---------- Start of Specification ----------

Name of the Equipment: Chemiluminescence Immunoassay Analyzer with accessories
Quantity: 01
Estimated Cost: Rs. 45 Lakh inclusive GST
Proprietary item: No

MII exemption list Sl. No. 108 and Name: Autoanalyzer immunoassay (Chemiluminescence based) - fully automated with UPS back up; (GTE OM No.F.4/1/2023-PPD Dt. 03-04-2023)

Specification

1. Fully automated, continuous loading, random access floor top analyzer based on highly sensitive glow chemiluminescence/ electrochemiluminescence technology for various immunoassays. The analyzer should be on wheels for easy movement during relocation if required.
2. The analyzer should have an inbuilt refrigeration system with controlled temperature and humidity for reagent storage to maintain the stability of reagents on-board.
3. The analyzer should have the capability of an inbuilt inventory management system by tracking all the reagents and supplies automatically.
4. The analyzer should be capable of loading 20 or more integrated reagent packs at any time and stored on-board for continuous, random-access operation.
5. Ready-to-use reagent packs with no mixing or reconstitution required for integrated and compact with reagents and reaction wells in one pack only.
6. Reagent packs with the on-board stability of at least 6 weeks. Reagents can be accessed at any time during the test in progress without interruption.
7. The analyzer should use disposable tips or an effective washing system for sample aspiration to avoid any carryover and contamination of infectious blood samples.
8. The analyzer should have the capacity to load more than 50 samples at a time with immediate testing facility of any sample at any time.
9. Analyzer should have a wide test menu for infectious markers, thyroid hormone markers, infertility markers, tumor markers, bone health markers, cardiac markers, inflammatory markers, anaemia markers.
10. The analyzer should have a minimum throughput of at least 80 test /hour
11. Calibration stability of all the assays should be more than 3 weeks.
12. The analyzer should have sample rack/tray to accommodate sample tubes of different size
13. Sample bar code reading facility should be available.
14. It should have detection capability for clot, fibrin, bubble & sample viscosity along with liquid level detection.
15. The analyzer should have sample volume requirement max 100 µl per test
16. Every results report must be able to be viewed along with a traceable process control report of that particular result-tagged sample. Besides the result, the traceability report for any test can be retrieved for documentation purposes. The system should have process monitoring software to

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monitor every step during the process and give a report for every test performed, assuring the integrity of the test.

17. Installation Qualification, Operational Qualification, and Performance Qualification certificates to be submitted at the time of installation/ commissioning.
18. 220-240 VAC with 50Hz and standard make UPS with at least 30 minutes back up to be provided.
19. Software: User-friendly software with a comprehensive data processing and management system.
20. Complete backup of the database for calibration, control, and patient sample data of at least 5,000 patient results storage.
21. Certification: Must be USFDA /CE certified or equivalent for both the analyzer and the reagents
22. Warranty & AMC 3 years warranty and post 2 years AMC

---------- **End of Specification** ----------

Sujoy K Dasgupta

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