Reference Specification of Surgical Filter Mask, Ear-loop Type

M : Mandatory Requirement **D : Desirable Requirement** The product offered shall incorporate the following components / requirements / features.	Seller **MUST** indicate below the extent of compliance of the offered product(s) by filling in "**Yes**" or "**No**" and **provide the specifications of the offered product(s)** point by point against each clause of the Reference Specifications.

			Yes	**No (provide details)**
			(Please tick as appropriate)	
1	**General Description**			
1.1	It should be rectangular shaped containing three-fold pleats which open to form a cup-shaped mask covering the nose and mouth areas of the face with low breathing resistance and excellent filter characteristics.	(M)	√	
2	**Material Standards**			
2.1	The masks should be composed of latex free, fibreglass free and hypoallergenic material. Masks should be odourless, free of lint and offensive smell.	(M)	√	
2.2	Outer Facing: Non-woven fabric with fluid repellent property. Green or blue in colour.	(M)	√	
2.3	Filter Medium: White melt blown high quality filter media made of polypropylene or similar materials.	(M)	√	
2.4	Inner Facing: White non-woven fabric with fluid repellent property. Void of dyes, chemicals and inks. Soft and odourless.	(M)	√	
2.5	Nose Piece: malleable flat aluminium or polyethylene covered steel wire.	(M)	√	
2.6	Elastic Ear Loop: Knitted Polyester elastic / Polyurethane covered with Nylon & Polyester Yarn.	(M)	√	
3	**Measurements:**			
3.1	Length : 18cm ± 10%	(M)	√	
3.2	Width : 9cm ± 10% (M) (Not less than 16cm when fully extended)	(M)	√	
3.3	Number of pleats: 3	(M)	√	
3.4	Nose Strip : Not less than 100mm x 2mm	(M)	√	
3.5	Elastic band : Standardized ear-loop for optimal periphery seal. Ample in length, yet soft and strong for maximum comfort. Suggested inner circumference : 14.5cm	(M)	√	
4	**Appearance**			
4.1	Free of holes, cuts, tears or any other imperfections or defects that will detract the appearance of the mask or impair its serviceability.	(M)	√	
4.2	The inner facing fabric of the mask is folded over the longer sides of the mask ultrasonically welded to prevent fabric delamination.	(M)	√	

			Yes	No (provide details)
			(Please tick as appropriate)	
4.3	The elastic band is ultrasonically welded at each corner.	(M)	√	
4.4	The nose strip should be provided to afford maximum comfort and maintaining the contours of the nose of wearer.	(M)	√	
4.5	The nose strip should be put into the centre position of the mask body completely and prevent protruding out easily.	(M)	√	
4.6	Top and bottom of the mask body shall be ultrasonically welded completely.	(M)	√	
4.7	The short sides of the folded mask are secured by ultrasonically welded.	(M)	√	
5	**Filtration Efficiency, Air Exchange Pressure Test, Fluid Resistance & Flammability Class** Independent accredited laboratory report to prove the product compliance has to be submitted.	(M)	√	
5.1	The mask shall have a bacterial filtration efficiency (BFE) rate of not less than 95 percent efficiency with mean particle size of 3.0 microns. Testing Method: ASTM F2101-01 Standard Test Method for Evaluating Bacterial Filtration Efficiency of Surgical Masks Using a Biological Aerosol of Staphylococcus aureus; or equivalent.	(M)	√	
5.2	The mask shall have a particulate filtration efficiency (PFE) rate of not less than 95 percent efficiency with mean particle size of 0.1 micron. Testing Method: ASTM F2299 Penetration by Particulates Using Latex Spheres; or equivalent.	(M)	√	
5.3	The value of the Differential Pressure (Delta P) test should not greater than 4.0 mm H2O/cm2. Testing Method: MIL-M-36945C 4.4.1.1.1 Method 1 Military Specifications: Surgical Mask, disposable; or equivalent.	(M)	√	
5.4	Synthetic Blood Penetration Resistance should be ≥ 80 mmHg Testing Method: ASTM F 1862: Standard Test Method for Resistance of Surgical Mask to Penetration by Synthetic Blood; or equivalent.	(M)	√	
5.5	Flammability class: Class 1 or Class 2 Testing Method: CPSC CS-191-53 Flammability Test Method (16 CFR 1610) Standard for Flammability of Clothing Textiles; or equivalent.	(M)	√	
6	**Shelf-life**			
6.1	The shelf-life of Goods shall not be less than three (3) years from the date of manufacturing. Please specify the shelf life of goods offered : 3 years	(M)	√	

