SIRIM QAS INTERNATIONAL

APRIL 2022
FIRST EDITION

GUIDELINE FOR THE

CERTIFICATION OF NON-MEDICAL FACE MASKS

CONTENTS

1. INTRODUCTION

1.1 This document specifies the minimum requirements and process guideline for all applicants on the certification of non-medical face masks.

1.2 All applicants shall adhere to the requirements and processes as specified in this document.

2. PRODUCT DETAILS

2.1 Product: Non-Medical Face Masks.

2.2 Standard Title & No.:

i. Non-medical face masks - Specification (SIRIM 40)
ii. Community Face Coverings – Guide to minimum requirements, methods of testing and use (CWA 17553)
iii. Barrier Masks – Guide to minimum requirements, methods of testing, making and use (AFNOR SPEC S76-001)

2.3 Product details will appear in the license as per Annex I.

3 SCOPE OF APPLICATION

3.1 This guideline covers certification of non-medical face masks.

3.2 It is applicable for certification for local manufacturer or trader or overseas manufacturer.

4 BRIEF DESCRIPTION OF PRODUCT'S CHARACTERISTIC

4.1 Non-medical face masks are intended to be used by healthy people without any clinical symptom or viral infection. Wearing of non-medical face masks provides a barrier against possible penetration of virus in the user's mouth and nose area from nearby persons. It is also intended to protect the protection area.

4.2 The use of non-medical face masks is envisaged, for example, for people leaving their home to their workplace or shops, during commuting in public transport and generally in places where physical distancing cannot be maintained.

4.3 Non-medical face mask may be designed in different shapes and structures which include flat-fold or duckbill (disposable) or fabric type (reusable).

4.4 Non-medical face mask shall be designed to cover the nose, cheeks and chin, and sides of the wearer.

4.5 Performance Requirement as in Table 1 below:

Performance Requirement	Standard					
	SIRIM 40		CWA 17553		AFNOR SPEC S-76	
	Disposable	Reusable	Disposable	Reusable	Disposable	Reusable
Breathability / Breathing resistance	√	√	√	√	√	√
Microbial Cleanliness	√					
Filtration Efficiency	√	√	√	√	√	√
Flame spread (flammability)	√	√				
Cleaning		√		√		√
Ear band strength test	√	√				

5 CERTIFICATION PROCESS

5(a) Type 5 : Product Certification

5.1 The certification of face masks consists of five main processes to be carried out in the following order:

i. Application for certification (Refer Annex 2).
ii. Initial Audit at manufacturer's site
iii. Sampling for testing by SIRIM QAS
iv. Recommendation for approval of certification
v. Yearly surveillance program

5.2 Beside the normal information required in Questionnaire & Application forms, applicant shall declare the percentage of filtration efficiency.

5(b) Type 1(b): Batch Certification

5.1 The batch certification of face masks consists of four main processes to be carried out in the following order:

i. Application for batch certification + Type Test Report (Refer Annex 2)
ii. Verification for batch at applicant's warehouse ((serial no., batch no., production date)
iii. Samples for testing / verification for critical testing
iv. Acceptance for batch certification

6 SCHEDULE OF FEE

6(a) Product Certification

No.	DESCRIPTION	FEE (RM)	FEE (USD)
1	Application Fees	500	160
2	Evaluation Fees	2000	640
3	License / Renewal Fee per Year	600	200
4	Audit Fee	From 1500	From 1280
5	Incidental	As charged where applicable for accommodation, living allowances and flight ticket / transportation / mileage	
6	Testing Fee (per model):		
	Breathability	1200	380
	Microbial Test	500	160
	Particle Filtration	1800	570
	Flame Spread	500	160
	Cleaning	300	100
	Ear band	600	190

6(b) Batch Certification

No.	DESCRIPTION	FEE (RM)	FEE (USD)
1	Application fees	500	160
2	Evaluation fees	1000	320
3	Warehouse Verification Fee	From 1500	From 1280
4	Incidental	As charged where applicable for accommodation, living allowances and flight ticket / transportation / mileage	
5	Testing Fee (per model):		
	Breathability	1200	380
	Particle Filtration	1800	570

7 AUDIT / VERIFICATION PROCESS

7(a) Factory Audit (TYPE 5)

