Issued to:

Handi As
Magnus Barfots Vei 5
N-4633 Kristiansand S
Norway

Notified Body: 2777

SATRA customer number: P1144

EU Type-Examination Certificate

Certificate number: 2777/11513-04/E07-01

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. It has been issued Under Module B of Regulation 2016/425 on personal protective equipment. This product group has been shown to satisfy the applicable essential health and safety requirements as a Category III product.

Product reference:

Handi 2490 - 2495 series

Description:

≥3.5 mil Powder free Nitrile disposable five fingered glove
Available in a longer cuff variant
Available in Sterile and Non-Sterile

Sizes:

6 (XS)
7 (S)
8 (M)
9 (L)
10 (XL)
11 (XXL)

Classification:

EN ISO 374-1:2016+A1:2018 Type B	Level	EN ISO 374-4:2019 Degradation
n-Heptane (J)	3	33.9%
40% Sodium hydroxide (K)	6	-19.9%
30% Hydrogen peroxide (P)	2	34.5%
37% Formaldehyde (T)	6	-11.0%

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

Standards/Technical specifications applied:
EN ISO 21420:2020; EN ISO 374-1:2016+A1:2018; EN ISO 374-5:2016; EN 421: 2010 (excluding clause 4.3)

Technical reports/Approval documents:
SATRA: SPC0198733/1143, CHM0210704/1301/RS, SPC0222133/1407, CHM0262885/1740/EN, CHM0266319/1802/CL, CHM0260727/1731/EN/B/Issue 2, CHM0260046/1729/SPT, CHM0260046/1729/EN/B, CHM0260727/1731/EN/C/Issue 2, CHM026727/1731/EN/A/Issue 2, CHM0268714/1811/EN/B,CHM0260727/1731/EN/C/Issue 2, CHM0260046/1729/EN/A/Final, SPC0236372/1528/1, CHM0268714/1811/EN/A, SPC0322475/2146, CHM0349469 2319 1, CHM0349475 2319 1, CHM0340174/2244/SPT/2,CHM0340174/2244/LH, SPC0347855 2314 1, SPC0341147 2247 1

Signed on behalf of SATRA: Kayleigh Aylward

Kayleigh Aylward

Date of issue: 19/03/2024
Expiry date: 09/08/2028

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 or UKCA 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.

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Application for a Module B Type-Examination Certificate

In accordance with the Personal Protective Equipment Regulation (EU) 2016/425 and or Regulation 2016/425 on personal protective equipment, as amended to apply in GB. Hereafter referred to as the PPE Regulation.

This application and the subsequent certification will only address the obligations under the PPE Regulation.
It is the responsibility of the manufacturer to ensure that all other legislative requirements and claims, including those relating to shelf life are met.

Please note that all relevant sections of this application should be completed in full. Failure to complete all relevant sections shall result in the rejection of this application.

Please indicate which Notified Body and or Approved Body this application relates. Where the application is for both EU and UKCA type examination then please tick both.

SATRA Technology Europe Limited Notified Body 2777	**EU Type Examination**	☒
SATRA Technology Centre Limited Approved Body 0321	**UKCA Type Examination**	☐

Guidance on the completion of this form

Application type	Tick to indicate application type	Sections to be completed	Submission requirements
All applications		Section 1 Section 7	• Completed and signed application form
Initial type-examination certificate	☐	Section 2 Section 6	• Example of product (s) • Complete technical documentation as per Annex III of the PPE Regulation. See guidance below for required content • Completed module C2/D application, where applicable
Review of existing type-examination certificate	☐	Section 3	• Example of products (s) where significant changes have been identified. • Amendments to technical documentation
Transfer of existing type-examination certificate	☐	Section 4 Section 6	• Example of product (s) where not previously seen by SATRA. • Copy of the approved technical documentation as per Annex III of the PPE Regulation. See guidance below for required content • Copy of certificate to be transferred • Completed module C2/D application, where applicable
Own brand manufacturer/extension type-examination certificate	☒	Section 5 Section 6	• Copy of OBM proposed artwork for user information, product marking and packaging. • Completed module C2/D application, where applicable

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Guidance on the technical documentation required by Annex III of the PPE Regulation

The information below has been copied from Annex III of the PPE regulation and is intended to provide guidance on the content of technical documentation (often referred to as the technical file) that is required to be submitted as part of the type examination application. SATRA can provide upon request a template technical file to aid with the collation of the required documentation.

