

To all participant of tender no: ICB/PSA6/Covid 19 supplies/MOH/MS/07/20

Subject : Amendment and Response for Requested Clarification

Clarification is made to the tender reference number mentioned above as follows:

1. In technical specification for item number 1,2,3,4 and 5 are amended as follow:

For Item No 1 - Reusable Face Mask

1. Technical Specification for Non-Clinical Face mask (For Public Use Only)

1.1 Description

Non-Clinical Face mask- is non-clinical personal protective equipment (PPE) that reduces the chance of exposure to COVID-19 and other small particles by protecting communities from inhaling “droplets” of infectious agents. **Non-clinical PPE** can be made in two and three layers with technical specification as listed below.

1.2 Technical Specification

Characteristic	Technical Specification		
Material Composition	Mask body- three layers	Outer Layer	woven Polyester fabric, GSM- 120-160
		Filter Layer	Nonwoven (PP, PET), GSM < 80
		Inner Layer	knitted Cotton fabric, GSM <120
	Mask body- three layers	Outer Layer	woven Polyester fabric, GSM- 140-180
		Inner Layer	knitted Cotton fabric, GSM -150-180
	Nose clip	Fusing materials- ማክራሚን, Aluminum(if locally available)	
Elastic Band	Polyurethane + Polyester and/or any textile fabric		
Color	Mask	Inner layer any light colour and outer layer dark colour	
	Elastic Band	Any colour	
Nose Clip Style	Flat Nose Clip		
Shape	Cone/ round/ oval- do not collapse against the mouth		

Dimension	Body Size	Length	131 mm
		Width	114.5 mm
		Height	50 mm
	Nose Clip	Length	88 mm
	Ear loop	Free size elastic ear loop	

Note: -

- Sum of layers GSM in single mask can be 300 -350 (More construction may create breathing difficulty and lower may create fluid and aerosol filtration limitation)
- Elastic twill tape which hold with ear shall be relax enough for longer duration
- utilization All material used for non-clinical mask preparation shall be allergic free and skin friendly



1.3 Non-clinical Face Mask:- Fabric, trims and accessories quality requirement and Test Method

S/No	Inputs Type	Parameters	Specification	Test Method	Sample Size
1	Fabric	• Warp	30 Ne/	ISO and ASTM	
		• Weft	30 Ne/		
		Weight of fabric (GSM)	As per technical specification		
		Tensile strength in N			
		• Warp direction	500N		
		• Weft direction	450N		
		Abrasion Resistance/5000rubs/	4-5		
		Color fastness to Light	>5		
		Color fastness to washing	4-5		
		Color fastness to Dry Rubbing	4-5		
		Color fastness to Wet Rubbing	4		
		Color fastness to Perspiration	4-5		
		Color fastness to chlorinated water (optional)	4-5		
		Water Repellency (optional)	Good		
Dimensional stability (% warp x fill) (After 3 washes)	<5				
2	Sewing thread	Material composition/blend	100% polyester		
		Yarn count (D)	40/2		
		Fabrication/	Double twist		
		Tensile strength in N			
		Color fastness to Light	>=6		
		Color fastness to washing	4-5		
		Stitch per inch	10-12		
3	Twill tape elastic	Material composition/blend	90% polyester 10% spandex		
		Yarn count (Ne)	50Ne		



		Color fastness to Light	≥ 6		
		Color fastness to washing	4-5		
		Elasticity recovering) (After use & washes)	8+-2		
4	Non-woven(PP, PET)	Material composition	100% polyester/PP		
		Dimensional stability (% After wear & washes)	<1		
5	Poly bag	Material composition	Plastic		
		Size (optional)	(4*6) and (5*8) inch		
6	Carton	Size (optional)	Lx W x H (38*30*25) cm		



For Item No 2 – Surgical Face Mask

Technical Specification for surgical, type IIR, level 2, S.U., non-sterile, ear loop

Description

A surgical face mask is used to protect both surgical patients and operating room personnel from the transfer of microorganisms, body fluids and particulate material and also it should protect from germs coming from patients side.