7.1 The minimum QC plan required shall be as below.

7.1.1 Incoming inspection

All major raw materials that have direct influence on product properties shall be subjected to incoming inspection prior to acceptance and/or production. The manufacturer shall identify, conduct and record test to be carried out on each raw material and compare the result to the material's specification for acceptance.

a) Disposal type

Incoming raw materials:

i. Inner & outer layer e.g. Spund bond - Verification on certificate of analysis (CoA) / test report of the batch / lot received and weight check (g/m^2).
ii. Filter layer e.g. Melt blown - Verification on certificate of analysis (CoA) / test report of the batch / lot received and weight check (g/m2).
iii. Nose strip - Verification on material specification
iv. Elastic band e.g. Ear loop - Verification on material specification

b) Reusable type

Incoming raw materials:

i. Inner & outer layer e.g. Polyester interlock - Verification on certificate of analysis (CoA) / test report of the batch / lot received and weight check (g/m2).
ii. Filter layer e.g. PU laminated polyester – Verification on certificate of analysis (CoA) / test report of the batch / lot received and weight check (g/m2).
iii. Head harness e.g. Polyester mix with spandex - Verification on material specification

7.1.2 In-process inspection

Applicant shall ensure that sufficient controls on in-process are implemented at factory. The manufacturer shall identify the control of intermediate process to ensure that the intended quality of product is achieved. Typical test or control conducted:

a) Disposal type

Production Process:

i. Unwind the inner, filter & outer layer – Visual inspection
ii. Joining – Visual inspection
iii. Folding – Visual inspection
iv. Flattening – Visual inspection
v. Put the nose strip – Visual inspection
vi. Seal – Visual inspection

vii. Cutting – Visual inspection
viii. Ultrasonic welding for ear loop - Visual inspection, elastic band test

b) Reusable type

Production Process:
i. Cutting – Visual inspection
ii. Sewing – Visual inspection
iii. Assembly head harness stopper – Visual inspection

7.1.3 Final inspection

Applicant shall ensure that a final inspection is implemented. The minimum frequency of testing
i. Visual inspection – 100%
ii. Width & length – Every batch
iii. Quantity – Randomly every batch

7(b) Warehouse Verification (TYPE 1(B))

Applicant shall ensure that sufficient information been submitted in application form. The applicant shall preserve all the batch quantity as per applied available during the batch verification. Auditor will take samples for verification of critical testing.

8 TESTING EQUIPMENT (Applicable for TYPE 5 only)

8.1 Applicant shall ensure that manufacturer has adequate testing facilities to conduct all the tests requirement. The minimum equipment to be maintained in the factory as below:
i. Steel ruler
ii. Weighing balance

8.2 Applicant shall ensure that all the equipment used are calibrated or verified.

9 SAMPLES FOR TESTING

9.1 For Type 5 Product Certification, detail of sample quantities is as below:
i. Disposable type: 2 boxes (for 50pcs per box)
ii. Reusable type: 25pcs Individual packaging)

9.2 For Type 1(b) Batch Certification, depend on batch size, sampling will be based on the Single Sampling Plan for Normal Inspection is to be used with Acceptable Quality Level (AQL) of 6.5 with special inspection level S-1 as in MS ISO 2859: PART 1: 2001.

10 MARKING, PACKAGING & LABELLING

10.1 On the Packaging

i. Name, trademark, or any other means of identification of the manufacturer or supplier
ii. Recommended period of use of the non-medical face mask.
iii. Number and year of the standard,
iv. A pictogram or instruction on how to put on the non-medical face mask.
v. SIRIM Certification Mark, see example in ANNEX 2
vi. SIRIM label on the packaging as in ANNEX 2.

10.2 Method of marking

i. Licensee may press print manufacturer's identification and MS Mark on the face mask.
ii. Printed onto each box.