a) A complete description of the PPE and of its intended use;
b) An assessment of the risks against which the PPE is intended to protect;
c) A list of the essential health and safety requirements that are applicable to the PPE;
d) Design and manufacturing drawings and schemes of the PPE and of its components, sub-assemblies, and circuits;
e) Any explanations necessary for the understanding of the drawings and schemes referred to in point (d) and of the operation of the PPE;
f) The references of the harmonised standards referred to in Article 14 that have been applied for the design and manufacture of the PPE. In the event of partial application of harmonised standards, the documentation shall specify the parts which have been applied;
g) Where harmonised standards have not been applied or have been only partially applied, descriptions of the other technical specifications that have been applied in order to satisfy the applicable essential health and safety requirements; the results of the design calculations, inspections and examinations carried out to verify the conformity of the PPE with the applicable essential health and safety requirements;
h) Reports on the tests carried out to verify the conformity of the PPE with the applicable essential health and safety requirements and, where appropriate, to establish the relevant protection class;
i) A description of the means used by the manufacturer during the production of the PPE to ensure the conformity of the PPE produced with the design specifications;
j) A copy of the manufacturer's instructions and information set out in point 1.4 of Annex II;
k) For PPE produced as a single unit to fit an individual user, all the necessary instructions for manufacturing such PPE based on the approved basic model;
l) For PPE produced in series where each item is adapted to fit an individual user, a description of the measures to be taken by the manufacturer during the fitting and production process to ensure that each item of PPE complies with the approved type and with the applicable essential health and safety requirements.

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Section 1 – Applicant details

Section 1.1 Applicant
Details of the applicant to whom the certificates are to be issued, or in the case of an extension application the holder of the main type-examination certificate.

Where additional correspondence has been requested then this shall be on a shared basis.

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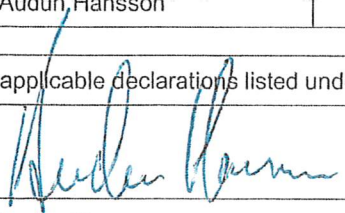
Section 1.3 – Invoice details (to be completed if different to the applicant in section 1.1)
Details of the company that is responsible for paying all fees and to whom the invoice shall be issued. Correspondence shall only be with the applicant listed in section 1.1 plus any additional contacts provided in section 1.2.

Company Name	Handi AS		
Relationship to applicant	Customer		
Address Line 1	Magnusbarfotsvei 5		
Address Line 2			
City	Kristiansand	**Country**	Norway
County/State/Province		**Post Code / ZIP**	4633
Telephone	+47 38003070	**Email**	audun@handi.no
Contact Name	Audun Hansson	**Position**	CEO

I have read and agree to the applicable declarations listed under section 7 of this form.			
Signature		**Date**	07.12.2023
Print Name	Audun Hansson	**Position**	CEO

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Section 2 – Application for initial type-examination certificate

Details of the product(s) to be certified

Product Reference [1]	Product Description	Product Standard (s) [2]

Notes

1) The reference, code, or name by which products can be uniquely identified.
2) The product standard to which certification is sought. If a harmonised or designated standard does not exist or is not been fully used then reference shall be made to the section of the technical file where this has been documented and justified.

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Section 3 - Application for review of existing type examination

Details of and reason(s) of the certificate to be reviewed

Certificate Number(s) (1)	Reason for review (2)
	Choose an item.
	Details of the change(s)
	Choose an item.
	Details of the change(s)
	Choose an item.
	Details of the change(s)
	Choose an item.
	Details of the change(s)
	Choose an item.
	Details of the change(s)
	Choose an item.
	Details of the change(s)
	Choose an item.
	Details of the change(s)
	Choose an item.
	Details of the change(s)

Please submit all amendments to technical documentation relating to the above certificate(s) as well as additional test reports and photographs where applicable with this application.
Please list all changes that you wish to be considered as part of this application. Only these changes shall be considered.

Where the application relates to expiry of a certificate and there have been no modifications or changes to the approved technical documents or products since the issue of the type examination certificate(s), (e.g., design, materials, suppliers, sub-components/assemblies, production locations) then please write "no changes"

Where there is an Own Brand Manufacturer (OBM) (extension) certificate associated with any of the above listed certificates then consideration shall be given to their ongoing validity and where appropriate an extension application completed and submitted.

Notes
(1) Please include the numbers of all certificates that require review.
(2) Please select the option that relates to the reason for the review being required.

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Section 4 – Application for transfer of existing type-examination

Details of the certificate(s) to be transferred, including where not SATRA details of the issuing body.

Certificate Number	Product Reference [1]	Name of Notified or Approved body that issued certificate (if not SATRA)

Have there been any modifications or changes to the approved technical documents or products since the issue of the type examination certificate(s)? (e.g., design, materials, suppliers, sub-components/assemblies, production locations)	Yes	☐	No	☐
If yes, then please provide further details of the changes and or modifications				

Notes

1) The reference, code, or name by which products can be uniquely identified.

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Section 5 – Application for Own Brand/Extension of existing type-examination

Section 5.1 Extension certificate details (Company to receive the extension certificate)

Company Name	Handi AS		
Address Line 1	Magnusbarfotsvei 5		
Address Line 2			
City	Kristiansand	Country	Norway
County/State/Province		Postal Code / ZIP	4633
Telephone	+47 38003070	Email	audun@handi.no
Contact Name	Audun Hansson	Position	CEO

Section 5.2 – Certificate details

Original certificate number(s)	Original certificate product reference(s)	Extension (OBM) product reference(s)
2777/11513-04/E00-00	Nitril Powder Free Examination Gloves	Handi 2490 series

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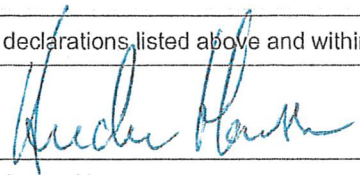
Section 5.3 Extension application declaration.

