

STATEMENT SHOWING THE PREBID QUERIES RAISED BY THE FIRMS ON THE TENDER NO 61(20-21)/APMSIDC/Medicine Wing/2020-22 Dt:03-06-2020

SI No	Name of the firm	Query by the firm	AS per tender specification	Remarks
1	M/s Johnson and Johnson pvt ltd	1) For Item code 5688, 5690, 5692: It is mentioned as anti bacterial coated but the name of the anti bacterial agent is not mentioned . Request to add the description as anti bacterial Triclosan coated with high purity triclosan material that needs USP specification for triclosan and contributes minimally to the exposure of the residues.	Antibacterial Absorbable Surgical suture 0-, 1, 2-0 Specifiction: Polyglactin 910 1/2 circle RB 40mm Needle violet braided coated - 90cm	Execute as per the rate contact agreement dt 22.1.2020
		2) Also in past tenders of APMSIDC there was clause that the manufacture floating in the tender must have supplied at least the 25% tender quantity to any government institutions every year and also provide orders copy for proof of supply. We understand that this was included with a view to purchase the material from companies who have past satisfactory of supplies to govt institutions. Hence we request you to kindly include this requirement in present tender also and ask for proforma for performance statement certificate for last three years.(2016-17,17-18,&18-19) along with details of first batch manufactured and no of batches manufactured each year and batch numbers. This become more important in the light of operational guidelines free drug services initiative issued by the GOI which clearly states that QUOTE 2.3: for each drug quoted in the present tender , the manufacture should have marketed the drug in India without interruption for at least 1095 days preceding the date on which the tender is submitted .In case of Importer their principal manufacture should have marketed the drug in India without interruption for at least 1095 days preceding the date on which the tender is submitted		Not considered
		3) For Items code no 10307 and 5670 ie Absorbable monofilament, undyed, polyglycaprone, sterile size - 3-0(suture code 1036) which is most commonly skin closure in most of the surgeries, Please consider the changing the specification to antibacterial triclosan coated absorbale , monofilament undyed, polyglycaprone, sterile size -3-0(suture code 1036) so that the surgical site infections could be reduced to a large extent.	3) "Absorbable, monofilament, undyed, Poliglecaprone, Sterile Size 3-0(Suture code: 1326)"	Not considered

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		4) Normally in most of the state tenders, include APMSIDC earlier tender no 44 market standing certificate duly issued by the competent authority (either state drug controller or CDSCO) for past three years was asked to ensure that corporation purchase these only from companies with genuine past experience.				Not considered
		5) Queries related to 10235 and 10257			Harmonic scalpel probe 5 mm	36cm shaft length, 7 mm vessel sealing with advanced haemostasis mode.
		Item code and name	Specification in tender	query		
		10235 Harmonic scalpel probe 5 mm	Laprosopic ace	Laprosopic shaft length and sealing capability is not given in the specification requesting to confirm below: shaft length-36cms or 45 cms. Sealign capacity-5mm vessel or 7mm vessel with adv haemostasis		
		10257 Harmonic scalpel probe open instrument	Open instrument	Open instrument sizes are notgiven in the specification. Request to confirm the sizes 23cms/9cms/17cms of open probesand with adaptive tissue technology or without adaptive tissue technology.	10257 Harmonic scalpel probe open instrument	23cm, 9cm & 17cm shaft length with adoptive tissue technology.
2	M/s Healthium Meditech pvt ltd	Tender Condition	Amendment /Clarification required			Not considered
		I. Average Annual turnover of manufacturer in the last three years i.e. 2016-17, 2017-18 and 2018-19shall not be less than Rs.5 Crores	Sutures and Mesh materials are essential products and ensuring the procurement of right quality suture is of utmost importance. To provide purchase of best Suture material, eligibility criteria regarding turnover requirements to be fixed at par with that of medicines. Therefore request you to amend the Annual Turnover requirements for Suture material as "Minimum Rs. 50 cr. (Rs. fifty Cr.) for each last three years, i.e. 2016-17, 2017-18, and 2018-19 for procuring high-quality products from reputed companies.			
		Products are called with item code no like	We request you to kindly call the products in generic and delete the code numbers since there will be a difference in code numbers of individual manufacturer			Not considered

