



Product Certification
Standard Malaysian Glove (SMG)
Specific Application



MALAYSIAN RUBBER BOARD

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1 Certification Program/Scheme

The terms Program/Scheme are used interchangeably in the Product Certification system, and relates to a scope of activity as part of the certification system practised by the Malaysian Rubber Board (MRB).

The details of the formal scheme/program protocol practised by the MRB for the certification of Standard Malaysian Glove (SMG) is spelt out in the document “Technical Requirements For Type I Standard Malaysian Gloves (SMG), SMG Scheme, Booklet No.1, 2013” and “Technical Requirements For Type II Standard Malaysian Gloves (SMG), SMG Scheme, Booklet No.1, 2013”, in which the quality system requirement and the standards the product needs to meet are included. A copy of this document will be made available to all applicants. The surveillance after successful certification is spelt out in the current document.

The additional rules and regulations governing the SMG certification program is given in Appendix 3, and should be read together with this application.

1.1 Scope

The certification of SMG is restricted to rubber glove manufacturers located within the country and shall establish quality management system to ensure continuous compliance with the standard or specification.

1.2 Application Procedure

A rubber glove manufacturer who wishes to have its product certified as SMG by the MRB has to apply to the Product Certification Secretariat using the application form (Appendix 1).

1.3 Evaluation process (Appendix 4)

1.3.1 On receipt of the application, the Product Certification Secretariat will provide a written acknowledgement to the applicant, if all fees have been received and all information required is in order. A new file would be opened for the applicant.

1.3.2 All application shall be processed within 3 – 4 months starting from receiving the application form until being certified without any failure during the certification inspection.

1.3.3 The applicant will be duly advised by the Product Certification Manager or Deputy on a mutually agreeable date for collection of samples and the verification of any other requirements at the applicant's premises. If subcontracting of testing or sampling is required, the Product Certification Manager or Deputy shall ensure it is carried out following the requirements

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stated under clause **5.3 – “Subcontracting”** of the main quality manual, and the applicant be informed of such.

- 1.3.4 One lot, for the purpose of sampling (refer SMG booklet), consists of two million gloves. Based on the monthly production capacity, ten percent (10%) of a factory’s production lots would be sampled on a random basis.
- 1.3.5 To ensure representative sampling, samples would be taken based on the proportion of the types of gloves (powdered and/or powder free) and the different sizes (small, medium, etc.) produced by the factory. This principle also applies when a company (applying for one certificate) has more than one production facility or factory. Samples taken for certification testing (and surveillance testing after successful certification) shall be taken from gloves that have been identified by the manufacturer as having “Passed internal QC”. Such samples may be taken from dispensers (1st priority), production bins or plastic bags.
- 1.3.6 If watertightness testing is to be carried out at the applicant’s premises, there should be documentary evidence that operators carrying out the test, to be witnessed by MRB Product Certification personnel, are trained and competent to carry out the test, and the equipment used for the test have been regularly calibrated. The MRB Product Certification personnel shall verify such.
- 1.3.7 If the initial samples fail to meet the technical specification, corrective action should be taken by the manufacturer immediately, with a maximum period of three (3) months from the date of official notification of the failure. Non-compliance with this requirement makes the manufacturer liable to reapply for certification as a new applicant, with all conditions applying, including the application and testing fees. Re-sampling and evaluation shall be carried out for a maximum of three times after corrective action has been taken. Any applicant whose product does not meet the technical specification after three re-samplings shall be required to submit a new application, if still interested.
- 1.3.8 Completed results of the evaluation will be compiled by the Product Certification Secretariat. The Product Certification Manager or Deputy shall vet the results and present such to the Product Certification Panel for a decision. This decision shall be transmitted to the application in writing.
- 1.3.9 The approved applicant shall be registered and added to the certified supplier list (which may be made public) in the Product Certification - Certification Register File. Each certification shall be address-specific. The Product Certification Committee (PCC) shall have access to this file at any time. Successful applicants shall be issued with a certificate attesting to their certification status (after signing the agreement on certification). The applicant shall also be permitted to use the MRB mark of conformity and the SMG logo on their dispenser boxes and cartons.