To be signed by the company to whom the extension type-examination certificate will be issued.

I, the undersigned:

1) Confirm that the extension certificate(s) will only be used to support the affixation of the CE or UKCA mark to products that have been supplied by the holder of the Module B Type Examination Certificate(s) referenced in Section 1 above and declared by them to have been manufactured in accordance with the technical documentation associated with the referenced Module B type-examination certificate(s) in section 5.2.
2) Confirm that for Category III products, a formal application regarding Module C2 or Module D assessment, as appropriate has been established with a Notified or Approved Body. (Note this could be based on an existing application between the company in Section 1 and a Notified or Approved Body)
3) Agree to provide copies of the proposed product marking and user information as intended for the products covered by the extension certificate(s).

I have read and agree to the declarations listed above and within section 7 of this form.			
Signature		**Date**	07.12.2023
Print Name	Audun Hansson	**Position**	CEO

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Section 6 – Ongoing conformity

To be completed for category III products only (as defined in Annex I of the PPE Regulation)
Please tick and complete one of the 4 following options

Option 1	Module C2 with SATRA	☐
Option 2	Module D with SATRA (Module D not currently in place with SATRA)	☐
Option 3	Module D with SATRA (Module D currently in place with SATRA)	☒
Option 4	Module C2 or D with another Notified or Approved body (i.e., Not SATRA) Please include Notified or Approved body number	☐

Where a Notified or Approved Body other than SATRA is selected for ongoing conformity then it should be noted that SATRA CANNOT approve the use of the Notified or Approved Body number on marking, user information or packaging. The applicant is required to seek approval directly from the body listed above. SATRA reserves the right to ask for evidence of approval.

Where options 1 or 2 are selected a separate application shall be provided, this shall be required to be completed and returned prior to the type examination certificate being issued.

Definition of products that fall within Category III as per Annex I of the PPE Regulation

a) substances and mixtures which are hazardous to health;
b) atmospheres with oxygen deficiency;
c) harmful biological agents;
d) ionising radiation;
e) high-temperature environments the effects of which are comparable to those of an air temperature of at least 100 °C;
f) low-temperature environments the effects of which are comparable to those of an air temperature of –50 °C or less;
g) falling from a height;
h) electric shock and live working;
i) drowning;
j) cuts by hand-held chainsaws;
k) high-pressure jets;
l) bullet wounds or knife stabs;
m) harmful noise.

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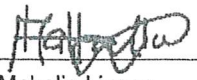
Section 7 – Declaration

1) I declare that an application for an initial Module B type-examination certification for the product(s) listed in this form has NOT been made to any other Notified or Approved Body under the terms of the PPE Regulation;
2) I understand that all technical documentation shall be reviewed at the same time. SATRA cannot accept requests to review or comment on individual documents outside of this formal review.
3) I agree to provide an example of the product(s) listed in this form as part of the initial application plus as many samples as required for testing purposes identified as part of the certification process and where SATRA is the test lab;
4) I confirm that samples comply with the innocuousness requirements of Annex II of the PPE Regulation;
5) I confirm that I have read, understood, and agree to abide by the content of the certification agreement included as Appendix 1 of this document;
6) I declare that SATRA have not been involved in the design process for the product(s) listed in this form;
7) I agree to comply with all obligations of a manufacturer as detailed in Article 8 of the PPE Regulation (and as copied out under section 5 of the certification agreement);
8) I agree that technical information and documents relating to this application may be shared internally within the SATRA group of companies;
9) I agree to address all findings identified within SATRA's review report(s) within 3 months of the date of issue of the report;
10) I agree that failure to address all findings within the required timeframe shall be assumed by SATRA as a wish to cancel this application which shall result in closure of the associated SATRA reference number, at which point, an invoice shall be issued for the full certification cost. Any associated payments received in relation to this application are non-refundable and non-transferable. Please note that upon cancellation, any product samples submitted to SATRA in relation to this application shall be disposed;
11) I agree that any request to resume a cancelled application shall require the submission of a new application.

To be completed by the applicant as listed in section 1.1.

Signature		**Date**	15.01.2024
Print Name	Mahalia Liyana	**Position**	Assistant Manager - RA

Please return the completed application form, together with a copy of your technical documentation to ppe@satra.com.

Guidance relating to the submission of samples will be provided upon receipt of this application by SATRA.

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Appendix 1 – Certification agreement

1. **General**

1.1 By signing this application form, the applicant (hereafter known as the 'Client') shall accept the application and Certification Agreement as a legally binding contract between SATRA Technology Centre Limited and or SATRA Technology Europe Ltd (hereafter referred as 'SATRA') and the 'Name of company' as stated in the 'Applicant Details' on Page 1 of the Application Form.

