

Bihar Medical Services & Infrastructure Corporation Limited

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CORRIGENDUM-IV

Tender for Rate Contract and supply of Drugs/ Medical Devices/ Consumables for different Healthcare facilities of State of Bihar in view of Pandemic Emergency situation prevailing due to Novel Corona Virus (COVID-19) outbreak for the year 2020-2022

Notice Inviting Tender Ref No.: - BMSIC/MEDICAL DEVICE/CONSUMABLES/20-01
Dated: 14/07/2020

(Only through E- Tender on website: -www.eproc.bihar.gov.in)

Bihar Medical Services and Infrastructure Corporation Limited (BMSICL) has invited e-Bids from the interested parties for "Tender for Rate Contract and supply of Drugs/ Medical Devices/ Consumables for different Healthcare facilities of State of Bihar in view of Pandemic Emergency situation prevailing due to Novel Corona Virus(COVID-19) outbreak for the year 2020-2022", vide Notice Inviting Tender No.- BMSIC/MEDICAL DEVICE/CONSUMABLES/20-01. Detailed tender document containing eligibility criteria, selection mechanism, other terms and conditions are available on the website www.eproc.bihar.gov.in.

After considering the suggestions/ queries received from the prospective bidders during and after Pre-Bid meeting the clarifications/ amendments with regard to the tender document have been made as per Annexure-A(Page No2-4), amendments with regard to the product list have been made as per annexure-B (Page No-5)(Revised Tendered Product List) and amendments with regard to the product Technical Specification have been made as per annexure-C (Page No6-10)of this Corrigendum-IV. All other terms and conditions along with the tender schedule as mentioned in corrigendum- III shall remain unchanged. All those bidders, who have already submitted their bids, shall have to resubmit their bids in the light of the above mentioned amendments.

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ANNEXURE-A (Amendments in Bid Clauses)									
Sl. No.			Present	t Clause	Amended Clause				
1.	Earn Dra Man and issu	nest M ft/ Ba nagin I Infr n ed fr	Money Deposit is ank Guarantee day Director, Biharastructure Corom any Schedul	is required to submit n the form of Deman rawn in favor of ar Medical Services poration Limited ed/ Nationalized band following table: - EMD Amount Rs 1,00,000/- (One Lakh only) Rs 2,00,000/- (Two Lakh only) Rs 3,00,000/- (Three Lakh only)		Clause 3(b) may be read as follows: - The bidder is required to submit Rs. 20 Lakh only irrespective of the number of items to be quoted, as Earnest Money Deposit in the form of Demand Draft/ Bank Guarantee drawn in favor of Managing Director, Bihar Medical Services and Infrastructure Corporation Limited issued from any Scheduled/ Nationalized bank payable at Patna.			
2	Clause 5(a): - Tender bid is invited directly from Manufacturers/ Loan Licensees or Direct Importers only. Distributors/agents/contract manufacturers are not eligible to participate in the tender.					Clause 5(a) may be read as follows: - Tender bid is invited directly from Manufacturers/ Loan Licensees only. Importers/distributors/agents/contract manufacturers are not eligible to participate in the tender.			
3	Clause 3(g): - Non-Conviction Certificate (NCC) issued by the concerned Licensing Authority from Drugs Control Administration/ Concerned Government Department of the State should be submitted (As Applicable). It should be not more than one year old. Self-attested copies are to be submitted.					Clause 3(g) may be read as follows: - The tenderer should give a self-declaration stating that the firm is Non-Convicted currently (as on the date of submission of the tender) by Central Government/ Central Government agencies/any State Government or any of the State Government agencies/ or any Drug procurement agencies or by BMSICL.			
4	Clause 3(i): - Maximum Batch Production Capacity Certificate (section wise) issued by concerned Licensing Authority from Drugs Control Department/ Concerned Government Department high lighting the quoted product section (As Applicable). Self-attested copies are to be submitted. In case of Importer, an affidavit (with Stamp) sworn before first class magistrate/ Notary stating the batch production capacity of the firm and also that the said production (Importing) capacity shall be adequate for					Clause 3(i) may be read as follows: - Maximum Batch Production Capacity Certificate (section wise) issued by concerned Licensing Authority from Drugs Control Department/ Concerned Government Department high lighting the quoted product section (As Applicable). Selfattested copies are to be submitted. In case such certificate is not issued by the concerned government department the onus shall lie on the bidder to provide its production capacity through			

