001 Quality Management Systems • ISO13485 Quality Management Systems

Note: The above information is a guideline of typical performance values and characteristic of the product; and not to be used as actual product specifications.

YOUR REF : 10289821
DATE RECEIVED : FEB 12, 2016
DATE REPORTED: FEB 24, 2016
PAGE: 1 of 1

Report No : CRSSA/03055/16
Company : Messrs. SGS (Malaysia) Sdn. Bhd.
No. 26, Jalan Anggerik Vanilla 31/93, Kota Kemuning,
40460 Shah Alam, Selangor D.E.

TEST REPORT

Client	:	WRP Asia Pacific Sdn Bhd
Product Description	:	Dermagrip Nitrile Ultra LS Powder Free Exam Gloves
Lot No.	:	602003402
Size	:	M
Quantity Tested	:	200 pieces
Test Conducted	:	Freedom from holes
Test Method	:	EN455 Part 1:2000
Testing Period	:	12 Feb 2016 – 24 Feb 2016

Based on submitted samples, the following results obtained :-

Acceptable Quality Limit (AQL) : 1.5 Accept : 7 Found : 4

Result : Within AQL

SGS (MALAYSIA) SDN. BHD.

LIM MENG HOE
B.Sc.(HONS) MMIC
ASSISTANT LAB MANAGER

SGS

YOUR REF : 10289821
DATE RECEIVED : JAN 26, 2016
DATE REPORTED: FEB 10, 2016
PAGE: 1 of 1

Report No : CRSSA/03056/16
Company : Messrs. SGS (Malaysia) Sdn. Bhd.
No. 26, Jalan Anggerik Vanilla 31/93, Kota Kemuning,
40460 Shah Alam, Selangor D.E.

TEST REPORT

Client	:	WRP Asia Pacific Sdn Bhd
Product Description	:	Dermagrip Nitrile Ultra LS Powder Free Exam Gloves
Lot No.	:	602003402
Size	:	M
Quantity Tested	:	13 pieces
Test Conducted	:	Dimensions
Test Method	:	EN 455 Part 2:2015
Testing Period	:	12 Feb 2016 – 24 Feb 2016

Based on submitted samples, the following results obtained :-

Size	M	M	M	M	M	M	M	M	M	M	M	M	M	Median
Width Median: 95±10mm	95	95	94	96	95	95	95	96	95	95	94	95	94	95
Length Median: ≥ 240mm	243	242	245	246	245	246	240	245	242	246	241	240	241	243

Acceptable Quality Limit (AQL) : 4.0 Accept : 1 Found : 0

SGS (MALAYSIA) SDN. BHD.

LIM MENG HOE
B.Sc.(HONS) MMIC
ASSISTANT LAB MANAGER

YOUR REF : 10289821
DATE RECEIVED : JAN 26, 2016
DATE REPORTED: FEB 10, 2016
PAGE: 1 of 1

Report No : CRSSA/03057/16
Company : Messrs. SGS (Malaysia) Sdn. Bhd.
No. 26, Jalan Anggerik Vanilla 31/93, Kota Kemuning,
40460 Shah Alam, Selangor D.E.

TEST REPORT

Client	:	WRP Asia Pacific Sdn Bhd
Product Description	:	Dermagrip Nitrile Ultra LS Powder Free Exam Gloves
Lot No.	:	602003402
Size	:	M
Quantity Tested	:	13 pieces per each (During Shelf Life and After Challenge)
Test Conducted	:	Force at Break During Shelf Life and After Challenge
Test Method	:	EN 455 Part 2:2015
Ageing	:	70 °C for 168 hrs
Testing Period	:	12 Feb 2016 – 24 Feb 2016

		Force at Break, N	
SIZE	**SAMPLE NO.**	**DURING SHELF LIFE**	**AFTER CHALLENGE**
M	1	6.6	6.4
	2	7.0	6.3
	3	6.9	6.6
	4	6.6	5.9
	5	6.8	6.4
	6	5.8	5.7
	7	6.3	7.4
	8	7.6	6.7
	9	5.8	6.6
	10	6.4	5.9
	11	5.7	6.4
	12	7.0	6.3
	13	6.2	6.0
Median		6.6	6.4
Requirement		≥ 6.0	≥ 6.0

SGS (MALAYSIA) SDN. BHD.

LIM MENG HOE
B.Sc.(HONS) MMIC
ASSISTANT LAB MANAGER

WRP Asia Pacific Sdn Bhd
147817V
Lot 1, Jalan 3, Kawasan Perusahaan
Bandar Baru Salak Tinggi,
43900 Sepang,
Selangor Darul Ehsan, MALAYSIA

Office +60-3-8706 1486
Facsimile +60-3-8706 1557
Website www.wrpworld.com

EC DECLARATION OF CONFORMITY

We, **WRP Asia Pacific Sdn Bhd**, being the manufacturer for the medical devices as described hereafter:

Dermagrip Nitrile Ultra LS Powder Free Exam Glove, Non Sterile
Size XS: D1100-24
Size S: D1101-24
Size M: D1102-24
Size L: D1103-24
Size XL: D1104-24

declare that the above product in Class I is manufactured per Rule 5 of Annex IX in conformity with the procedure relating to the EC declaration of conformity set out in Annex VII, and meet the requirements of Council Directive 93/42/EEC which apply to them under the supervision of the notified body British Standards Institution, and carrying an identification number of 2797.

The product is in conformity with the provisions of Regulation (EU) 2016/425 and, where such is the case, with the national standard transposing harmonized standard No. EN 420:2003 +A1:2009, EN ISO 374-1:2016, EN 374-2:2014, EN 16523-1:2015, EN 374-4:2013 and EN ISO 374-5: 2016 is subject to the procedure set out in Module D of Regulation (EU) 2016/425 is identical to the PPE which is the subject of EC certificate of conformity No. CE 688314 issued by BSI (2797), Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands.

Done at WRP Asia Pacific Sdn Bhd, on April 24, 2020.

Mr. Leong Wai Leong
President
WRP Asia Pacific Sdn Bhd

Representative Office in EU
REMESCO Handelsges.m.b.H
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