1.2 Where referenced within this document the SATRA Group of companies refers to SATRA Technology Centre Limited, SATRA Technology Europe Limited and SATRA Technology Services (Dongguan) Limited.

1.3 EU or UKCA module B Type Examination work will not be carried out for any Client until a fully completed and signed Application Form (and Certification Agreement) has been received by SATRA.

a) and or reinstatement of a certificate
b) Reassessment due to changes in the management system or products certified
c) Compliance with any subpoena for documents or testimony relating to activities undertaken by SATRA

2. **Client Responsibilities**

The Client shall:

2.1 Undertake to pay all agreed fees and costs charged in conjunction with this application and where applicable to provide free of charge any samples required for testing purposes.

Additional fees may be incurred for work not included within the quote provided and for work required where non-conformances are identified. These may include, without limitation, costs arising from:

a) Repeats of any part of the certification, due to the registration procedures and rules not being met
b) Additional work due to suspension, withdrawal and or reinstatement of a certificate
c) Reassessment due to changes in the management system or products certified
d) Compliance with any subpoena for documents or testimony relating to activities undertaken by SATRA

2.2 Inform SATRA, without delay, of any changes that may affect its ability to conform with the certification requirements, including changes significantly affecting the product's design or specification, or changes in the standards to which compliance of the product is relevant, or in the case of any other information indicating that the product may no longer comply with the requirements of the certification scheme.

Examples of changes may include the following:

a) the legal, commercial, organisational status or ownership,
b) organisation and management (e.g., key managerial or technical staff),
c) modifications to the product or the production method,
d) contact address and manufacturing sites,
e) major changes to the quality management system.

Where changes have taken place, the Client shall not release CE or UKCA marked products until the appropriate changes to the certified product, as agreed by SATRA and the Client, have been implemented.

2.3 Where applicable, provide access to certified products for surveillance activities.

2.4 Ensure that the certified product shall continue to fulfill the requirements of the product certification (e.g., levels or classifications achieved as part of the certification process).

2.5 Make all necessary arrangements for:

a) the conduct of the evaluation and surveillance (if required), including provision for examining documentation and records, and access to the relevant equipment, location(s), area(s), personnel, and the Client's subcontractors;
b) the investigation of complaints;
c) the participation of observers, if applicable.

2.6 Provide any applicable information regarding known or potential hazards likely to be encountered by SATRA personnel as a result of handling or coming in to contact with submitted samples or during visits in order to allow SATRA to comply with Health and Safety legislation

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2.7 Take all steps necessary to ensure that the manufacturing process, including the final inspection of PPE and tests, ensures the homogeneity of production and the conformity of PPE with the type described in the Module B Type Examination Certificate and with the relevant basic requirements of the PPE Regulation.

2.8 Ensure that any claims regarding certified products are consistent with the scope of product certification with respect to the identification of:

a) the product(s), process (es) or services(s) for which the certification is granted;
b) the applicable certification scheme; and,
c) the standard(s) and other normative document(s) (including date of publication) to which the product(s); process(es) or service(s) has been judged to comply.

2.9 Not use its product certification in such a manner as to bring SATRA into disrepute and does not make any statement regarding its product certification that SATRA may consider misleading or unauthorised.

2.10 Upon suspension, withdrawal, or termination of certification, the Client discontinues its use of all advertising matter that contains any reference thereto and acts as required by the certification scheme (e.g., the return of certification documents) and takes any other required measure.

2.11 Only provide copies of the certification documents to others, if the documents are reproduced in their entirety.

2.12 In referring to its product certification in communication media such as documents, brochures or advertising, the Client complies with the requirements of SATRA or as specified by the certification scheme.

2.13 Comply with any requirements that may be prescribed in the certification scheme relating to the use of marks of conformity, and on information related to the product. These being:

2.13.1 The CE or UKCA Mark can only be applied to stationery and publicity material which relates to the products for which certification has been granted. This can include the internet, brochures, advertisements etc. We would advise any Client to contact us prior to printing if there is any doubt regarding the intended use. The misuse of the CE, UKCA or other marks could result in the issue of a requirement to withdraw offending items.

2.13.2 Where possible the minimum height of the CE or UKCA mark must be no less than 5mm and shall only be increased in proportion.

2.13.3 The CE, UKCA or other mark may not be used in any way that may be interpreted as misleading nor shall the client make any misleading statements regarding its certification

2.13.4 The use of SATRA's Notified Body or Approved body number after the CE or UKCA mark is restricted to those products defined as Category III Products and where SATRA is responsible for Module C2 or Module D. However, it may be used on user information of all certified products as a means of identifying SATRA as the type approval body and the Module C2 or D body.

2.13.5 Upon suspension or withdrawal of its certification, The Client shall discontinue its use of the CE or UKCA mark as directed by SATRA and shall amend all advertising matter when the scope of registration has been reduced. The Client shall ensure that the CE, UKCA or other marks are not used in such a manner that would bring SATRA into disrepute and lose public trust.

