 

**Hong Kong Q-Mark Council**

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HONG KONG Q-MARK

PRODUCT CERTIFICATION SCHEME

*Certification / Recertification Questionnaire*

For initial application for certification and application for extension of scope / reduction of scope of certification, this questionnaire should be completed and returned to HK Q-Mark Council together with the application for SOP-02/04 and all relevant documents as listed in the checklist on page 2.

For recertification, this completed questionnaire together with any completed supplementary questionnaire must be returned to HK Q-Mark Council one month before scheduled recertification date accompanied by the relevant documents.

Fees payable are listed in

HKQ-03, Fee structure for Product Certification Scheme

You should study carefully the latest versions of the following documents before completing this questionnaire:

HK Q-Mark Product Certification Scheme

* Administrative Regulation
* Respective Technical Regulation (e.g. HKQM-FD-SA, etc)

HKQ-01 HK Q-Mark Council Product Certification Scheme Regulations

HKQ-02 Guideline on the usage of HK Q-Mark Logo and Message

**Attachment Checklist**

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| Before sending this completed questionnaire to HK Q-Mark Council, please check that all required documents are attached and tick the appropriate boxes below. |

This Form is related to: (more than one box may be ticked if appropriate)

□ Initial Certification □ Recertification □ Extension of Scope □ Reduction of Scope

□ application fees (for initial applications and applications for extension of certification only, no application fees are charged for recertification), in the form of a cheque payable to The Federation Of Hong Kong Industries. In addition to application fees, assessment fees shall be charged. Applicants will be informed of the exact amount when the on-site assessments have been arranged.

□ documents authenticating that the applicant organization is a legal entity or part of a legal entity in Hong Kong

□ quality manual

□ operation procedure manual

□ other quality documentation, please specify

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* latest internal audit schedule
* record of the latest management review
* organization charts, with key positions clearly identified
* scope of certification to be assessed
* related license or statutory requirements obtained, please specify

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* other documents, please specify

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**Scope of Certification**

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| Hong Kong Q-Mark Council provides certification service to applicant for product groups listed in the Hong Kong Q-Mark Council website. The list is reviewed from time to time.  For application for certification and application for extension / reduction of scope of certification, the activities to be included should be detailed in the section 3 “Scope of product certification / extension / reduction requested”.  For recertification, the “scope of certification to be recertified” has been sent to the licensee and the licensee should check this scope carefully. This scope should then be signed and returned to Hong Kong Q-Mark Council together with this completed questionnaire for confirmation.  If there is any need for addition of a product certification scheme to the scope of certification, the licensee should consult Hong Kong Q-Mark Council on whether an application for extension of scope of certification should be submitted. |