10.3 Licensee shall purchase SIRIM label maximum for 3 months production (Product Certification TYPE 5).

10.4 Licensee may include percentage of filtration efficiency based on approved declaration.

11 CLIENT CHARTER

Activity	Working Days
Issuance of quotation after complete information	3 – 5 days
Issuance of acceptance letter after payment	3 days
Testing upon complete application (payment, sample & application form)	14 – 21 days
Approval after audit, testing & complete documents	14 days

Annex 1

Example of Product Details

1)

Trademark (s)	Model (s)	Type (s)	Rating (s)	Size (s)	Remark
As Declaration	ABC	TYPE= DISPOSABLE; CONSTRUCTION= THREE LAYER	FILTRATION EFFICIENCY LEVEL 70%*	N/A	N/A

2)

Trademark (s)	Model (s)	Type (s)	Rating (s)	Size (s)	Remark
As Declaration	DEF	TYPE= DISPOSABLE; CONSTRUCTION= FOUR LAYER	FILTRATION EFFICIENCY LEVEL 95%*	N/A	N/A

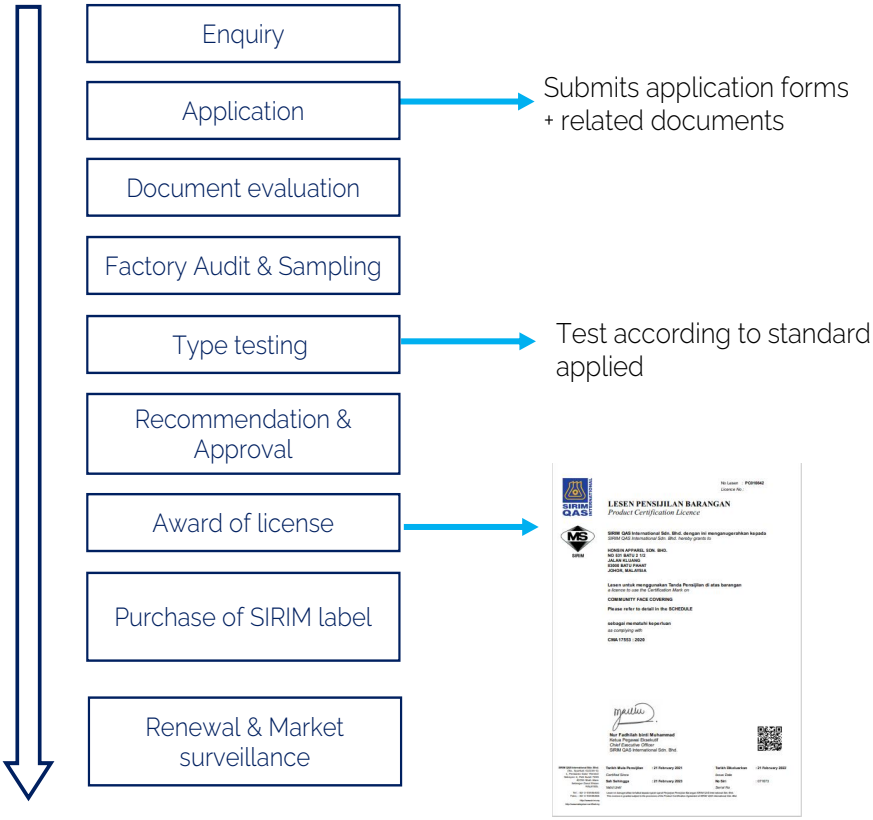
3)

Trademark (s)	Model (s)	Type (s)	Rating (s)	Size (s)	Remark
As Declaration	GHI	TYPE = REUSABLE; CONSTRUCTION = FABRIC	FILTRATION EFFICIENCY LEVEL 90%*	N/A	N/A