7. Contract Suppliers

Do you have any contract suppliers	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
If yes, do they all have a recognised quality system of at least ISO 9001?	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
If yes, are they all certified to the MRB Product Certification Program?	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>

8. We hereby agree to:

- a. to make a payment for the certification upon receiving invoice from MRB
- b. ensure the product manufactured and the manufacturing process comply with the relevant standard(s) and other product certification requirements.
- c. allow authorized MRB Product Certification personnel free access (together with factory representative factory, store and godown and to our office (records of production or other relevant documents).
- d. allow authorized MRB Product Certification personnel to access and carry out random sampling in our premises.
- d. temporarily suspend the export/local sale of any MRB certified product if instructed to do so by an MRB Product Certification Personnel.
- e. the opening at ports or elsewhere, marked as MRB Certified Product for inspection or otherwise.
- f. allow MRB Product Certification Personnel to inspect our productions at any time, either announced or unannounced.
- g. keep the MRB informed of any changes in the particulars given above and/or in the details of production, including processing changes and/or quality system.
- h. ensure that MRB certified product shipments are only made when we have a valid MRB Certificate of Conformity.
- i. abide by the rules and regulations contained in the document,Product Certification: MRB-PCB-01 General Rules Governing Product Certification, including those pertaining to the use of mark and certificate of conformity and the logo.
- j. sign the MRB Product Certification Agreement before grant of certification licence.

I/We* understand the term and conditions on certification requirements

9. I/We* declare that to the best of my/our* knowledge and belief all the information given is true and correct and tha I/we* understand that if any of the information given if found not to be true and correct this application will be refused and any certification awarded shall be declared null and void.

10. Date of application.....

11. Name and title of person authorized to sign on behalf of the applicant

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.....

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.....

.....

Signature:.....

* Delete whichever is not applicable

FOR OFFICE USE ONLY

Received Date :

Received Payment Date :

- 1. Client information is sufficient
- 2. Product information is sufficient
- 3. No Difference in Understanding Between the MRB and the Client
- 4. The scope of certification sought is defined
- 5. The means are available to perform all evaluation activities
- 6. MRB has the competence and capability to perform the certification activity.

Yes	No
<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>

Review by :
.....

Approve by :
.....

Inspection Date :

Team Leader :

PC Inspector :

**PRODUCT CERTIFICATION
Standard Malaysian Gloves (SMG)**

FEES PAYABLE

- One time application fee
 - RM 2,000.00

- Renewal fee for each certificate per year (payable yearly one year after the issuance of Product Certification: SMG certificate)
 - RM 500.00

- Cost of Testing (with effect from 13/3/2017)
 - RM 986.85/ lot : without Water Tightness Test
 - RM 1,986.85/ lot : with Water Tightness Test

**PRODUCT CERTIFICATION
Standard Malaysian Gloves (SMG)**

RULES AND REGULATIONS

1 General

The MRB Product Certification program/scheme for SMG is currently restricted to glove manufacturers located within the country and the type of certification program/scheme use is ISO certification system no. 5. The system no. 5 involves type testing and assessment of factory quality management system and its acceptance followed by surveillance that takes into account the assessment of factory quality management and testing of samples.

In addition to complying with the General rules governing the MRB Product Certification system (see Product Certification: MRB – PCB – 01: Rules Governing Rubber Product Certification), suppliers applying for certification as SMG manufacturers are also required to conform to the following:

- 1.1 Provide all necessary information required by the MRB for the purpose of evaluation of the product(s) to be certified. Applicants may be required to provide documentary proof that their productions are technically capable in meeting the SMG specification, including that all production lines at a single plant are capable of meeting all the technical requirements of the SMG program.
- 1.2 Provide documentary evidence that the certification of quality management system obtained were from accredited certification body.
- 1.3 Pay all relevant application fees to the MRB.
- 1.4 Allow the MRB evaluation personnel to collect samples for the evaluation process. There should be no interference on the part of the applicant in terms of how random samples are selected by the MRB's evaluation personnel.
- 1.5 Samples may be taken at any point after internal QC clearance from the manufacturer's plant. This may be effected at any time throughout the day, and samples may also be taken at export points or from the market.
- 1.6 While all information supplied by the applicant shall be treated with utmost confidentiality by the MRB, the applicant shall permit the MRB to use and release whatever information obtained in the course of the application to the public or government authorities as deemed proper and necessary by the MRB, or as required by existing law or regulation.

