

NON-MEDICAL FACE MASKS PRODUCT CERTIFICATION & TESTING

Ahmad Farihan

Product Certification & Inspection Department (PCID)

7th April 2022



Best Partner for Innovation



CONTENT



Category of Face Mask



List of Standards for Non-Medical Face Mask



Product Certification Scheme



Product Certification Process Flow



Testing Requirement



SIRIM Label



SIRIM QAS Mobile App



Schedule of Fee



Client Charter

Category of Face Mask

Medical Face Mask



Any face mask that is declared has medical benefit and shall be approved by MDA (Medical Device Authority). **Voluntarily** applicant may apply SIRIM Certification.

Non-Medical Face Mask



Other than medical face mask e.g fabric type (reusable), 3-ply face mask & Industrial face mask (N95, KN95)

Example of Non-Medical Face Masks



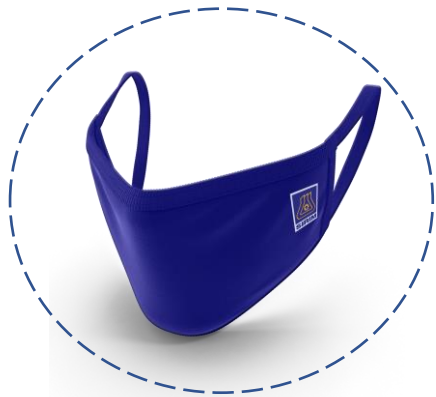
Flat Fold Type (3-ply)



Duck Bill Type



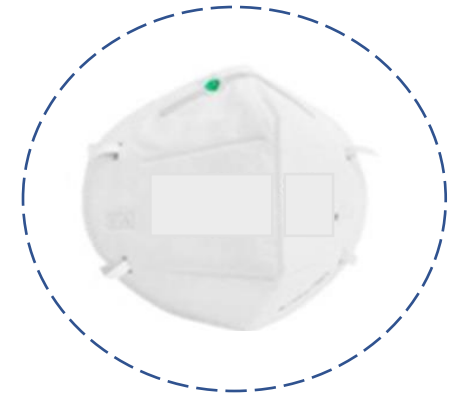
Industrial Face Mask Type



Fabric Type



Respirator - Disposable



Respirator - Reusable

List of Standard for Non-Medical Face Masks & Schemes

No.	Standard Title	Standard no.	Remark
1.	Non-medical face masks - Specification	SIRIM 40	SIRIM Product Certification
2.	Community face coverings - Guide to minimum requirements, methods of testing and use	CWA 17553	SIRIM Product Certification
3.	Barrier Masks - Guide to minimum requirements, methods of testing, making and use	AFNOR SPEC S76-001	SIRIM Product Certification
4.	Respiratory Protective Devices – Filtering Half Masks to Protect Against Particles - Requirements, testing, marking	MS 2323	SIRIM-DOSH Certification
5.	Respiratory Protective Devices – Filtering Half Masks to Protect Against Particles - Requirements, testing, marking	BS EN 149	SIRIM-DOSH Certification

**To purchase standard : www.sirimsts.my

Product Certification

Why do we need it...

- ✓ Provide independent assurance for products manufactured to conform consistently with standards or specifications.
- ✓ Give manufacturers the rights to affix the SIRIM Marking on their products.
- ✓ Provide basis and means for the regulatory agencies in making decision on approval and surveillance of products under its purview.
e.g. certification for non-medical face masks
- ✓ Assure customers of products' quality, safety & reliability.

Product Certification Scheme

TYPE 5



PRODUCT CERTIFICATION SCHEME

- Long term certification scheme
- Yearly license renewal
- Factory audit will be conducted at factory