**Application Details**

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| **1 Location and responsible persons** |
| 1.1 Supply facility (address in full): |
| 1.2 Person at supply facility with responsibility for handling matters pertaining to products assessed under this scheme: |
| Name: |
| Position: |
| Location: |
| Telephone: |
| E-mail: |
| Fax: |
| To whom does this person report? (name and position) |
| 1.3 Alternative responsible person: |
| Name: |
| Position: |
| Location: |
| Telephone: |
| E-mail: |
| Fax: |
| To whom does this person report? (name and position) |
| 1.4 Provide an organization chart showing the relationship of these persons to the organization.  If this application is for a facility depending on another location within the organization for planning the product realization and/or design and development, provide the information required in 1.2 and 1.3 for the location of control. |
| **2 Responsibility and authority** |
| 2.1 The individuals identified in 1.2 and 1.3 should have documented responsibility and authority to take the following actions.  a) Require correction of nonconformities before the application of the certification mark.  b) Require changes pertaining to the requirements in the specifications, drawings, procurement, etc.  c) Arrange for and verify the removal of the certification mark from products which do not comply with the Council’s requirements or from products which have not been covered by the scheme.  Do they have this authority? Yes 🞎No 🞎 |
| 2.2 The individuals identified in 1.2 and 1.3 should have the authority and responsibility for ensuring the following.  a) The certification mark is applied only to those products for which authorization has been given by the Council in writing.  b) The latest documents of the organization pertaining to the applicable requirements are available at the facility and are being worked to.  c) The products that bear the certification mark comply with the applicable requirements before shipment.  d) The applicable requirements of the following sections are implemented and being followed at the facility.  Do they have the above authority and responsibility? Yes 🞎No 🞎 |
| **3 Scope of product certification / extension / reduction requested\*** |
| 3.1 Please specify the product scheme(s) for certification / extension / reduction\*: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  3.2 Type of product  ………………………………………………………………………………………………………………………………………….  3.3 Product Name  ………………………………………………………………………………………………………………………………………….  3.4 Total number of products to be evaluated for full certification:  ………………………………………………………………………………………………………………………………………….  3.5 Please complete a separate ingredients list (below) for each product:   |  |  | | --- | --- | | **Product 1** | **Product 2** | | **Ingredient** | **Ingredient** | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  |  |  |  | | --- | --- | | **Product 3** | **Product 4** | | **Ingredient** | **Ingredient** | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  |     (add rows and attach more tables as necessary)  3.6 Number of production line(s)  ………………………………………………………………………………………………………………………………………….  3.7 Number of personnel (production / QA / QC / wharehouse, etc) )involved in each production line  ………………………………………………………………………………………………………………………………………….  3.8 Please indicate by type designation or model numbers those products that fit into a series or family range : (e.g. different favors, sizes, packaging, etc)  ………………………………………………………………………………………………………………………………………….  \* Delete whichever is not applicable.  3.9 Production flow chart (attach the chart as necessary)  3.10 Factory layout (attach the layout as necessary) |

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| **4 Quality management system** | **Reference system document** |
| 4.1 Has the organization implemented a quality management system in accordance with the requirements of ISO 9001 or ISO 22000, or an equivalent quality management system standard? Yes 🞎No 🞎  Where applicable, specify the equivalent quality management system standard\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.  If yes, please provide a copy of the quality manual and/or quality management system documentation. |  |
| 4.2 Is the quality management system certified by an accredited Certification Body? Yes 🞎No 🞎 |
| 4.3 Does the scope of the certification cover the activities of production and/or supply of the category of product for which certification is requested? Yes 🞎No 🞎 |
| 4.4 Are all the sites in charge of production and/or supply of the product covered by the certificate(s)? Yes 🞎No 🞎  If yes, please attach a copy of the current certificate(s) and, if available, a copy of the last audit report. |
| 4.5 The quality management system documentation should contain details of   1. organization structure, responsibility and authority, 2. inspection and test plans, 3. documented procedures, 4. required external documents (e.g. technical standards and statutory and regulatory requirements applicable to the product), 5. specific documents established by the organization (e.g. specifications, drawings, work instructions, and forms necessary for effective implementation of the quality management system and the control of production or supply and conformity assessment of the product), and 6. records.   Does the quality management system documentation provide this information? Yes 🞎No 🞎 |
| **5 Personnel**  Append the documentation of the quality management system that specifies the responsibility and authority of all personnel responsible for product design, calibration of measuring devices, verification of incoming products, testing or inspecting products to requirements and for writing product monitoring and measurement records. |  |
| **6 Planning of product realization**  Criteria: The quality management system shall comply with the requirements of planning of product realization of ISO 9001 or ISO 22000. |  |
| 6.1 Is the result of planning of product realization documented? Yes 🞎No 🞎 |
| 6.2 Are there exclusions from the requirements within design and development, purchasing process, validation of processes for production and service provision and customer property of ISO 9001 or ISO 22000 in the quality management system? Yes 🞎No 🞎  If yes, describe the exclusion and its justification\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