			Yes	No (provide details)
			(Please tick as appropriate)	
6.2	Goods with manufacturing date exceed eighteen (18) months will not be accepted upon delivery to site.	(M)	√	
7	**Each container (individual inner box)**			
7.1	Each container shall be legibly marked with the following information:			
7.1.1	The manufacturer's name or trade mark or recognized symbol	(M)	√	
7.1.2	Description of the content	(M)	√	
7.1.3	Lot Number	(M)	√	
7.1.4	Expiry date in month and year (e.g. MM/YY)	(M)	√	
7.1.5	Expiry date in day, month and year (e.g. DD/MM/YY)	(D)	√	
7.1.6	Manufacturing Date in month and year (e.g. MM/YY)	(M)	√	
7.2	Individual container shall be properly sealed (e.g. wrapped by shrink wrap or sealed with a sticker) to ensure the quality and quantity of Goods before use.	(M)	√	
8	**Packaging**			
8.1	The package should be free from foreign particle.	(M)	√	
8.2	10 boxes (50 pcs/box) of Goods per carton box	(D)		40 boxes per carton
9	**The transport container (outer carton)**			
9.1	The transport container (outer carton) shall be legibly marked with the following information:			
9.1.1	The manufacturer's name or trade mark or recognized symbol	(M)	√	
9.1.2	Description and colour of the Goods	(M)	√	
9.1.3	Lot Number	(M)	√	
9.1.4	Expiry date in month and year (e.g. MM/YY)	(M)	√	
9.1.5	Expiry date in day, month and year (e.g. DD/MM/YY)	(D)	√	
9.1.6	Manufacturing Date in month and year (e.g. MM/YY)	(M)	√	
9.1.7	Country of origin	(M)	√	
9.1.8	Recommended storage conditions. Please provide information for reference.	(M)	√	
9.1.9	Weight of transport container and Goods. Please provide information for reference.	(D)	√	
9.2	Proper packaging and sealing method to reinforce the transport container (e.g. by sealing the 6 edges with cellulose tape)	(M)	√	

			Yes	**No (provide details)**
			(Please tick as appropriate)	
9.3	The packaging arrangement of individual containers in the outer carton shall be designed to prevent the Goods from being affected by moisture outside (e.g. inner layer pouch for every 10 boxes or individual container wrapped by shrink wrap).	(M)	√	
10	**Submission of Documentary Evidence** Sellers are requested to submit with quotation copies of 2 sets (each set in separate file) of the following for consideration or otherwise offers will not be considered:		√	
10.1	Certified true copy of report by an independent laboratory that the product offered conforms to Clause 5 of this Specification. The laboratory report shall be conducted within twenty-four (24) months from the date of submission of quotation offer.	(M)	√	
10.2	Certified true copy of **Manufacturer Licence** or Permit issued by the Government or Health Authority of the country of origin to certify that the manufacturer is a legitimate manufacturer in the manufacture of the Goods being offered. If Manufacturer Licence or Permit is not necessary in that country of origin, Tenderers shall declare explicitly in the tender and submit a certified true copy of Manufacturer's statement to support. For manufacturer originated in China, the required Manufacturer Licence or Permit is referred to "Medical Device Manufacturing Enterprise License" (in Chinese: 醫療器械生產企業許可証) which is specified in Regulations for the Supervision and Administration of Medical Devices, State Food and Drug Administration, China.)	(M)	√	
10.3	Certified true copy of **ISO 13485** (latest version) Standard certificate issued by independent and authorized certification institute to certify that the Manufacturer obtains registration under ISO 13485 (latest version) Standard in production and quality assurance system for the Goods being offered.	(M)	√	

			Yes	**No (provide details)**
			(Please tick as appropriate)	
10.4	Certified true copy of Manufacturer's **Quality Assurance / Control Report (QCR)** of the Goods being offered. Tenderers are required to submit a QCR of the Goods manufactured in the most recent batch to serve as a sample of the report for inspection and evaluation. *Successful contractor shall submit the QCR of goods to hospitals for inspection during delivery. A copy of the QCR of each batch of goods shall be submitted to PMMS, HAHO for record.*	(M)	√	