2.14 Uses certification only to indicate that products are certified as being in conformity with the PPE Regulation and where applicable specified standards.

2.15 Shall confirm that the samples submitted for any testing required as part of the certification process shall be representative of the product to be certified in respect of all its characteristics taken together, and be made from production tools and assembling methods used for the production run.

2.16 Retains a record of all non-conformities and complaints relating to certification requirements of the certified product(s) and makes these records available to SATRA when requested, and:

a) takes appropriate action with respect to such complaints about any deficiencies found in products that affect compliance with the requirements for certification;
b) documents the action taken.

2.17 Retain the EU or UKCA Certificate of Conformity (or a copy of it) for a minimum of 10 years after the product to which it relates is last placed on the market

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3. SATRA Responsibilities

3.1 SATRA shall inform the Client of any changes that may affect the validity of the product certification.

3.2 After confirming the acceptance of the application, the SATRA Assessor shall discuss and agree with the Client the responsibility for carrying out the various tasks according to the requirements of Annex II of the PPE Regulation as applicable. Where testing is required, this shall be carried out in accordance with SATRA Technology Centre Limited's ISO 17025 Quality system and procedures. SATRA reserves the right to sub-contract testing, where this is required then this shall be agreed with the Client.

3.3 SATRA shall carry out the certification process against an agreed product standard (s) or specification (s) where possible. The normal route shall be to use an English language version of the appropriate European Harmonised, or UK designated standard. National forewords to such standards will not normally be considered unless specifically requested by the Client. Other standards or technical specifications may be used, where this is deemed necessary then it shall be by mutual agreement with the Client. Whichever option is chosen it shall satisfy all the relevant requirements of the PPE Regulation. This shall also include appropriate test data to demonstrate that the materials used to construct the products do not contain substances that may cause harm and that they are in compliance with the current requirements of all applicable product standards as well as the current version of Annex XVII of the EU and or UK REACH Regulation.

3.4 SATRA shall retain copies of technical files for a minimum of 10 years after the product is last placed on the market and/or the EU or UKCA Module B Type Examination certificate is cancelled, withdrawn or expires, whichever comes sooner. Such documentation shall be made available to the Surveillance Authorities upon demand.

3.5 Where review of an existing certificate is requested, the Assessor shall send the Client an appropriate application form for completion and return. On return of the completed application form, the Assessor shall decide on whether reduced Certification Procedures may be undertaken and shall document the decision.

3.6 Where an extension to an existing certificate is requested, the Assessor shall send the Client an appropriate application form for completion and return.

3.7 Where SATRA becomes aware that a registered Client has misused a certificate, schedule, logo or accreditation mark, the Client shall be required to ensure that the misuse is rectified. Incorrect references to the certification system or misleading use of information found in advertisements, catalogues etc. shall be dealt by suitable means including corrective action, publication of the transgression and, if necessary, legal action.

3.8 Suspension, termination, and withdrawal of certificates

3.8.1 Where a certificate is suspended, terminated, or withdrawn then the Client has the right to appeal. The appeal shall be received in writing, by SATRA, within twenty-eight working days of the Client having being informed of the intention to suspend, withdraw, or terminate the certificate.

3.8.2 The outcome of an appeal shall be final and binding on both parties and no counter claim by either party shall be accepted. Where an appeal is successful, the Clients costs may be reimbursed at the discretion of SATRA.

3.8.3 Suspension of certificates.

3.8.3.1 A Clients EU or UKCA Module B Type Examination Certificate may be suspended for the following reasons:

- Contravention of SATRA's rules and regulations relating to product certification;
- Where effective corrective action is not implemented within an agreed timescale against a major non-compliance found during a surveillance visit.
- Where significant non-homogeneity is highlighted during on-going surveillance.

3.8.3.2 SATRA shall inform the Client in writing that their certificate has been suspended, the reason(s) for the suspension and the actions required to reinstate the certificate.

3.8.3.3 SATRA shall inform the appropriate notifying authority when a Client's certificate has been suspended.

3.8.3.4 If product certification is reinstated after suspension, SATRA shall make all necessary modifications to formal product certification documents, public information, authorisations for use of marks, etc., in order to ensure all appropriate indications, exist that the product continues to be certified.

3.8.3.5 If a decision to reduce the scope of product certification is made as a condition of reinstatement, SATRA shall make all necessary modifications to formal product certification documents, public information, authorisations for use of marks, etc., in order to ensure the reduced scope of product certification is clearly communicated to the Client and clearly specified in product certification documentation and public information.

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3.8.4 Withdrawal or termination of certificates

3.8.4.1 A certificate shall be withdrawn 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 Directive or Regulation as applicable;
- The Client fails to settle their financial obligations to SATRA;
- The Client fails to effectively implement the actions agreed following the suspension of a certificate;
- Actions taken by the Client during their business activities that would bring SATRA and / or the Product Certification Scheme into disrepute;
- The Client does not wish to continue with certification;
- The Client goes out of business.