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| **7 Customer-related processes**  Criteria: The quality management system shall comply with the requirements of customer-related processes of ISO 9001 or ISO 22000. |  |
| 7.1 Is a review conducted prior to the organization’s commitment to supply a product to the customer to ensure that  — product requirements are defined,  — contract or order requirements differing from those previously expressed are resolved, and  — the organization has the ability to meet the defined requirements?  Yes 🞎No 🞎 |
| 7.2 Are records of this review maintained? Yes 🞎No 🞎 |
| 7.3 Are records of customers' complaints maintained? Yes 🞎No 🞎 |
| **8 Design and development**  (Only for organizations with product design and development)  Criteria: The quality management system shall comply with the requirements of design and development of ISO 9001 or ISO 22000. |  |
| 8.1 Is each product design verified? Yes 🞎No 🞎 |
| 8.2 Do records of these verifications exist? Yes 🞎No 🞎 |
| 8.3 Is each product design reviewed in order to  — evaluate the ability of the results of design to meet requirements, and  — identify any problems and propose necessary actions?  Yes 🞎No 🞎 |
| 8.4 Do records of these reviews exist? Yes 🞎No 🞎 |
| 8.5 Where are the product design, verification design and review design carried out?\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 8.6 There shall be evidence that prototype products comply with all relevant requirements before they are released for production if applicable.  Do the records at the facilities provide this evidence? Yes 🞎No 🞎 |
| **9 Purchasing**  Criteria: The quality management system shall comply with the requirements of purchasing of ISO 9001 or ISO 22000. |  |
| 9.1 A record of all verified ingredients/ components containing the following information shall be maintained:  a) a description of the ingredient(s) / component(s);  b) the name of the supplier;  c) the catalogue or designation sufficient to provide specific identification;  d) a record of the standards and other requirements used to determine conformity;  e) the results of the tests.  Is this record maintained? Yes 🞎No 🞎 |