Technical Specifications

Material Characteristic	Technical Specification			Test Method	References	
Material Composition	Mask body	Outer Layer	Spun-bonded non-woven polypropylene fabric, GSM 18-20, Width-180mm	NIOSH procedures	WHO	
		Filter Layer	Melt blown non-woven polypropylene fabric, GSM 25-30, Width-180mm			
		Inner Layer	Spun-bonded non-woven polypropylene fabric, GSM 25-30, Width-200mm			
	Nose clip	Aluminum				
	Elastic Band	Polyurethane + Polyester or Polyester with Lycra			ISO1833-1	
Color	Mask	White				
	Elastic Band	Yellow or white				
Thickness	80 Micrometers (um), ±10%			ASTM D1777		
Nose Clip Style	Flat nose clip					
Dimension	Body Size	Length	17.5cm	ASTM D668-12		
		Width	9.5cm			
		Height	150mm OR 15cm			
	Nose Clip	Length	88 mm			

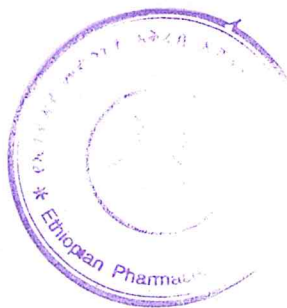


Quality Requirement, Test Method and required equipment

S.N.	Technical parameters	Requirement limits	Int. standards		Test equipment required
1	Bacterial filtration efficiency In Vitro (BFE)	BFE \geq 98%	ASTM F2101-19	EN14683 Rating – Type IIR Standard.	Bacterial Filtration Efficiency Test Apparatus, autoclave, <i>Incubator</i> , <i>Orbital Shaker</i> , <i>Refrigerator etc. see table 2</i>
2	Particle filtration efficiency	PFE \geq 98% @ 0.1 micron	ASTM F2299/F2299M-03(2017)		Bacterial and Aerosol Filtration Efficiency Test Apparatus
3	Breathability - Delta P	< 5.0 mm H ₂ O/cm ²	ASTM D737; (T2)		Differential Pressure Air (Delta P) Permeability Tester or Apparatus for measuring air resistance
4	Fluid Resistance	120 mmHg	ASTM F1862/F1862M-17		Fluid Resistance Test Apparatus
5	Flame Spread	Class 1	ASTM levels 1,2,3		Flammability Tester

Note: all testing apparatus and detail reagent requirement will be attached in Annex 1

- Pleat style with ear loops or ties
- Protective four-layer protection shall cover Nose, mouth and Chin with ear loop
- Splash resistant layer protection against blood and bodily fluids
- Color variety: with light and brighter colors
- Shape: flat pleated
- Reusability disposable product, single use only
- Fluid-resistant medical or surgical mask high fluid resistance. Good breathability.
- Internal and external faces should be clearly identified.
- Structured design that does not collapse against the mouth (e.g. duckbill or cup shape)
- Quality compliant with standards, including for fluid resistance level and breathability (differential pressure): EN 14683 type IIR performance, or ASTM f2100 level 2 or level 3, or equivalent.
- For Surgical Mask, Type IIR - EN14683., Disp , it require 100% import finished pp material as there is no technology in fabric production (non-woven but garment manufacturing can be done in Ethiopian.



For Item No 3 – N95/FFP2 Respiratory Mask

Technical Specification for Respirator, Mask, FFP2/N95/KN95, type IIR, S.U., UN-Valved , Nose Clip

Description

A **respirator** is personal protective equipment that prevents the wearer from inhaling aerosols (dust, smoke, mist) as well as vapors or gases (disinfectants, anesthetic gases) that are health hazards. It protects the wearer from airborne infectious agents i.e. against contamination by a virus such as corona virus, SARS, H1N1, etc.

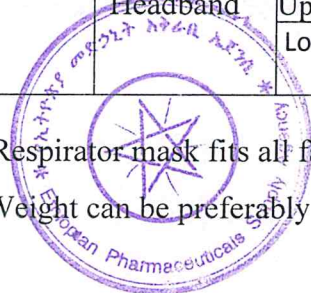
It should be noted that respirators also protect those who wear them from inhaling “droplets” of infectious agents. Respirators can be disposable or reusable. In the second case, it is possible to replace the filter when it is full.