3.8.4.2 SATRA shall inform the Client in writing that their certificate has been withdrawn, the reason(s) for the withdrawal and any actions required.

3.8.4.3 SATRA shall inform the appropriate notifying authority when a Client's certificate has been withdrawn.

3.9 Confidentiality

3.9.1 The results of Product Certification activities shall be treated by SATRA as confidential. Results obtained shall only be passed to third parties with the permission of the Client that originally commissioned it, except for requests from enforcement and surveillance authorities.

Note: SATRA reserves the right to share information relating to certification within the SATRA Group of companies unless advised otherwise.

3.10 Complaints and Appeals

3.10.1 Upon receipt of a complaint or an appeal which relates to product certification activities, the Business area head or their nominated deputy shall deal with it in accordance with SATRA's complaints and appeals procedure.

3.10.2 Where the complaint or appeal relates to the on-going conformity of a product certified by SATRA, it is possible that any agreed remedial actions may involve recalling non-compliant products in which case SATRA shall require documented evidence of such a recall.

3.10.3 Complainants raising issues regarding a) products not being CE or UKCA -marked when they should be or b) EU or UKCA Type Examination certificates issued by other Notified or Approved Bodies shall be directed to the appropriate enforcement authority.

3.10.4 SATRA shall only accept written appeals received within twenty-eight days of the client being informed of the decision that gave rise to the appeal.

3.10.5 Full details of the SATRA Complaints and Appeals procedure are available on request.

3.11 SATRA shall retain in its archive for the period required by the relevant accreditation body all materials relating to the certificate. After which SATRA shall dispose of said materials unless instructed otherwise by the Client. All fees for carrying out such instructions will be invoiced to the Client.

4.0 SATRA Requirements

4.1 Any test reports submitted to SATRA in support of EU or UKCA type examination shall meet the following criteria:

a) Reports shall reflect state of the art and be as current as possible, where reports are older than 5 years (60 months) then SATRA reserves the right to request additional supporting documentation, such as more recent check test data;

b) Where not undertaken by SATRA, all testing and reporting shall be carried out by a laboratory that is independent and impartial to any economic operator of the finished product and considered as being competent to conduct the work. Accreditation of a laboratory to ISO 17025 by a National Accreditation Body that is recognised by INAB or UKAS (see ILAC website) for the work undertaken will be taken as evidence of competence as long as it can also demonstrate that it has knowledge of, and access to, any appropriate recommendation for use sheets and guidance papers endorsed by the European Commission or UK Government. In the absence of such accreditation, a report will be accepted only when competence has been demonstrated to the satisfaction of SATRA, via an audit visit and, where judged necessary, check testing.

Note, in either case if the laboratory is not a Notified or Approved Body, SATRA may commission limited check testing on safety critical properties;

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c) Innocuousness test data which has been requested in addition to that required by the main European Harmonised or UK Designated Standard or performance specification. These additional innocuousness tests (i.e., not detailed in the product standard) need not be carried out by SATRA or an ISO 17025 accredited facility but it will be necessary to submit actual test data (declarations of conformity are not acceptable).

d) Reports shall contain where possible the following information:

(i) sample references given in any test report shall be the same as those detailed in the technical file,
(ii) reference to the manufacturer and manufacturing site(s),
(iii) identification of the organisation and personnel responsible for the test,
(iv) identification of the product(s) in accordance with the relevant technical specification,
(v) date(s) samples were received and the date(s) testing was undertaken,
(vi) details of samples received and the sampling procedure if applicable,
(vii) testing methods and procedures used according the relevant technical specification,
(viii) the results of all testing carried out, including analysis of these where relevant,
(ix) registration number of the Notified Body (when relevant),
(x) signature of the person authorised to sign such test reports;

e) The Test Report shall indicate compliance of the product(s) with the relevant clauses of the harmonised standard (s).

4.2 Copies of all test Reports used as part of the certification process shall be submitted to SATRA. Copies of Test Reports that form part of any on-going monitoring procedure should be retained by the manufacturer and made available on request.

4.3 All test reports submitted as part of the certification process shall, where applicable, include information relating to the use of uncertainty of measurement. When evaluating the suitability of results and reports SATRA will, where applicable to safety critical aspects of the product, take uncertainty of measurement into account. SATRA reserves the right to reject reports where the uncertainty of measurement cannot be determined for those tests/properties deemed by SATRA to be safety critical.

4.4 Where a technical file is required as part of the certification process then it shall include at least the following:

a) name & address of the manufacturer;
b) name and address of the Authorised representative in the EU (if relevant);
c) full description(s) of the product(s) included within the technical file, including specifications, annotated drawings and comprehensive photographs of all styles;
d) full details of all materials and components used in the construction of the product (s) including specifications, and supplier details (name and postal address);
e) quality control procedures, and where appropriate, a copy of the ISO9001 certificate for the manufacturing site(s), this should include a description of the control and test facilities at the manufacturing site(s) that are in place in order to check compliance of production with the harmonized standards / technical specifications to ensure ongoing compliance;
f) details of proposed packaging and product marking, including label artwork;
g) copy (ies) of all applicable user information sheets, these shall comply with the requirements of the agreed product standard;
h) check list showing compliance with the applicable health and safety requirements, Annex II of the PPE Regulation;
i) all applicable test reports, references to materials on submitted test reports must correspond with those in the material specifications.