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		2670, 2443, 4259, 4254 etc			Not considered
		10242 Absorbable, Braided, violet, PGA (Polyglycolic acid) Sterile, surgical suture 6/0 (Suture code: 2670)	Request you to amend the specification as Polyglycolic acid/ Polyglactin 910 sutures since Polyglactin 910 sutures are widely recommended by all surgeons against PGA		
		5690 Antibacterial Absorbable Surgical suture 1 inch	Please delete the word "Inch" as sutures are not mentioned in "inches"		Considered. Read as 1
		10356 5-0 black silk suture (Boxes)	Please specify the complete specification of the tendered product		5-0 black silk suture-3/8circle reverse cutting with 13mm needle &90cm length.
3	M/s Sensacore Medical instrumentation pvt ltd	Item code 5618 Sterile blood lancet Ethylene oxide- Confirmation requested on whether the requirement is for Auto disable lancet or twisted lancets used with lancing device		Sterile blood lancet Ethylene oxide	As per tender document
4	M/s Paramount pesticides ltd	1) Eligibility criteria (ii) valid product licence(for items notified as drugs it is from DCA/DCG(I) and for no drug items is from concerned statutory department) Paramount pesticides ltd is Indian manufacturer and having manufacturing the item Pyrethrum extract 2% issued by the state licensing authority. The sale permission for the state of the product not applicable on us. 2) EMD total amount Rs 3,00,000/- should be determination/assessment on the basis of per product/item wise 3) Latest non conviction certificate issued by the licensing authority of the state certifying the			1) If it is not drug, the firm shall submit valid licence given by concerned authorities. 2) 300000/- only for all the items 3) considered as per tender

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		firm/company has not been convicted certificate issued by CA. It should be issued by the company/firm as a self declaration / notarized affidavit.		condition.
5	M/s Neha pharma	Implementation of preferential market access policy in procurement GO No 104/103 Dt 19/5/20 & 15.5.20 of Industries & commerce (P&I) department		May be considered after qualified in tender.
6	M/s Collateral Medical pvt ltd	The firm is authorized distributors of surgical/medical consumables which mean we could also be suppliers and marketers of many products. Between point (iii) and point (v) we are not sure if we are eligible since we are eligible as per (iii) and might not be eligible as per(v).		As per tender condition
7	M/s Jaya venkata Infrastructure	<ol style="list-style-type: none"> 1) There are a lot of wearable and disposable in the list which come under non drug items manufactured locally, there is no clarity on non drug manufacturing companies participating as the paragraph A(i) is vaguely described and separate eligibilities not provided for drug items and non drug items. Please redefine drug and non drug item qualifications separately. 2) There is no clarity on quantities mentioned as there is a description box and an unit box , total quantities required for an year Ex; surgeon mask description pack of 100 , Unit-1 Quantity: 11272266 		<ol style="list-style-type: none"> 1.As per the Medical device rules 2. Unit means here 1 mask
8	Advanced Medtech solution	<p>With reference to above we also bring this in to your notice that in last tender Telangana Govt, Tender No. 4 /TMSIDC/MW/Surgicals/2019, Dt.15.10.2019 has asked for Turnover of Rs.2 Crores for other Bidders for an average of Three financial years of 2016-17, 2017-18 & 2018-19. (attached tender references for your ready reference)</p> <p>Request to consider our Bid against your above mentioned Tender No. and requesting for liberty in Turnover clause.</p>		Not Considered
9	M/s Swagath international	To clarify about exemption of EMD . In Page 10, 7.2 (VI) SSI units situated in AP state are exempted from the payment of EMD. Here we would like to inform you that ours is a Trading Company and we Possess service-based MSME Certificate Please clarify us whether we are eligible for exemption of EMD or Not		Not considered
10	M/s Auro lab	<p>Tender total requirement of Intraocular lens (IOL) is 1,12,700 units.</p> <p>Three different types of visco elastic solutions are used they are as under:</p> <ol style="list-style-type: none"> 1. Hydroxy propyl methyl cellulose 2%w/v 2ml prefilled glass syringe 2. Sodium hyaluronate 1.4%w/v 1ml prefilled glass syringe 3. Sodium hyaluronate 1.6%w/v 1ml prefilled glass syringe <p>We request you to consider the incorporation above items into the list of item enable</p>		<p>1 Hydroxy propyl methyl cellulose 2% W/V 2 ml prefilled glass syringe may be considered.</p> <p>2&3 Not considered.</p>

