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FIRST EDITION

JKKP/DOSH

SIRIM QAS INTERNATIONAL

GUIDELINE FOR THE

CERTIFICATION OF FILTERING HALF MASKS

CONTENTS

1. INTRODUCTION

1.1 This document specifies the minimum requirements and process guideline for all applicants on the certification of filtering half masks.

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

2. PRODUCT DETAILS

2.1 Product: Respiratory Protective Devices – Filtering Half Masks.

2.2 Standard Title & No.:

I. Respiratory Protective Devices – Filtering Half Masks to Protect Against Particles – Requirements, Testing, Marking (MS 2323)
II. Respiratory Protective Devices – Filtering Half Masks to Protect Against Particles – Requirements, Testing, Marking (BS EN 149)

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

3 SCOPE OF APPLICATION

3.1 This guideline covers certification of Respiratory Protective Devices – Filtering Half Masks (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 A particle filtering half mask covers the nose and mouth and the chin and may have inhalation and/or exhalation valve(s). The half mask consists entirely or substantially of filter material or comprises a facepiece in which the main filter(s) form an inseparable part of the device.

4.2 These devices are designed to protect against both solid and liquids aerosols.

4.3 Particle filtering half masks are classified according to their filtering efficiency and their maximum total inward leakage. These three classes of devices: FFP1, FFP2, FFP3. Particle filtering half masks also classified as single shift use only or re-usable.

4.4 Performance Requirement as in Table 1 below:

Performance Requirement	**Standard**			
	MS 2323		BS EN 149	
	Disposable	Reusable	Disposable	Reusable
Leakage – Total Inward Leakage	√	√	√	√
Leakage – Penetration of filter material	√	√	√	√
Flammability	√	√	√	√
Carbon dioxide content of inhalation air	√	√	√	√
Head harness	√	√	√	√
Field of vision	√	√	√	√
Exhalation valve (If applicable)	√	√	√	√
Breathing resistance	√	√	√	√
Clogging		√		√

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 1B: Batch Certification

5.1 The batch certification of face masks consists of three 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 Fees per Year	600	200
4	Audit Fee	From 1200	From 1280
5	Incidental	As charged where applicable for accommodation, living allowances and flight ticket/transportation/mileage	
6	Testing Fee (per Model) :		
	Leakage – Total Inward Leakage	2000	640
	Leakage – Penetration of Filter Material	1500	480
	Flammability	600	190
	Carbon Dioxide Content of Inhalation Air	890	285
	Head Harness	600	190
	Field of Vision	600	190
	Exhalation Valve (if applicable)	400	128
	Breathing Resistance	500	160
	Clogging	500	160

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 1200	From 1280
4	Incidental	As charged where applicable for accommodation, living allowances and flight ticket / transportation / mileage	
5	Testing Fee (per model):		
	Leakage – Penetration of Filter Material	1500	480
	Breathing Resistance	500	160

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.

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:

7.1.3 Final inspection

Applicant shall ensure that the finished product is inspected for the quality and performance.

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

Applicant shall ensure that sufficient information is provided in application form. The applicant shall ensure the correct quantity as per applied are available during the batch verification. Auditor will select samples for 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.

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. Non-valve type: 70pcs
ii. Valve type: 80 pcs

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 shall indicate to user shall read the information supplied by the manufacturer.
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 DOSH label maximum for 3 months production (Product Certification TYPE 5).

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)

Trade Mark (s)	Model (s)	Type (s)	Rating (s)	Size (s)	Remark
As Declaration	ABC	TYPE = DISPOSABLE; WITHOUT EXHALATION VALVE	FILTER TYPE = FFP1	N/A	N/A

2)

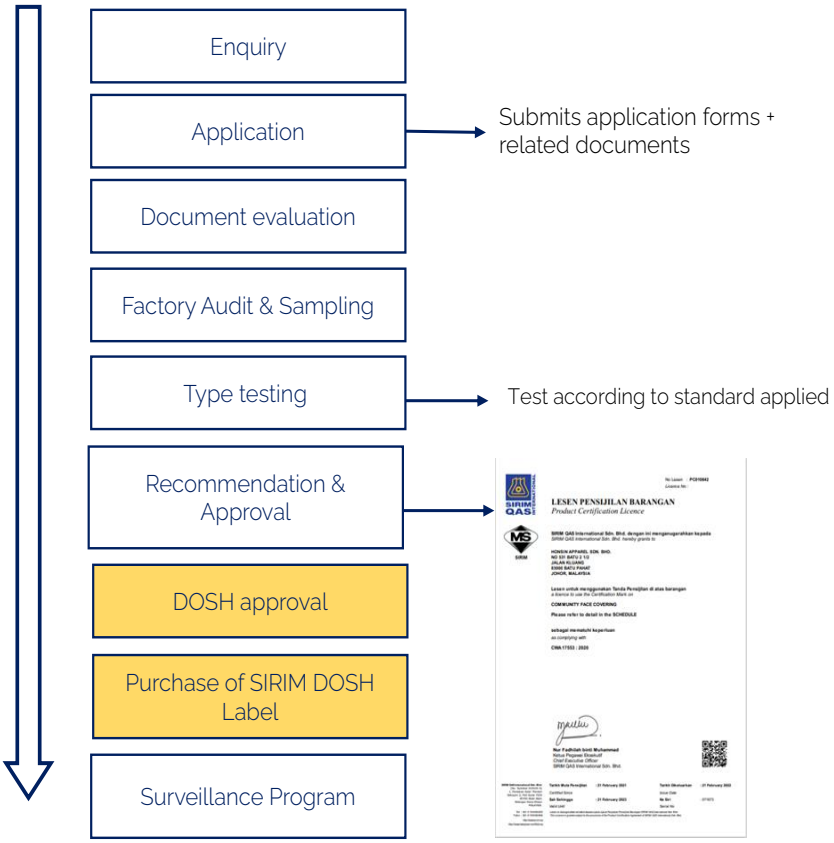
Trade Mark (s)	Model (s)	Type (s)	Rating (s)	Size (s)	Remark
As Declaration	DEF	TYPE : DISPOSABLE; WITH EXHALATION VALVE	FILTER TYPE : FFP2	N/A	N/A

