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No. Pur. **6(1)/2020-20/TENDER** **Dated:**

ADDENDUM

THE BELOW MENTIONED ADDENDUM REFERS TO THIS OFFICE TENDER NO. PUR. 6(1)/2020-21/TENDER DATED: 14.07.2020

The following items are added with the existing list of items

10. Surgeon Gown for HIV Protection – 50,000 Nos.

11.Surgical or Gynaecological Rubber Gloves Size 7” – 4,00,000 Nos

12. Surgical or Gynaecological Rubber Gloves 7.5” – 4,00,000 Nos

13 Surgical or Gynaecological Rubber Gloves 8” - 2,00,000 Nos

14. Reusable Face Shield to protect healthcare workers – 5000 Nos.

15. N95/FFP2 Mask-50,000 Nos.

The detailed specification are listed below:-

Specification of SURGEON GOWN FOR HIV PROTECTION

Gown Type	Surgeon gown for HIV protection
Colour	Medical Blue/green/volet
Disposable	Yes
Breathable	Yes
Antistatic Properties	Yes
Impervious to fluids	Yes
Reinforced	Yes
Sterilized	Yes
Method of Sterilization	ETO

DIMENSIONS

Gown Width	100 centimeter-125cm
Gown Length	195 centimeter-200cm
No of belts to tie (pair)	4
Length of each tying belt stitched(cm)	150 centimeter-160cm
Width of tying belt (cm)	5 centimeter

MATERIAL

Material used for gown	Non woven SMS
Composition of Non woven Reinforced Material	SMS+ Poly coated
Reinforced critical zones (front and sleeve up to elbows) to provide 100 % protection against any amount of fluid	Yes
GSM of Non woven Fabric (g/m2)	68 and above

CONSTRUCTION

Closing at neck	Hook and loop/Velcro Fastener with Piping of non woven material stitched to raw edges of Neck opening extending at both ends for tying
Pair of Disposable absorbent hand wipes	Yes
Sleeve Type	Raglan sleeve, full sleeve
Cuff end	With knitted cuff of at least 10 cm width
Wrap Around type	No

PACKING

Type of Packing	Sterile pack, must be double packed with outer pouch must be peel off made of Medical Grade paper
Type of Wrapping	Set in sleeve

CERTIFICATION

AAMI Protection level	Level IV
Certification	ISO 13485:2016
Submission of test report clearly specifying the nomenclature of fabric, Method of sterilization and AAMI protection level in addition to other parameter to the buyer on form 39 or from NABL/ILAC accredited or Central Government Lab to prove conformity of products to the specification	Yes
Product conformity certificate to be furnished to	Yes

buyer at the time of supply	

SPECIFICATION FOR SURGICAL OR GYNAECOLOGICAL RUBBER GLOVES

Type of Surgical Glove	Disposable surgical or Gynaecological rubber gloves conforming to IS 13422 (1992)-powder free
Sterility	Sterilized
Finish of outer surface	Rough
Colour	Translucent
Colouring Agent	No
Use	Single
Shelf Life in years	5
The product should have at least 2/3 rd of the total shelf life available at the time of supply	Yes

STANDARDS

Conformity to Indian Pharmacopoeia for Sterility (if Sterilized)	Yes

DIMENSIONS

Size (Number)	7,7.5,8
Thickness	0.24 millimetre

MATERIAL

Material	Natural Rubber Latex
Lubricant / Material used for surface treatment	Corn Starch Powder
Powdered	No

PACKING

Packed to maintain sterility during shipping & storage and permit opening without contamination of the gloves	YES
No. of Gloves in a pack	2 (pair)

MARKING

ISI Marked	YES
CM/ L No.	6105044

REPORTS

Submission of Test Reports on Form 39 or from Central Govt./NABL/IL AC acredited Lab to prove conformity to the specifications at the time of supply	ISO 9001-2008

Specifications for reusable face shield to protect healthcare workers from COVID 19

Quantity required – 5000 (Five thousand)

1. The transparent front part of the face shield should be optically clear and should not produce visual distortions at the centre or the sides.
2. The thickness of the transparent sheet should be a minimum of 2mm and above
3. The transparent part should be made out of unbreakable material like polycarbonate that will not create splinters on impact.
4. The transparent front part should have a hinge mechanism (preferable) to manually raise it over the head if required but should not vibrate or wobble even with quick head movements.
5. All materials should be compatible with a wipe (or spray) disinfection with alcohol (Ethyl alcohol, 2 propanol, 1 propanol combinations) or a 1% hypochlorite solution. Wiping with a soft cloth or tissue paper should not cause scratches.
6. The transparent part should have a gap of at least five cm from the forehead and about 7 cm from the nose so that it remains free of contact with an N95 mask and any vapor generated while respiring does not fog the transparent shield.
7. The transparent part should give protection to splashes to the eyes and should extend about 5 cm behind the outer edge of the eye but not cover the ears. It should also extend below the jaw for about 5 cm but should not hinder neck movements when the head is flexed maximally.
8. The frame that fits on the head should not have sponges that can absorb and retain sweat or cleaning agents.
9. The frame that fits on the head and forehead should have padding that is soft on the scalp and forehead.
10. The entire weight of the face shield should not exceed 250 grams
11. The frame that fits on the head should have a mechanism for adjusting to the user's head circumference (preferable) so that it does not slip down. This mechanism should not be based on hook and loop (Velcro) patches that accumulate lint and are difficult to clean.

Specifications for N95/FFP2 mask
Quantity required – 50,000 nos (Fifty thousand only)

1. A particulate respirator with filtration efficient of 94% or more against particulate aerosols > 0.3µm.
2. It should be disposable and be able to fit for wide range of face sizes. It would be preferable to come in various sizes (not compulsory)
3. The nose clip should be adjustable to allow moulding to fit on the nose. It would be preferable to have a foam on the inner surface to allow good fit on the nose
4. Ultrasonically/ thermal/ stapled welded head bands (adjustable preferred) and should be fitted robustly.
5. Should meet the NIOSH 42 CFR84 N95 standards or FFP2 (Europe EN149-2001) standards certified by appropriate labs.
6. The mask should not have a valve and either be a flat fold or cup shaped.

A sample of the mask need to be submitted within 10 days of closing of the tender.