=> Market surveillance & product complaint

TYPE 1B



BATCH CERTIFICATION SCHEME

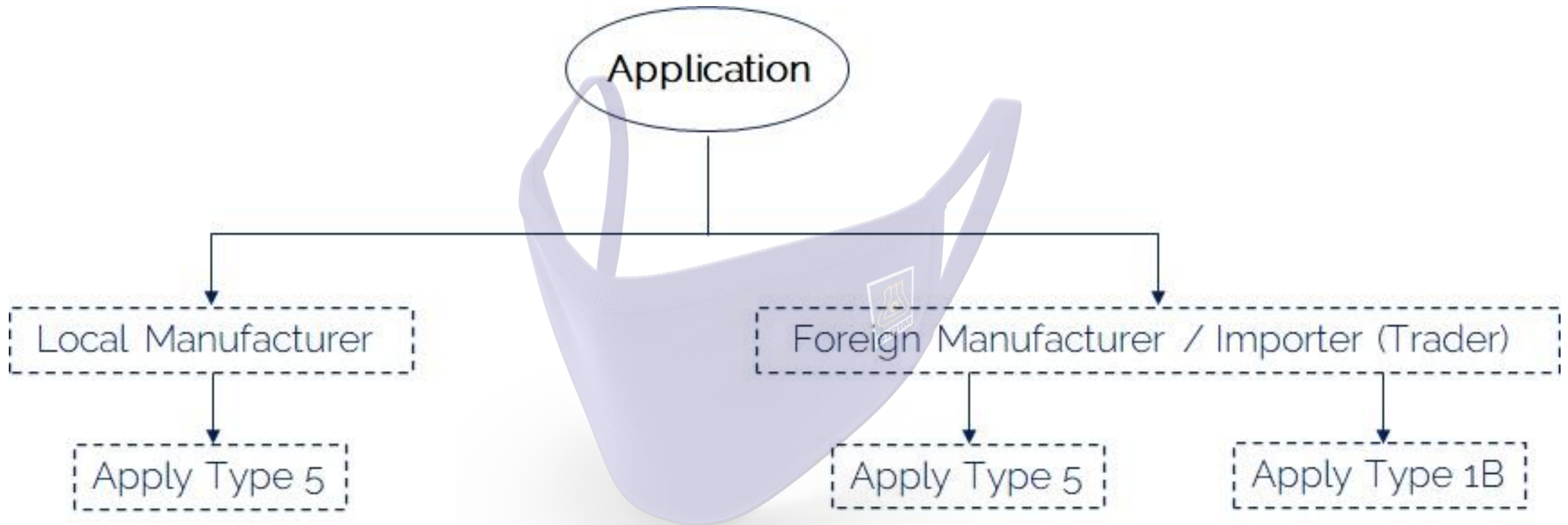
Short term certification scheme, based on batch consignment

