PR No. 1000050126   **RFX: 6100002389**

Item Description: PLM Software

Sr. No	Detailed Technical Specification	Technical Compliance (Yes / No)	Additional Information (if any)
1.	Teamcenter Author (For contributor)		
2.	Teamcenter Consumer (For Approver & Management)		
3.	Integration for SolidWorks (For Solid works User)-Floating License		
4.	Change Management User		

5.	I. Teamcenter Medical Device Solution
	II. PLM software Specification
	III. Teamcenter Author (For contributor)
	IV. Teamcenter Consumer (For Approver & Management)
	V. Integration for SolidWorks (For Solid works User)-
	VI. Floating License
	VII. Change Management User
	VIII. Teamcenter Medical Device Solution
	IX. Industrial Design
	    a. Integration with 3D Modelling tools (Rhino, etc.)
	    b. Early-stage design reviews and feedback loops
	    c. Rendering and concept document storage
	X. Mechanical Engineering
	    a. 3D CAD and BOM integration
	    b. Version control for mechanical drawings and CAD models
	    c. Integration with simulation tools (FEA, thermal, CFD) – ANSYS
	    d. Design FMEA management
	XI. Electronics Engineering
	    a. ECAD tool integration (e.g., Altium,		

	Mentor Graphics)		
	b. Component library management and BOM sync		
	c. PCB revision tracking and Gerber file management		
	XII. Embedded Systems		
	a. Firmware source control and versioning		
	b. Integration with Git or equivalent VCS		
	c. Linkage of test cases, unit test reports, and verification protocols		
	XIII. Software Development		
	a. Agile lifecycle support (Scrum/Kanban boards)		
	b. Requirement traceability matrices (RTM)		
	c. Risk management and software validation support (IEC 62304)		
	d. Integration with issue trackers (e.g., Jira)		
	XIV. Purchase		
	a. Approved Vendor List (AVL) management		
	b. Part sourcing information linked to BOM		
	c. Integration with ERP for procurement workflows		
	d. Supplier qualification and audit trail management		
	XV. Quality and Regulatory Affairs		
	a. QMS integration and document control		
	b. NC/CAPA management workflows		
	c. Risk management (ISO 14971)		
	d. Regulatory submission documentation (CE/FDA)		
	e. Compliance dashboards		
	XVI. Compliance and Validation		
	a. Siemens PLM must be validated to support ISO 13485, 21 CFR Part 11, EU MDR, and FDA QSR.		
	b. Electronic signature, audit trails, and access control features must be compliant with 21 CFR Part 11.		
	c. CAPA, Complaint Handling, and Post Market Surveillance modules should be customizable and reportable.		

	XVII. Integration Requirements
	    a. Integration with existing tools: ERP, GitHub, Jira, Altium, SolidWorks/NX, MATLAB (if used), and regulatory submission portals.
	    b. Support for RESTful APIs for custom integration with internal databases or legacy systems.
	XVIII. Deployment and Support
	    a. On-premise deployment options
	    b. User-based licensing model with role-based access
	    c. Custom training modules for each department
	    d. Post-implementation validation and IQ/OQ/PQ support
	XIX. User Roles and Access Control
	    a. Role-based dashboards for R&D, QA, RA, Management
	    b. Review and approval workflows tailored per department
	    c. Secure access for external collaborators (vendors, consultants)
	XX. Reporting and KPIs
	    a. Compliance dashboard for ISO 13485 readiness
	    b. Product development KPIs, Design timeline Gantt charts
	    c. Risk registers and open CAPA dashboards		

6.	Installation cost		

7.	**Terms and Conditions for Software Supply, Installation, and Support**
	
	i. Customer References
	
	    a. The supplier shall provide documented feedback from at least three government institutions that are existing users of the proposed software.
	
	    b. The supplier must have successfully installed similar or higher-configuration software at a minimum of three (3) sites within India and must provide contact details of the respective		

	clients for verification.		

	ii. **Training & Documentation**
	
	    a. The supplier shall provide comprehensive hands-on training to all engineers' post- installation. Training must cover all core functionalities of the software.
	
	    b. Training certificates must be issued for at least 10 personnel.
	
	    c. Onboarding documentation and three sets of user manuals (in English) must be supplied with the software.		

	iii. **Installation & Delivery**
	
	    a. The supplier shall be responsible for the complete installation and commissioning of the system.
	
	    b. The license key must be delivered within four (4) weeks from the date of the purchase order.		

	iv. **Warranty & Support**
	
	    a. A comprehensive warranty covering both hardware and software components shall be provided for a period of one (1) year from the date of commissioning.
	
	    b. Free software updates, including version upgrades, patches, and bug fixes, shall be provided for one (1) year post-commissioning.
	
	    c. Technical support for a period of one (1) year must also be provided, covering troubleshooting, maintenance, and performance optimization.		

	v. Extended Support
	
	    a. Support for reinstallation or migration in case of hardware changes shall be provided for up to one (1) year at no additional cost.
	    b. SaaS license support must be ensured for a period of One (1) year and 3 Years if Customer purchase for Three Years.		

	vi. Timeline The supplier shall complete the supply, installation, training, and commissioning within 15 days from the date of delivery.		
	vii. Payment Terms 100% payment shall be released upon delivery through funding agency on behalf of IIT Bombay.		