

File No.:- BMSIC/40030/204-2022/ 4651

Date: -31/07/2025

Order

The matter in issue is related to supply of certain batches of A.D Syringe 10 cc by the firm namely **M/s RR Medical Enterprises Pvt. Ltd.(In short firm)** to the Warehouses of BMSICL situated at Patna, Purnea & Muzaffarpur against various purchase orders which have been subsequently found as 'Not of Standard Quality' by the BMSICL empanelled Quality Testing Laboratories.

2. Facts which are not in dispute, are that, pursuant to the Tender Reference no.- BMSIC/MEDICAL DEVICES/CONSUMABLES/22-06, **M/s RR Medical Enterprises Pvt. Ltd.** was declared successful in the said tender and accordingly, Letter of Intent(LOI) was issued vide Letter No.-7366 dated 13-12-2022 by the BMSICL for submitting the requisite documents, security deposit and to execute the Rate-Contract within 15 days from the date of receipt of LOI for the products A.D Syringe 10 cc and, subsequently, BMSICL issued purchase orders to the said firm vide Order No.9560 dated 27.02.2023, Order No.3977 dated 09.08.2023 & Order No.7236 dated 23.11.2023.

3. When, a batch of A.D Syringe 10 cc supplied against Purchase Order No.9560 dated 27.02.2023 was found as 'Not of Standard Quality' by the BMSICL empanelled Quality Testing Laboratories, then, a show cause notice bearing Memo No.2624 dated 03.07.2023 was issued by General Manager(Procurement), BMSICL, Patna to the Managing Director of the firm, thereby, directing to comply with the terms and conditions as outlined in Clause-24(e), Clause-24(f) and Clause-27(B)(3) of the tender document and submit his reply. Pursuant thereto, show cause reply dated 21.07.2023 was submitted by the firm to the BMSICL regarding the failed batch of A.D Syringe 10 cc in which, few technical objections were raised which are as follows:-

(i) The concerned Non Government approved has issued unsigned certificate of Analysis; issued not in FORM39 (see rule 150E (f)).

(ii) As per rule 150E(f); the approved institution shall furnish reports of the results of test or analysis in Form-39.

(iii) As per rule 150E(g); in case any sample of a drug or a cosmetic is found on test to be not of standard quality, the approved institution shall furnish the approving authority (and the licensing authority of the state where the manufacturer and /or sender of the drug of cosmetic is located) with copy of the test report on the sample with the protocols of test applied.

(iv) As per chapter IV of the drug and cosmetic Act 1940; legalities lying behind Section 21, Section 22 & Section 23 of the Act.

4. Thereafter, once again, batch of A.D Syringe Needle 10 ml. against Purchase Order No.7236 dated 23.11.2023 was found 'Not of Standard Quality' by the BMSICL empanelled Quality Testing Laboratories then, vide Letter No.9035 dated 30.01.2024 show cause notice was issued by the General Manager(Procurement), BMSICL, Patna to the Managing Director of the firm, thereby, directing to comply with the terms and conditions as outlined in Clause-24(e), Clause-24(f), Clause-24(g) and Clause-27(B)(3) of the tender document and submit his reply within 07 days. Pursuant thereto, show cause reply dated 13.02.2024 was submitted by the firm to the BMSICL stating therein, that attached unnamed NABL test report cannot be considered authentic and the Laboratory has violated the Medical Devices Rules, 2017, as the Laboratory has conducted the sterility test with USP contrary to the laid down standard.

5. Thereafter, final show cause notice bearing Memo No.10050 dated 27.01.2025 was issued by the General Manager(Procurement), BMSICL, Patna to the Managing Director of the firm regarding the Failed Batch of A.D Syringe 10 cc with Needle 10 ml. directing him to comply with the Clause-24(e), Clause-24(f), Clause-24(g) and Clause-27(B)(3) of the tender document and submit show cause reply within 03 days from receipt of the said letter, failing which, BMSICL shall be at liberty to act on its own and in accordance with law but no show cause reply was submitted by the said firm till date.

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6. After careful examination of the underlying facts and law as well as show cause reply of the firm and on perusal of the test reports, BMSICL arrives at the following conclusions/findings:

(i) The following batches of **A.D Syringe 10 cc** supplied to Patna, Purnia and Muzaffarpur, warehouses of BMSICL against the above mentioned purchase order, has been declared as 'Not of Standard Quality' by the BMSICL empanelled Quality Testing Laboratories.

S. No	Name of the Medical Devices/Consumables	Batch No.	Date of Report	Report	Reason of NSQ
1.	A.D Syringe 10 cc	07723	23-05-2023	BMSICL Empanelled Laboratory	Failed in Sterility Parameter.
2.		07623	23-05-2023		
3.		07823	23-05-2023		
4.		07523	23-05-2023		
5.		09223	30-05-2023		
6.		08423	03-06-2023		
7.		08523	03-06-2023		
8.		08823	03-06-2023		
9.		08723	03-06-2023		
10.		08623	03-06-2023		
11.		31623	04-01-2024		
12.		28123	04-01-2024		
13.		28423	04-01-2024		
14		0082425	29-07-2024		Failed in sterility & BET Parameter

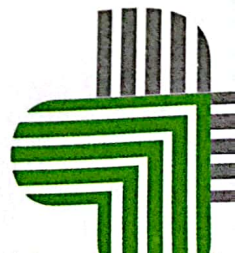
(ii) BMSICL has its own established system for the procurement and quality testing of medical devices, as clearly outlined in the Standard Bid Document. Form 39, as referred in Rule 150E(f) of the Drugs and Cosmetics Rules, 1945, pertains to the report of test or analysis by an approved institution for an individual, organization, or procurement agency. Specifically, it outlines the format for reporting the test results of samples received by the approved institution—whether from manufacturers or from individuals, organizations, or procurement agencies. BMSICL sends medical devices to empanelled laboratories that are registered for medical device testing. BMSICL then issues the test report to the manufacturing firm after defacing the name and address of the concerned laboratories in order to maintain transparency. Sections 21, 22, and 23 of the Drugs and Cosmetics Act deal with the powers and procedures of inspectors and are not applicable in this case.