Batch certificate is issued on a specific batch which has been verified & tested

Type test report shall be established before submit application

=> Market surveillance & product complaint

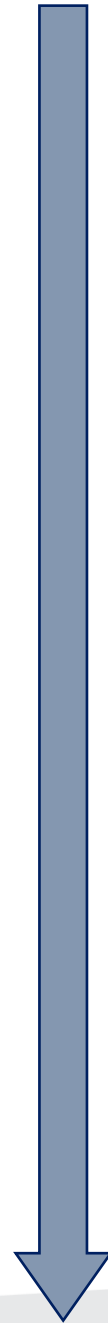
Route to Product Certification



Product Certification Process Flow



SIRIM Product Certification Type 5

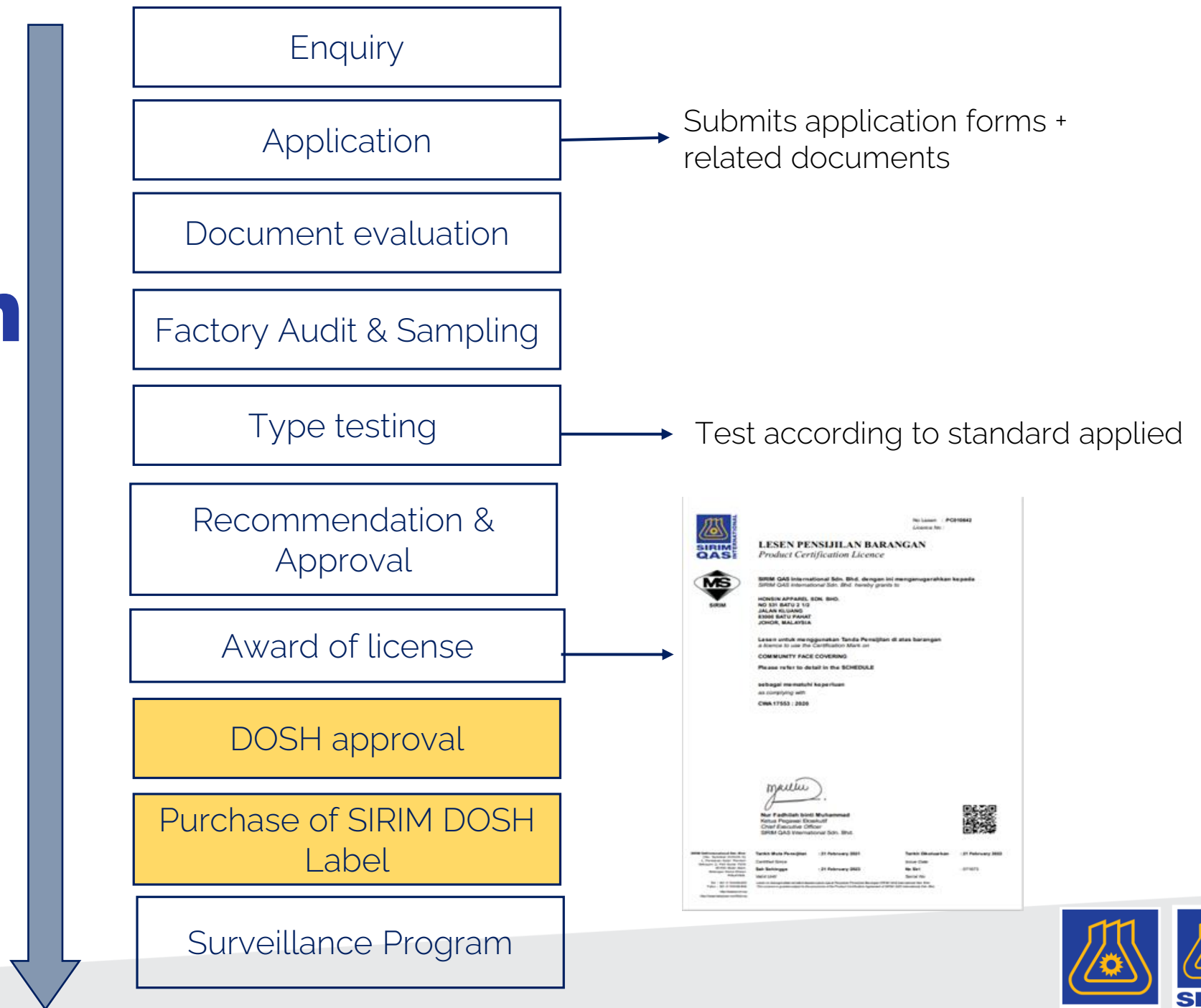


Submits application forms + related documents

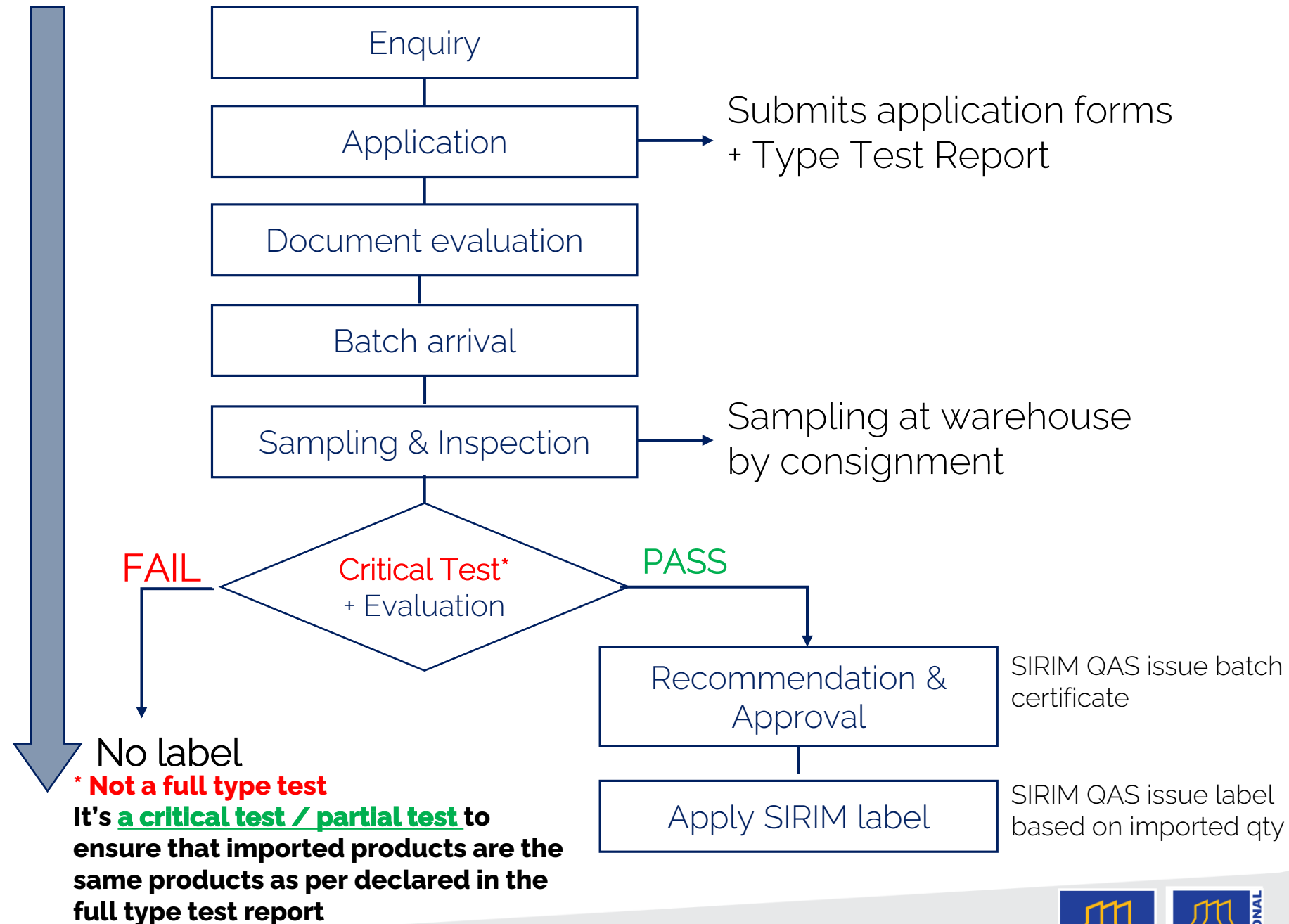
Test according to standard applied



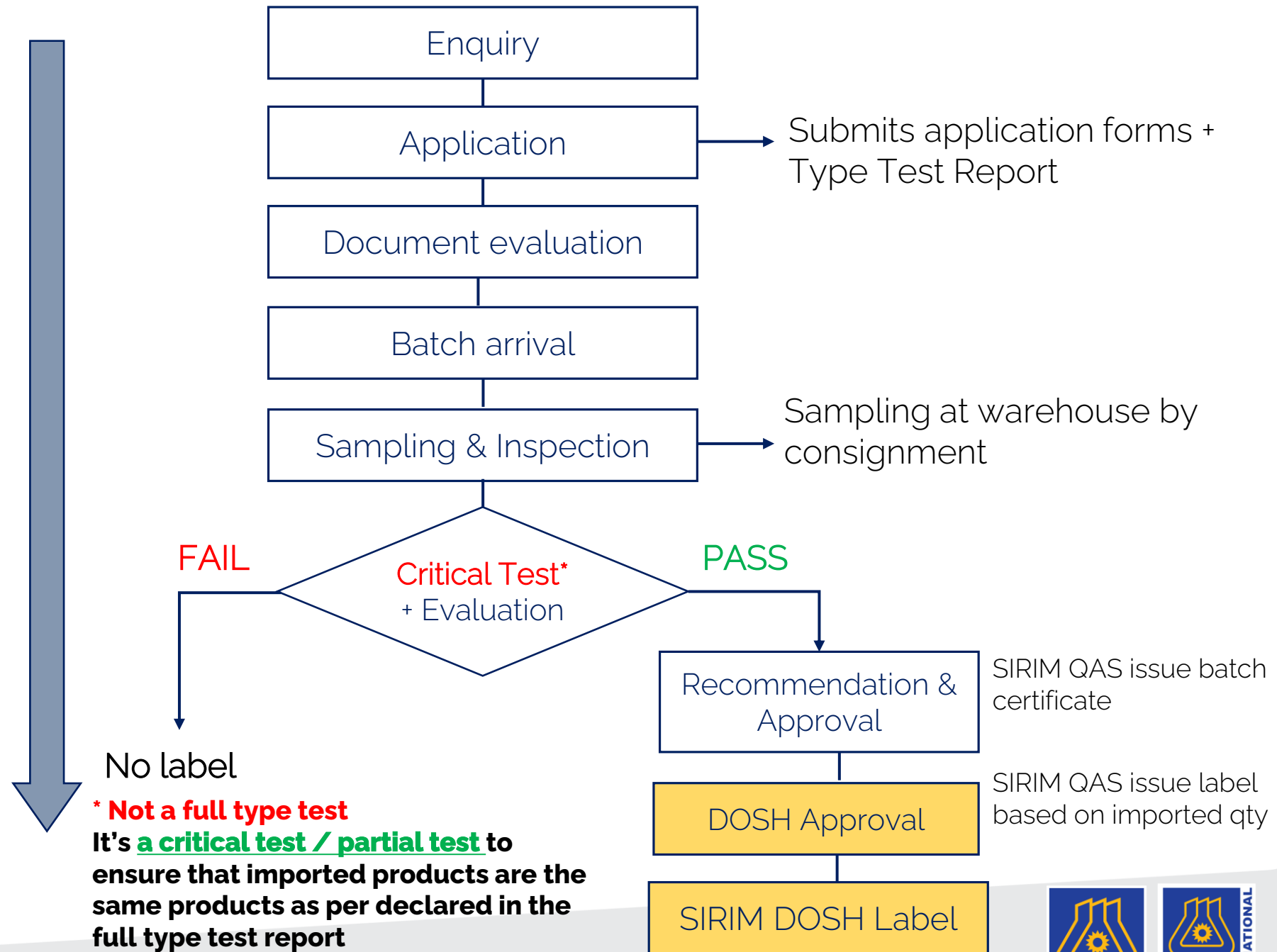
SIRIM DOSH Product Certification Type 5



SIRIM Batch Certification Type 1B



SIRIM DOSH Batch Certification Type 1B



Testing Requirement

	CWA 17553		SIRIM 40	
Type of Tests	Reusable Type	Disposable Type	Reusable Type	Disposable Type