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		availability alongwith IOL in ophthalmic speciality.																				
		<table><tr><th>Item Code</th><th>Tender specification</th><th>Recommended generic specification</th></tr><tr><td>10248</td><td>Foldable IOL drift powers</td><td>Hydrophilic foldable intraocular lens UV absorbing Poly HEMA, equiconvex optic, aspheric (zero aberration) A constant (Ultra sound):118.0 A constant (Optical): 117.8, ACD:5.0mm optic diameter-6.00mm, no position holes, overall diameter 12.00mm, zero degree angulations, diopter range: 0.0d to 40.0D increment 10.0D to 30.0d in 0.5D</td></tr><tr><td>5338</td><td>Intra Ocular Lenses, Posterior Chamber of various sizes from +17 to + 20</td><td>Single piece posterior chamber intraocular lens UV absorbing PMMA, equiconvex optic and modified "C" loop, A constant: 118.5, ACD:5.0mm optic diameter 6.00mm, no position holes, overall diameter 12.50mm, 10 degree angulations diopter range 10.0D to 30.0D increments 15.0D to 25.0D in 0.5D</td></tr><tr><td>5397</td><td>Intra Ocular Lenses, Anterior Chamber of various sizes</td><td>Single piece anterior chamber intraocular lens UV absorbing PMMA, equiconvex Kelmann Multiflex, 4 point fixation, A constant 115.3, ACD 3.0mm, optic diameter 5.50m, no position holes, overall diameter 12.50mm, 10 degree angulations diopter range 10.0d to 30.0D increments 15.0D to 25.0D in 0.5D</td></tr><tr><td>5394</td><td>Intra Ocular Lenses, Phaco various sizes from +19 to + 24</td><td>UV absorbing p-HEMA Hydrophilic foldable intraocular lens (26% water content) 360° square edge optical size 6.0mm, overall length-12.0mm, A constant 118.0 ACD 5.0mm, equiconvex, dual haptic diopter range 10.0D to 30.0D Model: FH560I</td></tr><tr><td>5430</td><td>Intra Ocular Lenses, Single piece of various sizes from +4 to + 29.5</td><td>Single piece posterior chamber intraocular lens UV absorbing PMMA, equiconvex optic and modified "C" loop, A constant: 118.5, ACD:5.0mm optic diameter 6.00mm, position holes-2, overall diameter 12.50mm, 10 degree angulations diopter range 6.0D to 40.0D increments 10.0D 30.0D in 0.5D</td></tr></table>	Item Code	Tender specification	Recommended generic specification	10248	Foldable IOL drift powers	Hydrophilic foldable intraocular lens UV absorbing Poly HEMA, equiconvex optic, aspheric (zero aberration) A constant (Ultra sound):118.0 A constant (Optical): 117.8, ACD:5.0mm optic diameter-6.00mm, no position holes, overall diameter 12.00mm, zero degree angulations, diopter range: 0.0d to 40.0D increment 10.0D to 30.0d in 0.5D	5338	Intra Ocular Lenses, Posterior Chamber of various sizes from +17 to + 20	Single piece posterior chamber intraocular lens UV absorbing PMMA, equiconvex optic and modified "C" loop, A constant: 118.5, ACD:5.0mm optic diameter 6.00mm, no position holes, overall diameter 12.50mm, 10 degree angulations diopter range 10.0D to 30.0D increments 15.0D to 25.0D in 0.5D	5397	Intra Ocular Lenses, Anterior Chamber of various sizes	Single piece anterior chamber intraocular lens UV absorbing PMMA, equiconvex Kelmann Multiflex, 4 point fixation, A constant 115.3, ACD 3.0mm, optic diameter 5.50m, no position holes, overall diameter 12.50mm, 10 degree angulations diopter range 10.0d to 30.0D increments 15.0D to 25.0D in 0.5D	5394	Intra Ocular Lenses, Phaco various sizes from +19 to + 24	UV absorbing p-HEMA Hydrophilic foldable intraocular lens (26% water content) 360° square edge optical size 6.0mm, overall length-12.0mm, A constant 118.0 ACD 5.0mm, equiconvex, dual haptic diopter range 10.0D to 30.0D Model: FH560I	5430	Intra Ocular Lenses, Single piece of various sizes from +4 to + 29.5	Single piece posterior chamber intraocular lens UV absorbing PMMA, equiconvex optic and modified "C" loop, A constant: 118.5, ACD:5.0mm optic diameter 6.00mm, position holes-2, overall diameter 12.50mm, 10 degree angulations diopter range 6.0D to 40.0D increments 10.0D 30.0D in 0.5D		May be considered
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11	Futura Surgicare Pvt Ltd	<p>This is with reference to Tender no 61(20-21)/APMSIDC/Medicine Wing/ 2020-22 Dated 03-06-2020, and in page no. 5, wherein Eligibility criteria on Anti bacterial(Coated) absorbable sutures is provided. This clause stipulate to obtain approval of CDSCO for manufacturing of Antibacterial Sutures. Further this condition is based on Memo No.426212/H2/2016 dated 1-02-2017 issued by the Principal Secretary to Government. We wish to submit the following:</p> <p>1. There was a similar condition in your tender No. floated in 2017. But the same condition has been dropped in the Tender no 44 (19-20) dated 23.09.2019. Bur surprisingly the old condition has again stipulated in the aforesaid tender. We do not understand the rationale behind bringing back this condition which is not relevant for the reasons given below:</p> <p>2. As per Drugs and Cosmetics Act, 1940, New Drugs shall be approved by CDSCO. Please note that CDSCO have approved Triclosan coated Sutures in 2004 for import into India and based on the same approval, J&J has been given manufacturing licence in 2005 by Drugs Controller for the State of Maharashtra. Based on the same principle, we were given manufacturing licence in 2012 for Triclosan coated Sutures by Drugs Controller for the State of Karnataka. We continue to hold the valid manufacturing licence.</p> <p>3. A New Drug cease to be a New Drug after 3 years of first manufacturing in the Country. Therefore, approval of CDSCO is not required since the same product is no more a New Product under the Drugs and Cosmetics Act. Based on this Rule, there are other companies listed below are also manufacturing Triclosan coated sutures, based on the licence issued by State Drug Control Departments situated in various parts of the Country:</p>		Execute as per the rate contact agreement dt 22.1.2020