2 Surveillance

- 2.1 Successful certified SMG manufacturers shall be subject to the MRB's surveillance program, which is at least twice a year. The frequency may be reduced after a good track record has been achieved. All visits shall be unannounced, to ensure the quality system is maintained at all times. All results of the surveillance testing will be sent to the manufacturer. Any failure will necessitate the manufacturer taking corrective action within a month from the date of notification. The number of lot(s) to be sampled on the follow-up re-testing will be equal to the number of lot(s) that failed during the surveillance testing earlier.
- 2.2 The manufacturer shall be responsible to inform MRB immediately should any major NC raised in the QMS audits and suspension or withdrawal has been imposed by Certification Body of QMS.
- 2.3 Ad-hoc surveillance visits may be conducted if there is reason to believe that a certified manufacturer has not fully controlled its production processes, or based on, for example, FDA Detention Report, or complaints. Samples may be taken for additional testing and appropriate action taken based on observation during such visits and test results.
- 2.4 In the event of no sample during surveillance inspection, certified SMG manufacturer shall inform MRB when the sample is available. Failure to comply will affect the renewal of SMG certificate.

3 Contract Manufacturing

Where a SMG certified manufacturer purchases/acquires gloves from another manufacturer to sell as part of its own production/shipment as SMG, the supplying manufacturer must also be a certified SMG supplier.

4 SMG logo

In addition to the licence to use the mark of conformity registered by the MRB for the Product Certification Scheme, as spelt out in the document: Product Certification: MRB – PCB – 01: Rules Governing Rubber Product Certification, certified SMG manufacturers may have the SMG logo (as shown in Appendix 5) printed on their dispenser boxes or on cartons. The logo is to be either printed or stencilled or applied by means of pre-printed stickers, and may be in any dominant colour and clearly visible.

5 Non-conformance and contravention to rules and regulations

The general rules regarding granting, suspension and withdrawal/cancellation of certification under the MRB product certification system has been spelt out in the document, Product Certification: MRB – PCB – 01: Rules Governing Rubber Product Certification. Specific rules applicable to the SMG certification program/scheme are as follow:

Action on non-conformance by certified suppliers may take the form of a suspension or withdrawal/cancellation of the certification status. The period of suspension shall be based on the nature and degree of severity of the non-conformance, and shall be decided on a case-by-case basis. The removal of suspension will only be effected after corrective actions have been instituted by the certified suppliers and verified by the MRB.

5.1 Suspension of Certification Status

The SMG certificate may be suspended for a limited period which shall be determined by the Director General, as advised by the Product Certification Panel (PCP), under the following circumstances:-