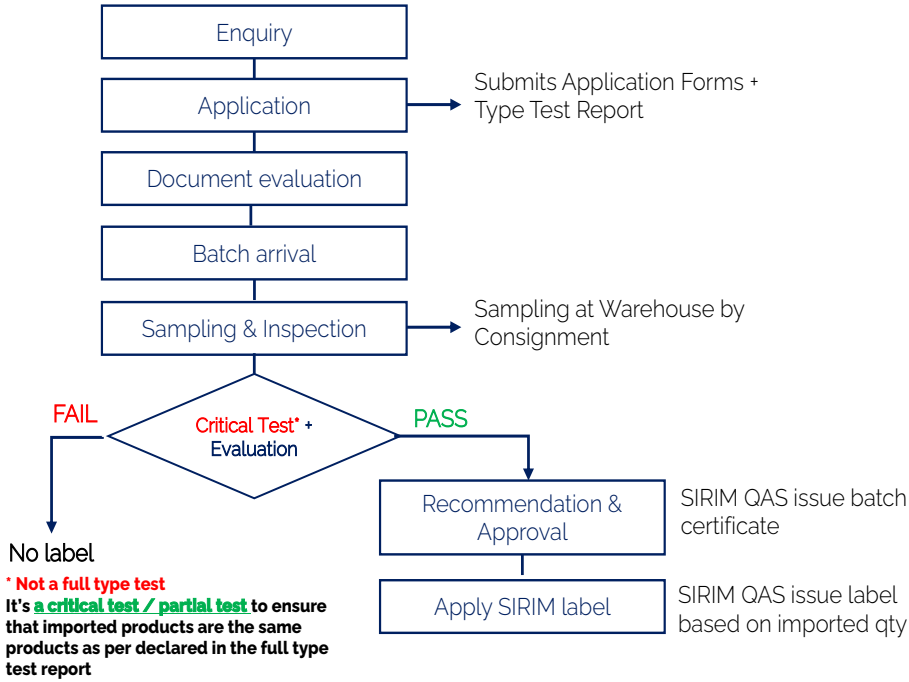
Note *: Filtration efficiency as declared by manufacture and approved by SIRIM with minimum 70%.

Annex 2

Type 5 : Product Certification



Type 1(B) : Batch Certification



*** Not a full type test**
It's a critical test / partial test to ensure that imported products are the same products as per declared in the full type test report

Annex 3

1. Examples for MS Mark

SIRIM 40

SIRIM
Certified to SIRIM 40:2020
Certification No.: PCXXXXXX*

SIRIM
SIRIM 40:2020
PCXXXXXX*

CWA 17553

SIRIM
Certified to CWA 17553 : 2020
Certification No.: PCXXXXXX*

SIRIM
CWA 17553 : 2020
PCXXXXXX*

AFNOR SPEC76-001

SIRIM
Certified to AFNOR SPEC76-001 : 2020
Certification No.: PCXXXXXX*

SIRIM
AFNOR SPEC 76-001 : 2020
PCXXXXXX*

* Note: Please refer to the number printed on the license

2. Place to affix SIRIM label onto the packaging/smallest box.

SIRIM label with unique QR Code to be placed on the opening of the face mask packaging / individual packed. It can ensure the traceability of the non-medical face masks.

For packed product

For individual packed product

Annex 4

No Lesen : **PCxxxxxx**
Licence No :

LESEN PENSIJILAN BARANGAN
Product Certification Licence

SIRIM QAS International Sdn. Bhd. dengan ini menganugerahkan kepada
SIRIM QAS International Sdn. Bhd. hereby grants to

NON-MEDICAL MASK SDN. BHD.
1, PERSIARAN DATO' MENTERI,
SEKSYEN 2,
40700 SHAH ALAM,
SELANGOR, MALAYSIA

Lesen untuk menggunakan Tanda Pensijilan di atas barangan
a licence to use the Certification Mark on

NON-MEDICAL FACE MASK

Please refer to detail in the SCHEDULE

sebagai mematuhi keperluan
as complying with

SIRIM 40 : 2020

No Lesen : **PCxxxxxx**
Licence No :

SCHEDULE

NON-MEDICAL MASK SDN. BHD.

Brand : 123
Model : ABC
Type : TYPE = DISPOSABLE; CONSTRUCTION = THREE LAYER;
Rating : FILTRATION EFFICIENCY LEVEL 70%

Brand : 456
Model : DEF
Type : TYPE = DISPOSABLE; CONSTRUCTION = FOUR LAYER;
Rating : FILTRATION EFFICIENCY LEVEL 95%

Brand : 789
Model : GHI
Type : TYPE = REUSABLE; CONSTRUCTION = FABRIC;
Rating : FILTRATION EFFICIENCY LEVEL 90%

SIRIM QAS INTERNATIONAL SDN.BHD.

SIRIM Complex No.1, Persiaran Dato' Menteri,
Section 2, P.O Box 7035, 40700,
Shah Alam, Selangor Darul Ehsan,
Malaysia

Tel: 603 5544 6400
Fax: 603 5544 6810
Email: cserviceqas@sirim.my
Website: www.sirim-qas.com.my

Scan here for
Guideline for Certification of Non-Medical Face Masks