4.5 SATRA reserves the right to request additional supporting documentation including further testing, where the certification process becomes protracted.

5.0 Article 8 of the PPE Regulation – Obligations of manufacturers

5.1 When placing PPE on the market, manufacturers shall ensure that it has been designed and manufactured in accordance with the applicable essential health and safety requirements set out in Annex II.

5.2 Manufacturers shall draw up the technical documentation referred to in Annex III ('technical documentation') and carry out the applicable conformity assessment procedure referred to in Article 19 or have it carried out.

Where compliance of PPE with the applicable essential health and safety requirements has been demonstrated by the appropriate procedure, manufacturers shall draw up the EU or UKCA declaration of conformity referred to in Article 15 and affix the CE or UKCA marking referred to in Article 16.

5.3 Manufacturers shall keep the technical documentation and the EU declaration of conformity for 10 years after the PPE has been placed on the market.

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5.4 Manufacturers shall ensure that procedures are in place for series production to remain in conformity with this Regulation. Changes in the design or characteristics of the PPE and changes in the harmonised or Designated standards or in other technical specifications by reference to which the conformity of the PPE is declared shall be adequately considered.

When deemed appropriate regarding the risks presented by PPE, manufacturers shall, to protect the health and safety of consumers and other end-users, carry out sample testing of PPE made available on the market, investigate, and, if necessary, keep a register of complaints, of non-conforming PPE and PPE recalls, and shall keep distributors informed of any such monitoring.

5.5 Manufacturers shall ensure that the PPE which they place on the market bears a type, batch or serial number or other element allowing its identification, or, where the size or nature of the PPE does not allow it, that the required information is provided on the packaging or in a document accompanying the PPE.

5.6 Manufacturers shall indicate, on the PPE, their name, registered trade name or registered trade mark and the postal address at which they can be contacted or, where that is not possible, on its packaging or in a document accompanying the PPE. The address shall indicate a single point at which the manufacturer can be contacted. The contact details shall be in a language easily understood by end-users and market surveillance authorities.

5.7 Manufacturers shall ensure that the PPE is accompanied by the instructions and information set out in point 1.4 of Annex II in a language which can be easily understood by consumers and other end-users, as determined by the Member State concerned. Such instructions and information, as well as any labelling, shall be clear, understandable, intelligible, and legible.

5.8 The manufacturer shall either provide the EU or UKCA declaration of conformity with the PPE or include in the instructions and information set out in point 1.4 of Annex II the internet address at which the EU declaration of conformity can be accessed.

5.9 Manufacturers who consider or have reason to believe that PPE which they have placed on the market is not in conformity with this Regulation shall immediately take the corrective measures necessary to bring that PPE into conformity, to withdraw it or to recall it, as appropriate. Furthermore, where the PPE presents a risk, manufacturers shall immediately inform the competent national authorities of the Member States in which they made the PPE available on the market to that effect, giving details of the non-conformity and of any corrective measures taken.

5.10 Manufacturers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation, in paper or electronic form, necessary to demonstrate the conformity of the PPE with this Regulation, in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by PPE which they have placed on the market.

For more information, please contact:
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website: www.satra.com