Technical Specification

Material Characteristic	Technical Specification			Test Method	Remark
Material Composition	Mask body	Outer Layer	Spun-bonded Fabric	ISO1833-1	Fabrics can be produced from a thermoplastic polymer such as polyester, nylon, polypropylene, or polyethylene
		Filter Layer	Melt blown Fabric		
		Inner Layer	Needle bonded fabric		
	Nose clip	Aluminum			
	Elastic Band	Polyurethane + Polyester or Polyester with Lycra		ISO1833-1	
Color	Mask	White			
	Elastic Band	Yellow or white			
Nose Clip Style	Flat Nose Clip				
Dimension	Body Size	Length	131 mm	ASTM D668-12	
		Width	114.5 mm		
		Height	50 mm		
	Nose Clip	Length	88 mm		
	Headband	Upper Length	300mm		
		Lower Length	280mm		

Note: - Respirator mask fits all face shapes, without inspiration/expiration air-leakage

- Weight can be preferably light weight (20gm)



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Quality Requirement and Test Method

S.N	Quality parameter	Standard value	Description	Test method
1.	Max. total inward leakage	8%	10 individual wearer arithmetic means	EN 149:2001 A1:2009
		11 %	At least 46 out of the 50 individual exercise results	
2.	Min. Air borne particles filtration efficiency	94%	The filter penetration after loading the filter with 120 mg paraffin oil	
3.	Flammability	5 sec	Shall not burn or not to continue to burn for more than 5 s after removal from the flame.	
4.	Breathing Resistance	0.7 mbar, During Inhalation	At 30 l/min	
		2.4 mbar, During Inhalation	At 95 l/min	
		3 mbar, During Exhalation	At 160 l/min	

Required Test Equipment

1. Particle Filtration Efficiency Tester:- **Need to be purchased**
2. Flammability Tester:- **We have already this equipment**
3. Breathing resistance tester:- **Need to be purchased**

Note: - Detail specification of equipment, Apparatus and reagents required need to be further work out.



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For Item No 4–Cover All

Coverall

Description

Disposable coverall are designed to be discarded after a single use and are intended to cover the whole body from the head to shoes; it is constructed from composite of non-woven fabric, which is a spun bond and melt blown composite products, or of the SSMMS type (its structure comprises of three spun bond layers interlaid with two melt blown layers) with high strength, good filter performance, without adhesive, non-toxic and so on.

S.N.	Characteristics	Specification or Quality Requirement	Testing Method	Reference
1	Description	1.Single Use, Fluid Resistant, Disposable 2.Impermeable to Pathogens ,Infectious Diseases(non-airborne),and Large amounts of fluid exposure Over long periods 3.Low Linting 4.Completely Safe for people engaged in care and treatment 5. Non-Sterile		
2.	Material composition	polypropylene textile adhesive fabric, new polyester fiber, polymer coated fabric, SMS nonwovens, polyethylene breathable film/nonwoven composite or poly tetra fluoro ethylene (PTFE)	ES ISO 1833-11:2012	
2	Covering size	Head to Feet Height 66-69 Inch (167-176 cm) Chest 33-36 inch (84-92cm)		
3	Viral penetration resistance	Material shall be resistant to viral penetration at 2 psi (13.8 kPa) pressure	ASTM F1671 Viral Penetration Test	CDC
	Blood Penetration resistance	Material shall be resistant to viral penetration at 2 psi (13.8 kPa) pressure	ASTM F1670 Synthetic Blood Penetration Test	CDC



Common test standards and requirements are as follows:

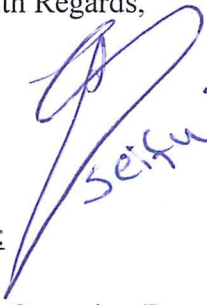
Test project	EN 13795	NFPA 1999	ISO 16603, ISO 16604
Liquid barrier performance	EN 20811, Hydrostatic test	ASTM F135, Over Liquid Integrity	—
Synthetic blood penetration	—	ASTM F1359, Over Liquid Integrity	ISO 16603
Microbial filtration	EN ISO 22612, EN ISO 22610	ASTM F1671, Phi-x-174	ISO 16604, Phi-x-174

For Item No 5– Biohazard Waste Bag

Disposal bag for bio-hazardous waste, 30x50cm, with "Biohazard" print, autoclavable polypropylene. 50 or 70 micra thickness.

NB:- All bidder should be submit compliance sheet based on the above technical specification and as we know the tender closing and opening date mentioned under ITB 26.1 and ITB 29.1 are May 20,2020G.C.

With Regards,


Seifu Isa



Cc:

- Operation Deputy Director General
- Tender Management Directorate
- Chemical and Medical Supplies case team

EPSA