General	Reusable/Disposable	Reusable/Disposable	Min. 3 layers	Min. 3 layers
Visual Inspection	No visible defects	No visible defects	Not required	Not required
Design & Dimensions	Visual evaluations	Visual evaluations	Visual evaluations	Visual evaluations
Packaging	Visual evaluations	Visual evaluations	Not required	Not required
Materials and Constructions	Able to withstand handling and wear throughout the lifetime as specified by the manufacturer	Able to withstand handling and wear throughout the lifetime as specified by the manufacturer	Able to withstand handling and wear throughout the lifetime as specified by the manufacturer	Able to withstand handling and wear throughout the lifetime as specified by the manufacturer
Cleaning and Drying	No visible defects	Not required	No visible defects	Not required
Surface Conditions of the parts	Free from sharp edges and burrs	Free from sharp edges and burrs	Not required	Not required
Filtration Efficiency of the Material (Particle size $3\pm 0.5\mu\text{m}$)	i) Level 90%: $\geq 90\%$ ii) Level 70%: $\geq 70\%$	i) Level 90%: $\geq 90\%$ ii) Level 70%: $\geq 70\%$	$\geq 70\%$	$\geq 70\%$
Head Harness or Ear band	No visible defects	No visible defects	Joint strength $\geq 10\text{N}$	Joint strength $\geq 10\text{N}$
Breathing Resistance and Air Permeability	$\leq 70 \text{ Pa/cm}^2$	$\leq 70 \text{ Pa/cm}^2$	$< 60 \text{ Pa/cm}^2$	$< 60 \text{ Pa/cm}^2$
Microbial Cleanliness	Not required	Not required	Not required	Maximum 30 cfu/g
Flame Spread	Not required	Not required	Class 1	Class 1