	requirement laid in NIT. Importers will have also to submit Invoices/Evidence of import in items of said product with quantity details. The onus lies on the bidder to provide its production capacity through the production capacity (Self Declaration) to be submitted by the bidder as contained in Annexure-IX. This statement shall be in addition to the Production Capacity Certificate (section wise) obtained by the bidder from the concerned competent authority.	Self Declaration, to be submitted by the bidder as contained in Annexure-IX.
5	Clause 3(1): - The tenderer should give an affidavit sworn before a First Class Magistrate/ Notary stating that the firm & its quoted product is not black listed currently (as on the date of submission of the tender) by Central Government/ Central Government agencies/any State Government or any of the State Government agencies/ or any Drug procurement agencies or by BMSICL as per Annexure-II.	Clause 3(1) may be read as follows: - The tenderer should give self-declaration stating that the firm & its quoted product is not black listed currently (as on the date of submission of the tender) by Central Government/ Central Government agencies/any State Government or any of the State Government agencies/ or any Drug procurement agencies or by BMSICL as per Annexure-II. In place of Notarized affidavits as and where required in the bid document, a bidder may submit self-declaration provided he submits the proof that due to lockdown the affidavit is not possible to be notarized on a stamp paper. However, the bidder has to submit the notarized affidavit on stamp papers after easing of lockdown
		situation. Clause 5(k) may be read as follows: -
6.	Clause 5(k):- Affidavit declaration regarding acceptance of tender conditions to be submitted by the bidding firm as per Annexure-IV.	Self-declaration regarding acceptance of tender conditions to be submitted by the bidding firm as per Annexure-IV. In place of Notarized affidavits as and where required in the bid document, a bidder may submit self-declaration provided he submits the proof that due to lockdown the affidavit is not possible to be notarized on a stamp paper. However, the bidder has to submit the notarized affidavit on stamp papers after easing of lockdown situation.
	Clause 21. (point-2): - Schedule of purchase order and Supply of MEDICAL DEVICES/ CONSUMABLE: - Within 15 Days: 50% Within 25 Days: 100% Within 35 Days: *Unexecuted Supply	Clause 21. (point-2) may be read as follows: - Schedule of purchase order and Supply of MEDICAL DEVICES/ CONSUMABLE Within 25 Days: 50% Within 40 Days: 100% Within 50 Days: *Unexecuted Supply
7.	*After 25 th days penalty will be @ 1% of value of unexecuted supply order per day subject to a maximum of 20% penalty.	*After 40 th day penalty will be @ 1% of value of unexecuted supply order per day subject to a maximum of 20% penalty.
	On the 35 th day from the date of issue of PO at 1700 Hrs. the PO stands cancelled.	On the 50 th day from the date of issue of PO at 1700 Hrs. the PO stands cancelled. * NOTE- The supply conditions may be modified keeping in view the interest of general

* NOTE- The supply conditions may be increased or decreased keeping in mind to favour General patients of state may be decided by the Managing Director, BMSICL from time to time.

patients of the state as decided by the Managing Director, BMSICL from time to time.