(iii) Form MD-32 relates to the report of test or evaluation of medical devices by a Medical Device Testing Officer. However, these are not applicable in this case, as private testing laboratories are not authorized to issue Form MD-32 or Form 31—both of which are specific to government entities. Also, Indian Standard of IS/ISO 11737-2: 2019 deals with 'Sterilization of Health Care Products—Microbiological Methods. In Para A 6.6 (c), it is mentioned that the guidance of the procedures, organisms, titres and incubation times for method suitability can be found in current Pharmacopoeias, and the United State Pharmacopoeia is mentioned in that.

(iv) Clause 20(a) of the Tender Document is relevant for such cases which reads as: "The MEDICAL DEVICES/CONSUMABLE supplied by the successful bidder shall be of the Standard Quality and shall comply with the specifications, stipulations and conditions specified under Drugs and Cosmetics Act and Rules there under and also should confirm to Terms and Conditions laid down in NIT and Rate Contract/agreement."

(v) Clause 24(c) of the Tender Document is relevant for such cases which reads as: "Random samples of each supplied batch will be chosen at the point of supply or distribution/storage points for testing. The samples will be sent to different BMSICL empanelled laboratories."

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(vi) Clause 24(e) of the Tender Document is relevant for such cases which reads as: "The MEDICAL DEVICES/CONSUMABLE shall be of standard quality throughout the shelf-life period of the item. Samples can be drawn for quality testing periodically throughout the shelf-life period. If the sample is declared to be "NOT OF STANDARD QUALITY" or spurious or adulterated or misbranded, such batch / batches will be deemed to be rejected goods and action will be taken as per tender clause."

(vii) Clause 24(f) of the Tender Document is relevant for such cases which reads as: "If the product/sample fails in quality test, every failed batch shall be taken back by the supplier at their own cost and BMSICL shall not be responsible for any damage during this period".

(viii) Clause 24(g) of the Tender Document is relevant for such cases which reads as: "If a sample is found as not of standard quality by the Tender Inviting Authority, the distribution of NSQ batch will be frozen. The bidder will be liable for appropriate action as per the tender conditions and also for other legal actions under the Drugs & Cosmetics Act & Rules. The Tender Inviting Authority, at his discretion may terminate the Contract and in case of such termination, the supplier shall be liable for all losses sustained by the Tender Inviting Authority, which may be recovered from the Security Deposit made by the Supplier and / or any other money due or becoming due to him. In the event of such amounts being insufficient, the balance may be recovered from the Supplier as per the provisions of Law."

(ix) Clause 27 (B) (1) of the Tender Document is relevant for such cases which reads as: "Each and every batch of MEDICAL DEVICES/CONSUMABLE supplied by the supplier shall be subjected to quality test by the Empanelled laboratories as per the procedure adopted by BMSICL."

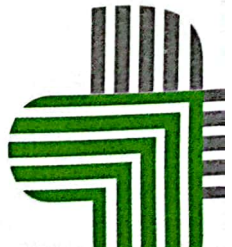
(x) Clause 27(B) (3) of the Tender Document is relevant for such cases which reads as: If 3 batch of a particular item supplied by the suppliers reported to be failing in ASSAY content (above 50% but below prescribed limit) and/or other parameters, then the particular item of the firm shall be blacklisted for two minimum of two years besides forfeiture of security Deposit of that particular product(s).

(xi) Clause 27(C) of the Tender Document is relevant for such cases which reads as: "The blacklisting of particular product or company/firm will be done without prejudice to other penalties which may be imposed as per the conditions of Tender documents and also to other actions which may be initiated under Drugs and Cosmetics Act, 1940 or any other law of Land. BMSICL will display names of such blacklisted product(s) and company/firm on its website for general notice."

(xii) Clause 2(b) & 2(g) of the agreement mentions that the complete tender document shall be deemed to form and be read and construed as part of this agreement, and as per Clause 5 (k) of the standard bid document, "affidavit declaration regarding acceptance of tender conditions to be submitted by the bidding firm as per Annexure IV." The firm has submitted the concerned affidavit regarding acceptance of tender conditions in Annexure IV. The sample was sent for analysis as per Clause 24 (a) and (c) of the Bid document. As per Clause 27(B) (3) of the Bid document, more than 3 batches (total 14) have been declared as 'Not of Standard Quality' by the BMSICL empanelled Quality Testing Laboratories.

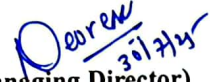
(xiii) The Hon'ble High Court of Kerala in M/s Peekay Mediequip Limited vs. Kerala Medical Services Corporation Limited [WA No. 650 of 2012] held that "On a reading of Sections 23(3) and 25(4) of the Drugs and Cosmetics Act, 1940, it can be seen that the said provisions have no application to the facts of the present case. The sample and testing procedure contained in the above provisions will not apply in a case where there is violation of agreement conditions".

Dr. W.



Order

Therefore, in the light of the provisions as contained in the tender document and agreement, the firm, **M/s R R Medical Enterprises Pvt Ltd**, situated at 2H/81, Bahadurpur Housing Colony, Kankarbagh, Patna- 800026. is hereby blacklisted for its quoted product **A.D Syringe 10 cc** for a period of two (02) years from the date of issue of this order apart from forfeiture of security deposit of that particular product. The unexecuted Purchase Orders issued earlier shall also stand cancelled.


(Managing Director)