Testing Requirement Standard

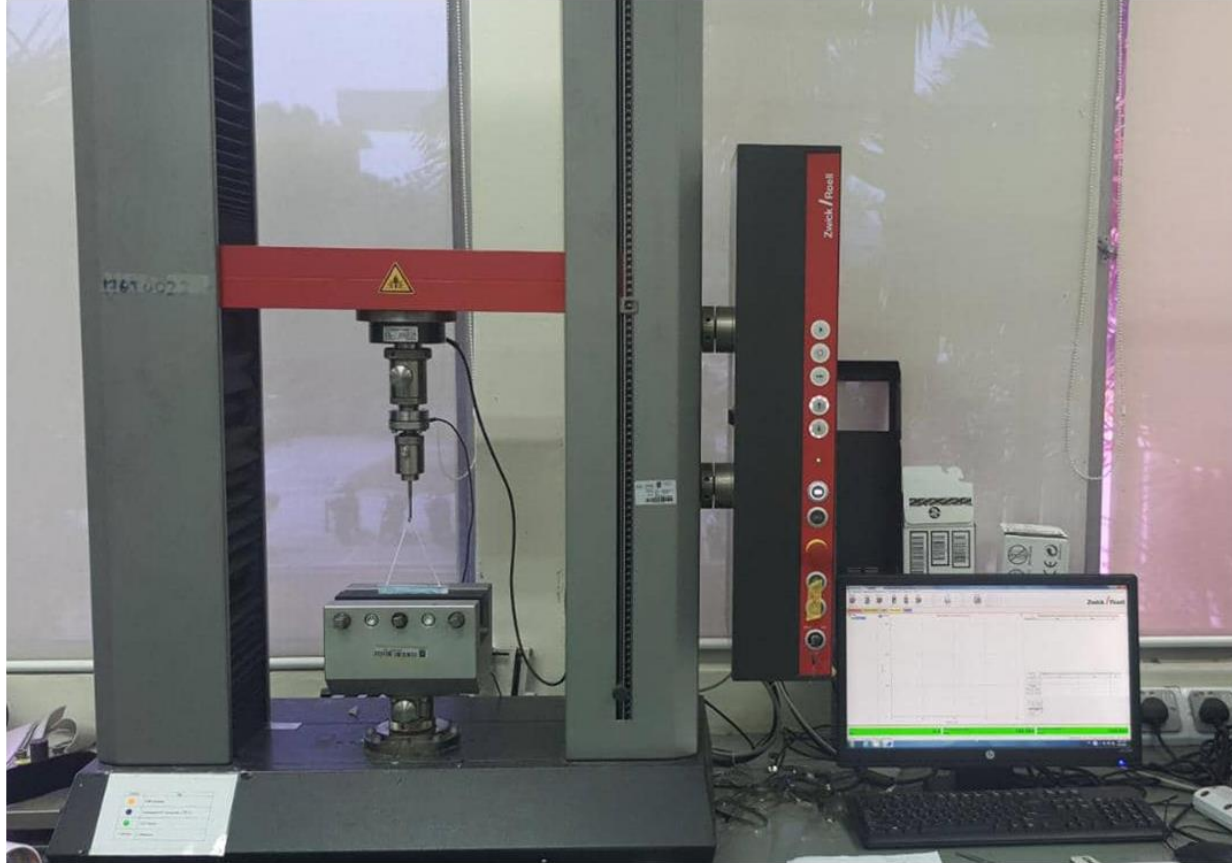
CWA 17553

Type of Tests	Requirements
General	Reusable or disposable
Visual Inspection	There shall be no defects visible (tears, detachment of the head harness, less accurate fit, deformation, wear, etc.)
Dimensions	the community face coverings dimension shall be adapted to the morphology of the user
Packaging	Community face coverings shall be packaged in such a way as to protect them against any mechanical damage and any contamination before use
Materials	The materials used for manufacturing the community face coverings shall be able to withstand handling and wear throughout the lifetime of the community face coverings, indicated by the producer
Cleaning and Drying	The community face coverings specified as reusable shall withstand the number of cleaning cycles claimed by the producer (at least 5 cleaning cycles) with a minimum washing temperature 60°C
Surface Conditions of the parts	The parts of the community face covering shall be free of sharp edges and burrs. The use of staples for connecting parts is forbidden as it poses a safety hazard to the user
Filtration efficiency of the material	Two levels of community face coverings are considered according to their filtration efficiency to particles around $3\pm 0.5\mu\text{m}$: i) Level 90%: $\geq 90\%$ ii) Level 70%: $\geq 70\%$
Head Harness	The head harness shall be designed such that the community face coverings can be easily put on and removed. It shall withstand 5 cycles of being put on and removing (donning and doffing)
Breathing Resistance and air permeability	Differential pressure of the material less than or equal to 70 Pa/cm^2 correlates to about 80 l/s/m^2 for a vacuum pressure of 100 Pa Or, Breathing resistance: i) Inhalation resistance of 2.4 mbar ii) Exhalation resistance of 3 mbar Or, The air permeability greater than or equal to 96 l/s/m^2 for a vacuum pressure of 100 Pa

Testing Requirement Standard SIRIM 40

Type of Tests	Requirements
General	Minimum 3 layers
Design & Dimensions	Design in different shapes and structure, cover the nose, cheek, chin and side of the wearer, not incorporate any inhalation/exhalation valve, can be fitted closely, free from sharp edges/burrs, ergonomics (comfort to the wearer)
Materials and constructions	Shall be able to withstand handling and wear throughout the lifetime of the community face coverings, as specified by the manufacturer
Head Harness or Ear band	Joint strength $\geq 10\text{N}$
Breathability	$< 60 \text{ Pa/cm}^2$
Microbial cleanliness	Maximum 30 cfu/g (for disposable type-single use)
Filtration efficiency	$\geq 70\%$ (Particle size around $3\pm 0.5\mu\text{m}$)
Flame spread	Class 1
Cleaning	Reusable mask shall withstand the number of cleaning cycles claimed by the producer (at least 3 cleaning cycles) with a minimum washing temperature 60°C (No damage such as deformation, well fitting, wear, etc)