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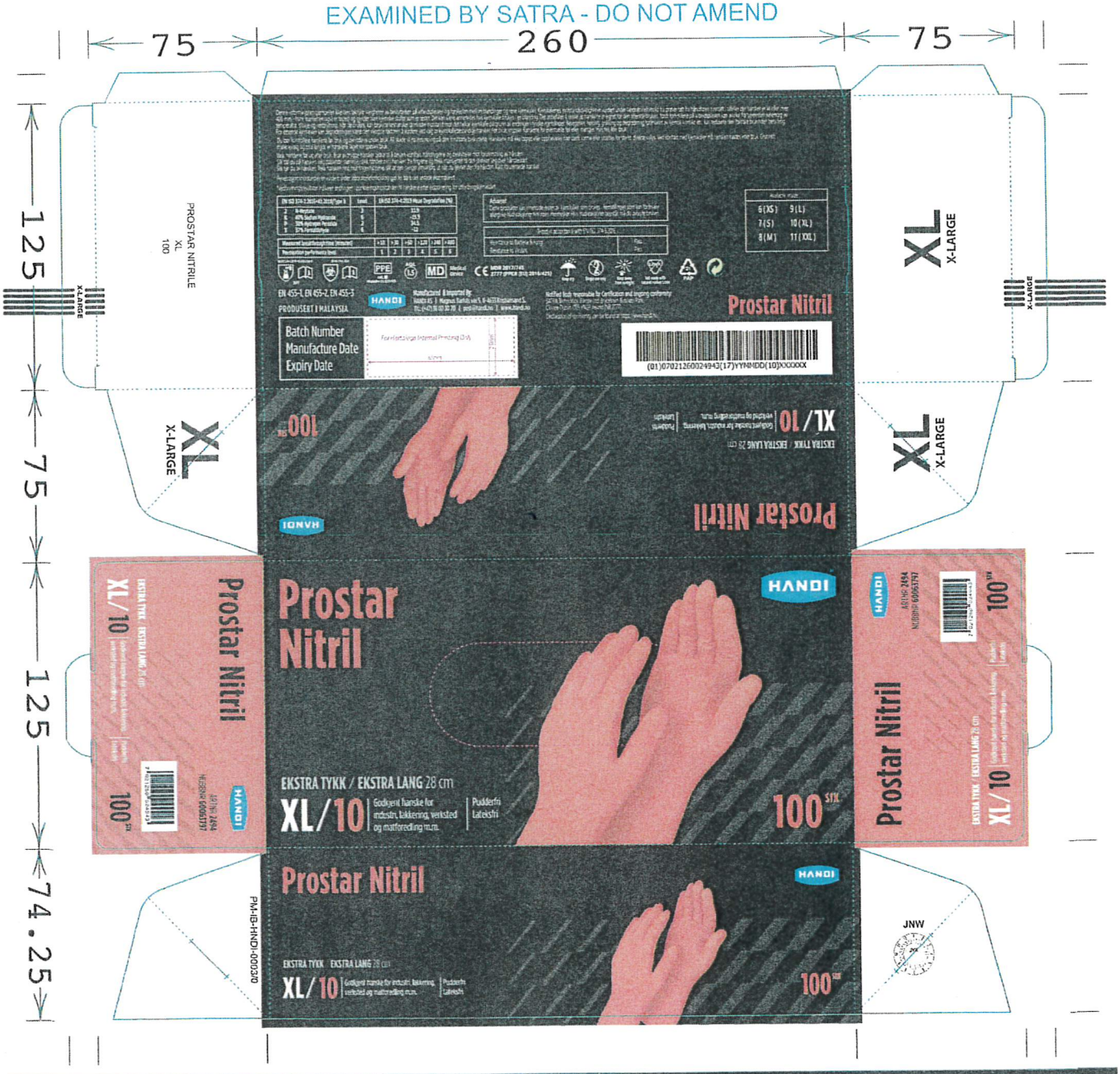

Artwork Details		Approval
Customer	:	*This Artwork has been read and approval by the client for all requirement and may pass onto the next stage of production. No changes are required.*
Brand	:	
PM Code	:	**Checked / Approval by :** _____
Dimension	: 260(L) X 125(W) X 75(H) mm	
Window	: 115 (W) X 45 (H) mm	**Date :** _____
Finishing	: Waterbased Varnished	***DIGITAL PROOFS*** *are for guide and are not intended as actual printing proofs.*
Board Quality	: 450gsm Greyback	
Barcode Format	: EAN-13 & GS1-128	

Colors	Remark / Revised Artwork
Cyan Magenta Yellow Black	Rev 3 :

Revision 3 : 10-01-2024

By Printer : JNW(H)

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Disposable gloves:

This information does not reflect the actual duration of workplace protection and the difference between mixtures and pure chemicals. Chemical resistance is assessed under laboratory conditions from samples taken from the palm of the hand (except in cases where the glove is equal to or over 400 mm - where the cuff is also tested) and applies only to chemicals that have been tested. It may be different if the chemical is used in a mixture. It is recommended to check that the gloves are suitable for the intended use because workplace conditions may vary from the type test depending on temperature, wear, and degradation. When used, protective gloves may provide less resistance to the hazardous chemical due to changes in physical properties. Movements, snagging, rubbing, and degradation caused by chemical contact, etc., can significantly reduce the actual period of use. For corrosive chemicals, degradation may be the most important factor to consider when choosing chemical-resistant gloves. Before use, inspect the gloves for any defects or deficiencies. If in doubt, do not use.

You should check the gloves before use and periodically during use. Any damage will impact the assumed protection. Gloves must not be stored or kept near strong heat or exposed to strong, direct sunlight. When in contact with chemicals, the glove must be discarded after use. Due to material choice and total length, the gloves are made for specific use.

Wash hands before and after use. Using proper gloves helps maintain comfort, hand hygiene, and protection against hand contamination.

To put on the glove: choose the appropriate size, insert the hand into the glove from the fingers, and pull the cuff until it stretches over the wrist.
To take off the glove: pull the glove down towards the fingertips, allowing it to turn inside out as you remove it from the hand. Dispose of contaminated gloves.

Penetration resistance is assessed under laboratory conditions and applies only to the tested specimen.

Degradation results indicate the change in puncture resistance of the gloves after exposure to the challenging chemical.

WARNING:

This product may contain residues of chemicals used in the manufacturing that can cause allergic skin reactions in some people. If skin reactions occur, discontinue use.

Manufactured in Malaysia.

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