ANNEXURE- B								
REVISED TENDERED PRODUCT LIST								
S. N.	Name of the Products	Specification	Estimated Tendered Quantity					
1	PPE Kit (with N-95 Mask)	As per Annexure-C	25,00,000 units					
2	N-95 Mask with Expiratory Valve	As per Annexure-C	25,00,000 units					
3	3 Ply Surgical Face Mask	As per Annexure-C	5,00,00,000 units					
4	Face Shield with Head Cover	As per Annexure-C	20,00,000 units					
5	Reusable Vinyl gloves (For House Keeping)	Medium size: Covering Upto elbow region	1,00,000 pairs					
6	Disposable Nitrile Gloves (Small)	Nitrile Non-sterile Powder free The gloves should cover mid-forearm (minimum 280mm total length) Quality compliant with any of the following standards: a. EU standard directive 93/42/EEC	20,00,000 pairs					
7	Disposable Nitrile Gloves (Medium)	Class I/EN 455 b. EU standard directive 89/686/EEC	20,00,000 pairs					
8	Disposable Nitrile Gloves (Large)	category III/EN 374 c. ANSI/SEA 105-2011 d. ASTM D6319-10 e. ISO/BIS Standard	10,00,000 pairs					
9	Hand Sanitizer 500 ml bottle	Each 100ml contains: Iso propyl Alcohol IP-75% v/v, Hydrogen Peroxide IP- 0.125%v/v, Glycerol IP- 1.45%v/v Solution. Note: - Dispenser is optional Or, Each 100ml contains: Ethanol IP- 80%, Hydrogen Peroxide IP- 0.125%v/v, Glycerol IP- 1.45%v/v Solution Note: - Dispenser is optional	12,00,000 bottles					
10	Cetrimide Solution	2% w/v, 5 Litre containers	1,00,000					
11	Sodium Hypochlorite Solution	5%, 5 Litre containers	2,20,000					
12	Viral Transport Medium (With Double Swab)	As per Annexure-C	containers 20,00,000 test units					

Note:

- 1. This is the centralized tender for the State of Bihar. The required quantity may vary in accordance with the actual need as the situation warrants.
- 2. Two products i.e. Viral RNA Extraction Kit (Open System) & RT-PCR Kit (Open System) floated vide NIT S.N. 13 & 14 are hereby deleted from the original product list.

ANNEXURE – C

(Revised Technical Specifications of the tendered Products)

1. SPECIFICATION OF PERSONAL PROTECTIVE EQUIPMENTS (PPE) KIT

Components of PPE KIT are as follows: -

- i) Coverall (garments)
- ii) Face Shield
- iii) Goggles
- iv) Nitrile Gloves
- v) N-95 face mask with Expiratory Valve
- vi) Bio Safety Waste Bag

Note: - The items no. (ii) to (vi) are complimentary to the items no. (i) which is the main item for bidding purpose.

i) Specification of Coverall (Garments) with Tape over Seam along with Shoe cover:

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- Coverall should be made of a non-woven, breathable fabric which passes ASTM 1670 test or equivalent for Blood Penetration Test.
- The Fabric, Garment/Coverall and Seam should pass Synthetic Blood Penetration test at designated Laboratories for this purpose by the Ministry of Textiles, Government of India.
- Impermeable to blood and body fluids
- Avoid culturally unacceptable colors e.g. black.
- Light colors are preferable to better detect possible contamination
- Coverall shall be designed to be universal Fit
- Coverall shall have in built Hood Cap
- Zipper of the coverall shall be covered with a flap to avoid accumulation of microbes
- Soft Elastic to be fitted around Front of hood, wrists & ankles
- The seams should be hot sealed with impermeable tape.
- Quality compliant with any of the following standard: Meets or exceeds ISO 16603 class 3 exposure pressure / IS:17423:2020.
- The PPE (Body Coverall for COVID-19) garment manufacturer will either print in indelible ink, or stick a tamper-proof sticker, on the body of the garment on the inside of the PPE with the following particulars;
 - ➤ Name of Manufacturer:
 - ➤ Unique Certification Code (UCC) issued by the above mentioned testing laboratories.
 - > Test Standard
 - ➤ Date of Manufacturing/ Batch Number
 - ➤ BIHAR GOVERNMENT SUPPLY NOT FOR SALE
 - ➤ BMSICL Logogram
- Boot Cover: Pair of Boot Covers made of same fabric as of Coverall Soft elastic to be fitted at two levels, ankle and end.

NOTE:

1) Bidders shall quote for the complete coverall (from head to toe), for bidding purpose but must supply the above maintained complimentary items {S.N. (ii) to (vi)} along with the coverall.