3)

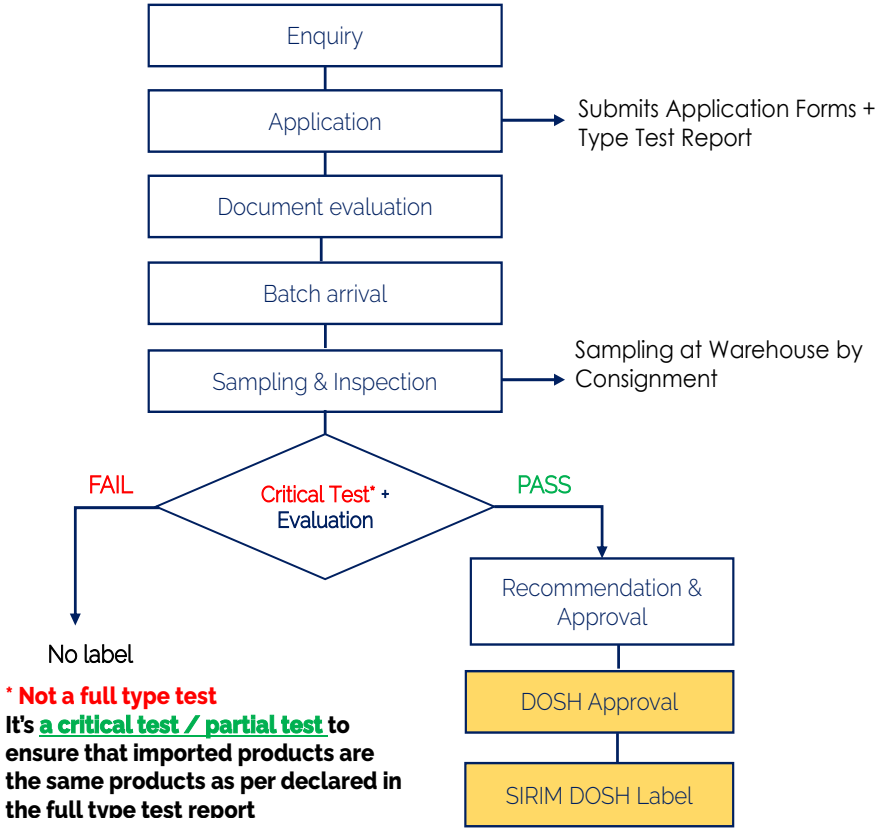
Trade Mark (s)	Model (s)	Type (s)	Rating (s)	Size (s)	Remark
As Declaration	GHI	TYPE = REUSABLE; WITH EXHALATION VALVE	FILTER TYPE : FFP3	N/A	N/A

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

MS 2323

SIRIM
Certified to MS 2323:2010
Certification No.: PCXXXXXX*

SIRIM
MS 2323:2010
PCXXXXXX*

BS EN 149

SIRIM
Certified to BS EN 149:2001+A1:2009
Certification No.: PCXXXXXX*

SIRIM
BS EN 149:2021+A1:2009
PCXXXXXX*

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

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

SIRIM DOSH label with serial number and QR Code to be placed on the packaging box. It can ensure the traceability of the filtering half masks.

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

HALF 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

RESPIRATORY PROTECTIVE DEVICES -FILTERING HALF MASKS

Please refer to detail in the SCHEDULE

sebagai mematuhi keperluan
as complying with

MS 2323 : 2010

No Lesen : **PCxxxxxx**
Licence No :

SCHEDULE

HALF MASK SDN. BHD.

Brand : 123
Model : ABC
Type : DISPOSABLE; WITHOUT EXHALATION VALVE;
Rating : FILTRATION TYPE : FFP1

Brand : 456
Model : DEF
Type : DISPOSABLE; WITH EXHALATION VALVE;
Rating : FILTRATION TYPE : FFP2

Brand : 789
Model : GHI
Type : DISPOSABLE; WITH EXHALATION VALVE;
Rating : FILTRATION TYPE : FFP3

LMRCQ

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Scan here for
Guideline for Certification of Filtering Half Masks