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| **10 Production and service provision**  Criteria: The quality management system shall comply with the requirements of production and service provision of ISO 9001 or ISO 22000. |  |
| 10.1 Does the product identification apply Yes 🞎No 🞎  If not, please explain\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 10.2 Does the monitoring and measurement product status identified? Yes 🞎No 🞎 |
| 10.3 Does the product traceability apply? Yes 🞎No 🞎 |
| 10.4 Does the customer provide any property that is to be incorporated in the final product?  Yes 🞎No 🞎  If yes, please list them\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 10.5 Is a process validation carried out? Yes 🞎No 🞎 |
| **11 Control of monitoring and measuring devices**  Criteria: The quality management system shall comply with the requirements of control of monitoring and measuring equipment of ISO 9001 or ISO 22000. |  |
| 11.1 Are all measuring device calibrated at intervals? Yes 🞎No 🞎 |
| 11.2 Are written calibration procedures available for each type of measuring device? Yes 🞎No 🞎 |
| 11.3 Is the calibration status of measuring devices identified? Yes 🞎No 🞎 |
| 11.4 Are calibration records maintained for each measuring device? Yes 🞎No 🞎 |
| 11.5 Is each measuring device marked to show when it was last calibrated? Yes 🞎No 🞎 |
| 11.6 Is there any standards used for calibration? Yes 🞎No 🞎 |
| 11.7 Is the standards traceable to international or national standards? Yes 🞎No 🞎 |
| 11.8 Are the required environmental conditions that specified for monitoring and measurement controlled well? Yes 🞎No 🞎 |
| **12 Monitoring and measurement of product**  Criteria: The quality management system shall comply with the requirements of monitoring and measurement of product of ISO 9001 or ISO 22000.  Note: The product inspection or test activities are included in ISO 9001 as monitoring and measurement of product. |  |
| 12.1 A documented monitoring and measurement plan shall be developed which describes all of the production monitoring and measurement necessary to ensure that each product under this product certification scheme complies with the requirements before delivery. This plan shall include details of its implementation as follows:  a) details of verification controls as applied to incoming materials and components, in-production and final product monitoring and measurement;  b) a system for recording the results of production line monitoring and measurement;  c) details of the methods used for control of nonconforming products;  d) details of all required monitoring and measurement of product;  Has such an inspection and test plan been documented? Yes 🞎No 🞎  Please attach a copy of this plan if applicable. |
| 12.2 A list of the characteristics to be inspected and/or tested and the related acceptance criteria shall be available at each location where inspection and/or tests are performed to verify conformance requirements by the Council. Is such information available at these locations? Yes 🞎No 🞎 |
| 12.3 Criteria concerning monitoring and measurement product records  Monitoring and measurement records that demonstrate the conformance of the final product to the requirements shall include as a minimum:  — identification of the product;  — monitoring and measurement performed;  — monitoring and measurement results;  — criteria of acceptance;  — nonconformities;  — date of monitoring and/or measurement;  — person(s) authorizing release of product.  Are such records maintained? Yes 🞎No 🞎  Do they contain the information described? Yes 🞎No 🞎 |
| 12.4 Criteria concerning product records  The following records shall be maintained for each product under this product certification scheme:  a) a copy of the package or label that shows the certification mark, and unique identification number of the product;  b) materials usage, process/environmental conditions, and control parameters of each production batch and results of monitoring/inspection and measurement performed on the product to verify conformity to the requirements;  c) photographs with and without packaging materials of the product;  Are such records maintained? Yes 🞎No 🞎  Do they contain the information described? Yes 🞎No 🞎  Has the authority and responsibility to maintain these records established? Yes 🞎No 🞎 |
| **13 Control of nonconforming product**  Criteria: The quality management system shall comply with the requirements of control of nonconforming product of ISO 9001 or ISO 22000. |  |
| 13.1 The organization shall establish a documented procedure for control of nonconforming products.  Has such a procedure been implemented? Yes 🞎No 🞎 |
| 13.2 Final products that have been reworked or repaired to comply with the requirements shall be re-verified. Is this done? Yes 🞎No 🞎 |
| **14 Corrective action**  Criteria: The quality management system shall comply with the requirements of corrective action of ISO 9001 or ISO 22000. |  |
| 14.1 The organization shall establish a documented procedure for corrective action.  Has such a procedure been implemented? Yes 🞎No 🞎 |
| 14.2 The product nonconformities shall be investigated to determine the cause.  Is this done? Yes 🞎No 🞎 |
| 14.3 After the cause of nonconformity has been determined, appropriate action shall be taken to avoid repetition. Is this done? Yes 🞎No 🞎 |
| 14.4 Provide an example of a record of corrective action. |
| **15 Preventive action**  Criteria: The quality management system shall comply with the requirements of preventive action of ISO 9001 or ISO 22000. |  |
| 15.1 The organization shall establish a procedure for preventive action.  Has such a procedure been implemented? Yes 🞎No 🞎 |
| 15.2 Any potential nonconformities of the product should be investigated to determine the cause.  Has this been carried out? Yes 🞎No 🞎 |
| 15.3 When the cause of a potential nonconformity has been determined, appropriate action should be taken to prevent repetition. Has this been carried out? Yes 🞎No 🞎 |
| 15.4 Provide an example of a record of preventive action. |
| **16 Control of documents**  Criteria: The quality management system shall comply with the requirements of control of documents of ISO 9001 or ISO 22000. |  |
| 16.1 The organization shall establish a procedure for control of documents.  Has such a procedure been implemented? Yes 🞎No 🞎 |
| **17 Control of records**  Criteria: The quality management system shall comply with the requirements of control of records of ISO 9001 or ISO 22000. |  |
| 17.1 The organization shall establish a procedure for record control.  Has such a procedure been implemented? Yes 🞎No 🞎 |
| **18 Summary of general details**  18.1 Responsible Person authorized for handling matters relating to the Hong Kong Q-Mark Certification  Responsible Person’s name: ...............................................................................................................  Position: ......................................................................................................................................  Location: ..................................................................................................................................... | |
| 18.2 Scope of product manufactured at manufacturing location:  .................................................................................................................................................... | |
| 18.3 Application  Completed by organization’s representative:  Name: .........................................................................................................................................  Signature: ....................................................................................................................................  Date: ........................................................................................................................................... | |