- 2) Garments must be tested for Synthetic Blood Penetration Resistance Test conducted at Laboratories designated by the Ministry of Textiles, Government of India for fabric, Garment, complete suit and feet/Shoe cover. The test report pertaining to a previous batch must be submitted along with this bid for the purpose of technical evaluation.
- 3) The interested bidders must comply with the Quality Control Mechanism in accordance with the rules and regulations of Ministry of Textiles, Government of India.
- 4) Packing Every PPE Kit with all the complimentary items must be packed in sterilized medical grade pouch.

ii) Specification of Face Shield: -

- Made of clear plastic of at least 250 microns thickness and provides good visibility to both the wearer and the patient.
- Adjustable band to attach firmly around the head and fit snuggly against the forehead.
- Fog resistant (preferable).
- Completely covers the sides and length of the face.
- May be re-usable (made of material which can be cleaned and disinfected) or disposable
- Quality compliant with any of the following standards:
 - a. EU standard directive 86/686/EEC or EN 166/2002
 - b. ANSI/SEA Z87.1-2010
 - c. ISO/BIS Standard

iii) Specification of Goggles: -

- With transparent glasses, zero power, well fitting, covered from all sides with elastic band/or adjustable holder.
- Should ensure good seal with the skin of the face.
- Flexible frame to easily fit all face contours without much pressure.
- Should cover the eyes and surrounding areas and should accommodate prescription glasses.
- Fog and scratch resistant.
- Adjustable band to secure firmly so as not to become loose during clinical activity.
- Indirect venting to reduce fogging.
- May be re-usable (made of material which can be cleaned and disinfected) or disposable.
- Quality compliant with any of the following standards:
 - a. EU standard directive 86/686/EEC or EN 166/2002
 - b. ANSI/SEA Z87.1-2010
 - c. ISO/BIS Standard

iv) Specification of Nitrile gloves (Size 6.5, 7 & 7.5): -

- Nitrile
- Non-sterile
- Powder free
- The gloves should cover mid-forearm (minimum 280mm total length)
- Quality compliant with any of the following standards:
 - f. EU standard directive 93/42/EEC Class I/EN 455
 - g. EU standard directive 89/686/EEC category III/EN 374
 - h. ANSI/SEA 105-2011
 - i. ASTM D6319-10
 - i. ISO/BIS Standard

v) Specification of N-95 Masks with Expiratory Valve: -

- Shape that will not collapse easily.
- High filtration efficiency.

- Good breathability, with expiratory valve.
- Quality compliant with standards for surgical N-95 respirator: NIOSH N95/EN 149 FFP2/BIS.
- Fluid resistance: minimum 80 mm Hg pressure based on ASTM F1862/ISO 22609.
- Quality Compliant with standards for particulate respirator that can be worn with full-face Shield.
- It should be a 5-layered mask consisting of:
 - a. First layer -50 GSM SS
 - b. Second layer 25 GSM Melt blown
 - c. Third layer 50 GSM Hot Air Filter
 - d. Fourth layer -28 GSM Melt blown
 - e. Fifth layer -25 GSM SS
- Nose Pin Double core plastic coated
- UV C Sanitized
- Ear loop Ultrasonic Welding & Automatic (no manual welding or stitching)
- Mask should have online printing of BMSICL
- Individual printed poly packaging should also have BMSICL label
- Packing Strong 3-ply box containing 25 pcs.

All batches of each item of PPE Kits (to be supplied) must be accompanied with certificate of analysis from the laboratories designated for this purpose by the CDSCO/Ministry of Textiles/Health, Government of India indicating conformity to standards.

2. SPECIFICATION OF N-95 FACE MASK WITH EXPIRATORY VALVE

- Shape that will not collapse easily.
- High filtration efficiency.
- Good breathability, with expiratory valve.
- Quality compliant with standards for surgical N-95 respirator: NIOSH N95/EN 149 FFP2/BIS.
- Fluid resistance: minimum 80 mm Hg pressure based on ASTM F1862/ISO 22609.
- Quality Compliant with standards for particulate respirator that can be worn with full-face Shield.
- It should be a 5-layered mask consisting of:
 - a. First layer -50 GSM SS
 - b. Second layer 25 GSM Melt blown
 - c. Third layer 50 GSM Hot Air Filter
 - d. Fourth layer 28 GSM Melt blown
 - e. Fifth layer -25 GSM SS
- Nose Pin Double core plastic coated
- UV C Sanitized
- Ear loop Ultrasonic Welding & Automatic (no manual welding or stitching)
- Mask should have online printing of BMSICL
- Individual printed poly packaging should also have BMSICL label
- Packing Strong 3-ply box containing 25 pcs.