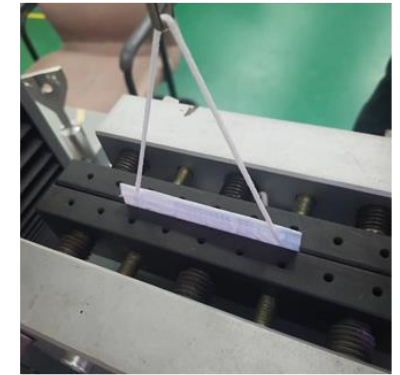
Head Harness (Joint Strength)



SIRIM 40 Clause 5.2

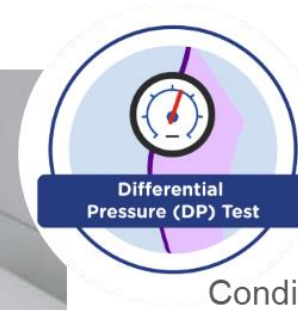
Speed: 100mm/min

Hook mounted on upper clamp



5 Test Specimens

Breathing Resistance / Breathability



Air permeability of the mask, measured by determining the difference of pressure across the mask under specific conditions of air flow (8 L/min)

Conditioning: $21 \pm 5^{\circ}\text{C}$, $85 \pm 5\%$ RH for min. 4 hours

Breathability: BS EN 14683 Annex C

Other test method:

Breathing Resistance:

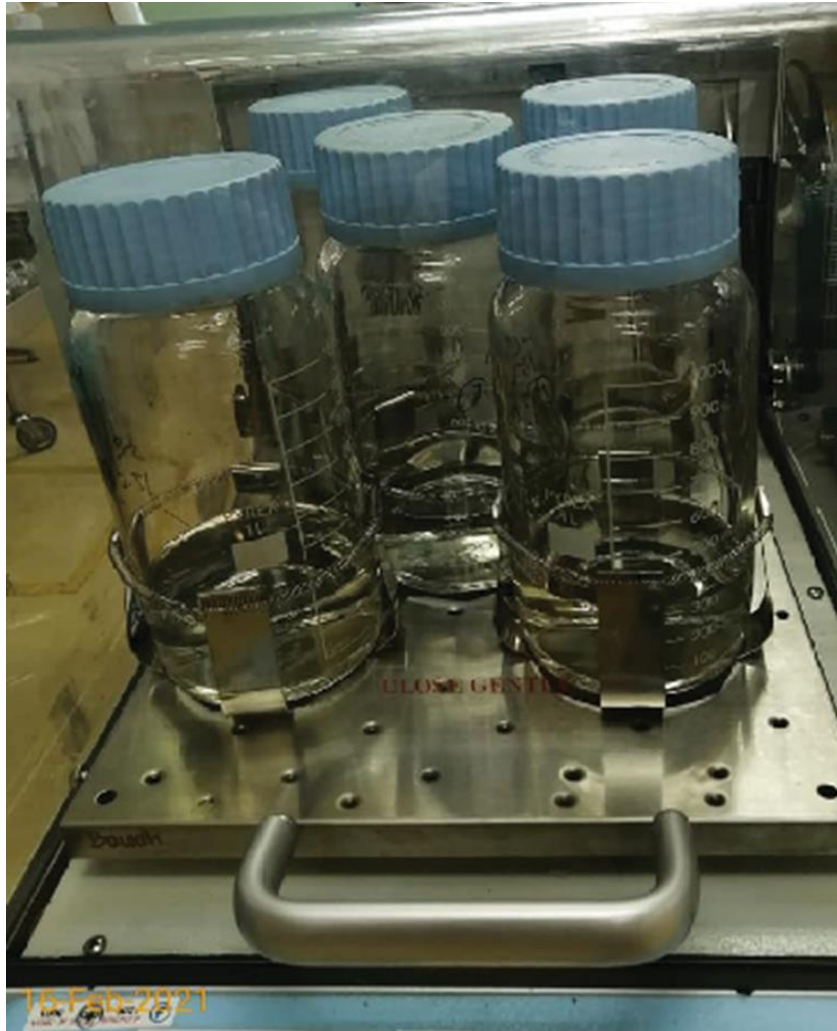
EN 13274-3 (Flow 95 L/min)

Air Permeability:

EN ISO 9237

5 Test Specimen

Microbial Cleanliness



MS/BS EN 14683 Annex D, EN ISO 11737-1

Freedom from population of viable micro-organisms on a product and/or a package

Quality control of process during manufacturing

Ensure the masks produced are clean

5 Test Specimens

Filtration Efficiency

Particle size around 3.0 ± 0.5 microns



ASTM F 2299

Air flow: 28.3 L/min

Aerosol: suspended latex spheres

Conditioning: $21 \pm 3^\circ\text{C}$, 30 to $50 \pm 5\%$ RH



MS/BS EN 14683 Annex B

Aerosol: *Staphylococcus aureus*

Conditioning: $21 \pm 5^\circ\text{C}$, $85 \pm 5\%$ RH for min. 4 hours

Other test method:

EN 13274-7

EN ISO 16890-2

EN ISO 21083-1

Recommended Aerosol:
Solid particle – NaCl, PSL,
Talcum powder
Liquid particle – Oil
paraffin, DEHS

Velocity 6 ± 1 cm/s

5 Test Specimens

Flame Spread



16 CFR Part 1610



Characteristics of a material that pertain to its relative ease of ignition and relative ability to sustain combustion

16mm flame impinge on a specimen mounted at a 45° angle for 1 second

specimen is allowed to burn its full length or until it the stop thread is broken, a distance of 127mm

5 Test Specimens

SIRIM Label



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.



SIRIM label for packed product

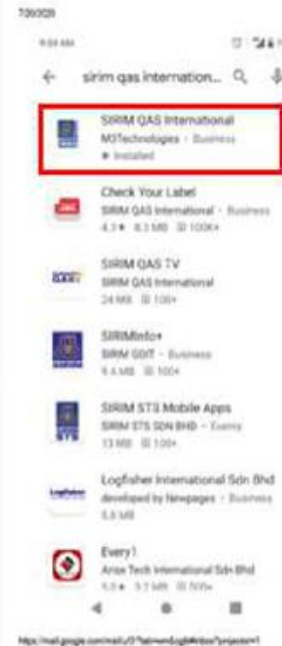


SIRIM label for individual packed product

SIRIM QAS Mobile App



Download SIRIM QAS International Sdn Bhd app in Google play store or Apple App Store



App downloaded into your mobile phone as shown below



Click on the app and launch of SIRIM QAS app




Click on the first right, right button "Check SIRIM Label"




SIRIM QAS Mobile App

Click here for QR Scan




 SIRIM QAS International ...

Serial No:

QR SCAN 




 SIRIM QAS International ...

Serial No:

Product Status
CERTIFIED

Type of Product
REUSABLE OR DISPOSABLE COMMUNITY
FACE COVERINGS

This Label Assigned To
HONSIN APPAREL SDN. BHD.
[View Details](#)

QR SCAN 



SCHEDULE OF FEE

Schedule of Fee (Certification Type 5)

No	Description	Fee (RM)	Fee (USD)
1	Application Fee	500	160
2	Evaluation Fee	2000	640
3	License / Renewal Fee (yearly)	600	200
4	Audit Fee	From 1200	From 1280
5	Incidental	As charged where applicable for accommodation, living allowances and flight ticket / transportation / mileage	

**Cost for label per piece = 20cent per piece

Schedule of Fee (Type 1B)

No	DESCRIPTION	FEE (RM)	FEE (USD)
1	Application fees	500	160
2	Evaluation fees	1000	320
3	License / Renewal Fee per Year	-	-
4	Warehouse Verification Fee	From 1200	From 1280
5	Incidental	As charged where applicable for accommodation, living allowances and flight ticket / transportation / mileage	
6	Verification Testing Fee (per model) : Non-Medical Face mask i) Breathability ii) Particle Filtration SIRIM DOSH Face mask i) Leakage – Penetration of Filter Material ii) Breathing Resistance	1200 1800 1500 500	380 570 480 160

Schedule of Fee (Testing)

Non-Medical Face Masks

Testing Fee (per model) : a) Breathability b) Microbial Test c) Particle Filtration d) Flame Spread e) Cleaning f) Earband	Total : RM4900
--	-------------------

SIRIM DOSH Face Masks

Testing Fee (per model) : a) Leakage – Total Inward Leakage b) Leakage – Penetration of filter material c) Flammability d) Carbon dioxide content of inhalation air e) Head harness f) Field of vision g)Exhalation valve (If applicable) h)Breathing resistance i) Clogging	TOTAL : Non Valve : RM7500 Valve : RM10000
---	--

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

Thank You!

You can find us at:

cserviceqas@sirim.my

Tel: +603-5544 6400

Any enquiry you may email to:-

Product Certification:

jailani@sirim.my/farihan@sirim.my/ramzi@sirim.my

Testing :

mdrizal@sirim.my