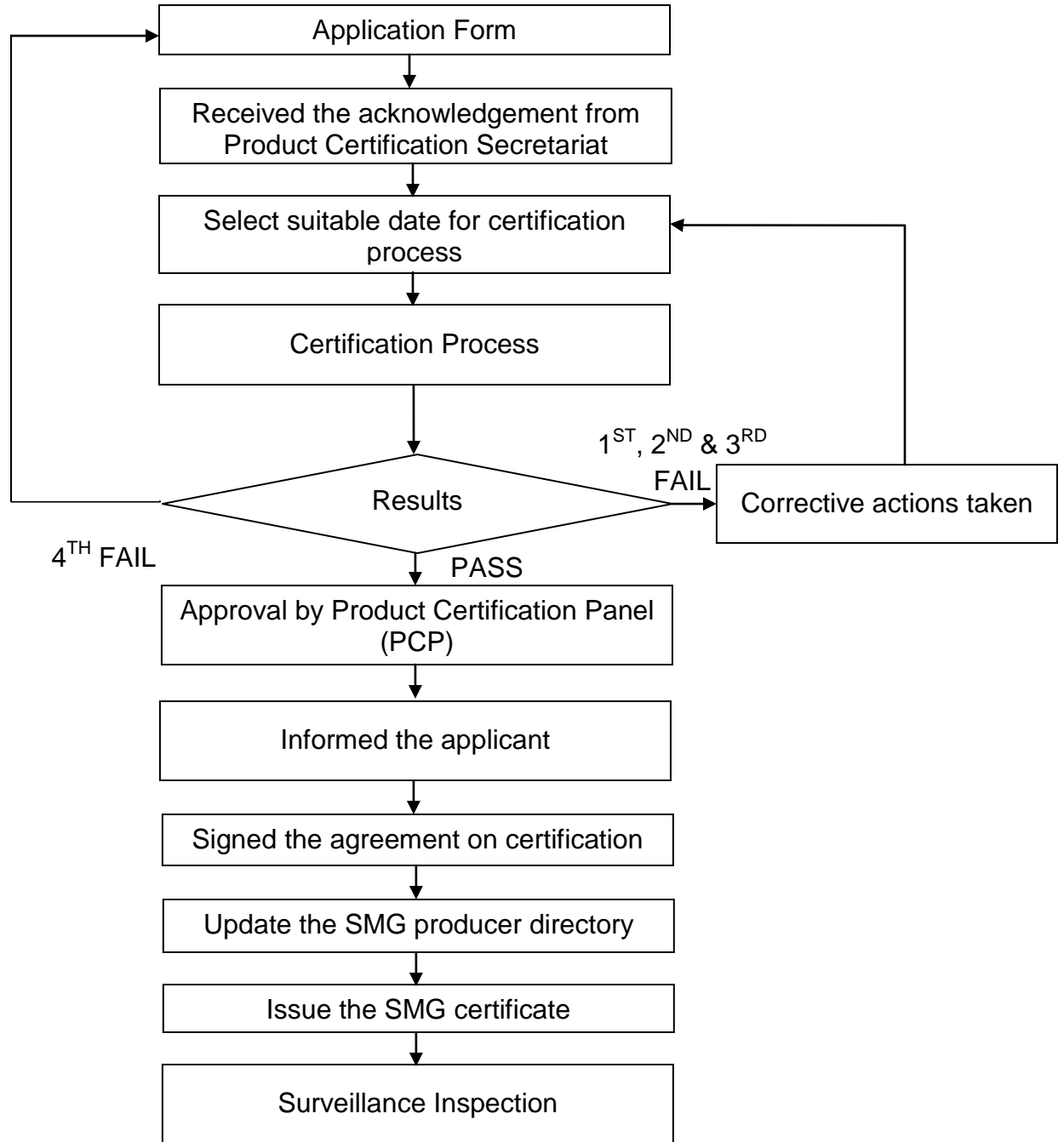
- 5.1.1 when a factory fails a QC Surveillance, **and** is not able to take **corrective action** within **a month** of being notified of its short-coming.
- 5.1.2 non-compliance with the SMG technical specification. Corrective actions may include re-inspection/re-testing of the examination gloves and removal of mark of conformity and SMG logo prior to shipment from the factory.
- 5.1.3 improper use of the certificate or mark of conformity or SMG logo, e.g. in misleading prints, advertisement, promotional materials or other literature. Corrective actions may include the amendment or discontinuance of such advertising promotional material.
- 5.1.4 failure to furnish samples as may be required by the MRB for examination and testing purposes.
- 5.1.5 obstructing the immediate access by the Product Certification personnel of the MRB to the factory or warehouse premises covered by the certificate during the working hours of the factory.
- 5.1.6 failure to provide co-operation to facilitate the inspection of books or records by the officers.
- 5.1.7 non-payment of the annual fees to the Board.
- 5.1.8 failure to pay costs of testing of the (SMG) examination gloves.

5.2 Withdrawal/Cancellation of a certificate

Apart from the suspension of a certificate, a certificate may be withdrawn in the following cases:-

- 5.2.1 non-compliance is of a serious nature
- 5.2.2 Certificate holder fails to comply with due settlement of his financial obligations
- 5.2.3 Inadequate measures taken by the certificate holder in the case of suspension
- 5.2.4 Fails a QC Surveillance, and is not able to take **comprehensive corrective action within three (3) months** of first being notified of its short-coming. **Legal action on the misuse of the SMG certification by a third party**
- 5.2.5 No person shall use the SMG logo unless the person holds a valid certificate issued by the MRB.
- 5.2.6 A person who contravenes the above rule shall be guilty of an offence and shall be subjected to the Trade Descriptions Act 1972 (Act 87)

FLOW CHART OF STANDARD MALAYSIAN GLOVE (SMG) CERTIFICATION



SMG logo

 <p>Standard Malaysian Glove Type I Powdered Certificate Approval No. 2XXX-I</p>	 <p>Standard Malaysian Glove Type II Powdered Certificate Approval No. 2XXX-II</p>
 <p>Standard Malaysian Glove Type I Powder Free Certificate Approval No. 1XXX-I</p>	 <p>Standard Malaysian Glove Type II Powder Free Certificate Approval No. 1XXX-II</p>

* The Certificate Approval No. can be obtained from the SMG Certificate of Conformity issued by MRB.