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		<p>1. Merill Endosurgery Pvt Ltd , Gujarat since 2015.</p> <p>2. Helathium Meditech Pvt Ltd [earlier known as Sutures India Pvt Ltd], Bangalore since 2016.</p> <p>3. Lotus Surgicals Pvt Ltd, Himachal Pradesh.</p> <p>4. Orion Pharmaceuticals and Sutures Pvt Ltd, Bangalore and</p> <p>5. Unisur Life Care Pvt Limited, Bangalore.</p> <p>Some of above manufacturers' licences issued by State Drugs Departments have expired and renewed by CDSCO as per Medical Devices Rules 2017/2018 on routine basis. This shows clearly that Triclosan coated suture is not a New Product any more.</p> <p>4. Our company's manufacturing licence issued by State Drug Controller is valid up to 22-7-2022 and there is no Rule that we shall obtain fresh approval from CDSCO until the expiry of our licence. This condition is clearly stated in Medical Devices rules. Therefore, we have not approached CDSCO for any approval for Triclosan Coated Sutures. Insisting on CDSCO approval is not relevant now and insisting on this condition will go against genuine manufacturers who are following the Rules of the country sincerely. This is a transition stage where many Suture manufacturing companies are governed under CDSCO as well as State Drug Control authorities.</p> <p>5. Insisting on CDSCO approval will amount to discrimination in favour few companies without any legal sanctity.</p> <p>6. In fact, we request you to see the background under which Memo No.426212/H2/2016 dated 1-02-2017 issued by the Principal Secretary to Government and circumstances have changed thereafter. Reason for issue of this Memo is explained below:</p> <p>a. The Memo was issued based on the CDSCO letter dated 30th July 2013 file no. CLAA/MD/KR/03/2010-DC [copy enclosed]. As per this CDSCO letter, State Drug licensing Authorities have been instructed that Antibacterial Absorbable Surgical suture coated with chlorohexidine Diacetate 0.02% is a New Drug and further directed manufacturers to obtain new drug permission from CDSCO. Please note that this CDSCO circular is not for Trichlosan coated antibacterial sutures, but applicable only Antibacterial Absorbable Surgical suture coated with chlorohexidine Diacetate 0.02% .</p> <p>b. There is no circular stating that Triclosan Coated is a New Drug as per CDSCO. This is supported with various licences issued by CDSCO as well as State Drug Controllers.</p> <p>c. But in Tender no-61 [20-21] dated 3-6-2020, Eligibility criteria 2.A has asked all Anti Bacterial(Coated)Absorbable sutures to get CDSCO approval instead of asking only Chlorohexidine Diacetate coated Anti bacterial sutures to get CDSCO approval.</p> <p>7. Further we are supplying our antibacterial sutures to various state corporations which includes RMSCL-Rajasthan Govt and TNMSC-Tamilnadu Govt, KDLWS-Karnataka Govt, Municipal Corporation of Greater Mumbai and Chhattisgarh Medical Corporation etc since 2015-16 and none of these State Government agencies asked for approval of CDSCO for Triclosan coated Antibacterial sutures.</p>		

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13	Dr. Sabharwals manufacturing labs ltd	Requested to reduce the turnover below 5 cr and their firm is MSME /NSIC accept the turn over 2 cr.		Not considered.
14	M/s Medivac Surgical pvt ltd	To consider Turn over clauses as 2017-18,18-19,19-20 instead of 2016-17,17-18,18-19.	As per tender condition the bidder submit the turn over for the years 2016-17, 17-18,18-19	May be considered only after "certified by the CA"