All batches to be supplied need to be accompanied with certificate of analysis from the laboratories designated for this purpose by the CDSCO/Ministry of Textiles/Health, Government of India indicating conformity to standards.

3. SPECIFICATION OF 3 PLY SURGICAL FACE MASK

• Fabric & Construction: -

It must have a 3-ply type construction consisting of:

- a. First layer -30 GSM SS
- b. Second layer 25 GSM Melt blown
- c. Third layer -25 GSM SMS
- UV C Sanitized
- Sealing: The mask should be heat sealed and no stitching to keep three layers together.
- Size: Not less than 17cm x 09cm of mask and having comfortable elastic ear loop. The length of elastic loop should be minimum of 24cm in normal condition i.e., without stretching.
- Nose Clip: Rust proof adjustable nose clip.
- Ear loop:- Must be with ultrasonic welding (No manual welding or stitching is permitted).
- Packaging: 25 nos. in individual poly packaging with adequate labelling/noting
- Must be ISI marked or European CE/ USFDA Approved.
- Breathability: Differential pressure (Delta P) As per IS 16289 Standard.
- Splash Resistance: As per ASTM F1862 Standard.
- Particulate Filtration efficiency at 0.3-microns: As per ASTM F2299.
- Bacterial Filtration Efficiency: As per ASTM F2101.
- Flammability: As per 16 CFR.
- All batches to be supplied need to be accompanied with certificate of analysis from laboratories designated for this purpose by the CDSCO/Ministry of Textiles/Health, Government of India.

4. SPECIFICATION OF FACE SHIELD WITH HEAD COVER

A) SPECIFICATION OF FACE SHIELD

- Made of clear plastic of at least 250 microns thickness and provides good visibility to both the wearer and the patient.
- Adjustable band to attach firmly around the head and fit snuggly against the forehead.
- Fog resistant (preferable).
- Completely covers the sides and length of the face.
- May be re-usable (made of material which can be cleaned and disinfected) or disposable
- Quality compliant with any of the following standards:
 - o EU standard directive 86/686/EEC or EN 166/2002
 - o ANSI/SEA Z87.1-2010
 - o c. ISO/BIS Standard

B) SPECIFICATION OF HEAD COVER

Surgical Head cover, disposable type, should be manufactured from non-woven fabric Blue/Green/colour Round upon wearing, with elastic Air permeable/breathable, should retain skin and hair particles.

All batches to be supplied need to be accompanied with certificate of analysis from the laboratories designated for this purpose by the CDSCO/Ministry of Textiles/Health, Government of India indicating conformity to standards.

As and when required the Face Shield and Head Cover may be used separately.

5. SPECIFICATION OF VIRAL TRANSPORT MEDIUM WITH DOUBLE SWAB TYPE (ICMR APPROVED)

- The VTM Kit (Double Swab) should be ICMR Approved.
- Required for transport of swab samples for testing of Viral Infections like; SARS-CoV-2, H1N1 etc.
- Composition of the medium should be as per specified by WHO/CDC/ NCDC.
- 10-15 ml volume screw- cap, leak- proof plastic tube.
- Should contains 3 ml viral transport media.
- The media should be clear and pink in Colour.
- The medium should be stable at room temperature
- pH 7.3 (+/- 0.3)
- Osmolality in mOsm/Kg H2O 500.00-600.00
- It should contain a protective protein antibiotic to control microbial contamination and buffers to control the pH.
- Shelf life should be at least one year at the time of delivery.
- Method of sterilization and date of expiry should be mentioned both on the box and individual tubes.
- Each tube should have a label for writing patient details.

SPECIFICATION OF STERILE DACRON /POLYESTER/RAYON SWAB WITH BREAKPOINT

- Two sterile synthetic fibre swabs (Dacron/ Polyester/ Rayon) with plastic shafts or wire shaft (flexible shaft).
- Swabs should be appropriate for collection of nasopharyngeal and oropharyngeal samples for viral testing.
- It should be flexible and provided with breakpoint at suitable point as per the tube size.
- The swabs should be packed individually.
- Method of sterilization and expiry should be mentioned on the wrapper.
- No quote for "Single Swab VTM" supplemented with additional (Separate) swab will be entertained.

-END-

Sd/-GM (Procurement) BMSICL