



**INDIAN INSTITUTE OF TECHNOLOGY BOMBAY
MATERIALS MANAGEMENT DIVISION**

Powai, Mumbai 400076.

PR No. 1000052322

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Technical Specification of Product Life Cycle Management Software

Sr. No	Detailed Technical Specification	Technical Compliance (Yes / No)	Additional Information (if any)
1.	PLM Software Author (For contributor)		
2.	PLM Software Consumer (For Approver & Management)		
3.	Integration for SolidWorks (For Solid works User)-Floating License		
4.	Change Management User		
5.	I. PLM Software Medical Device Solution II. PLM software Specification III. PLM Software Author (For contributor) IV. PLM Software Consumer (For Approver & Management) V. Integration for SolidWorks (For Solid works User)- VI. Floating License VII. Change Management User VIII. PLM Software Medical Device Solution IX. Industrial Design <ul style="list-style-type: none"> 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 <ul style="list-style-type: none"> 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 <ul style="list-style-type: none"> a. ECAD tool integration (e.g., Altium, 		

	<ul style="list-style-type: none"> Mentor Graphics) b. Component library management and BOM sync c. PCB revision tracking and Gerber file management <p>XII. Embedded Systems</p> <ul style="list-style-type: none"> a. Firmware source control and versioning b. Integration with Git or equivalent VCS c. Linkage of test cases, unit test reports, and verification protocols <p>XIII. Software Development</p> <ul style="list-style-type: none"> a. Agile lifecycle support (Scrum/Kanban boards) b. Requirement traceability matrices (RTM) c. Risk management and software validation support (IEC 62304) or substantially equivalent. d. Integration with issue trackers (e.g., Jira) <p>XIV. Purchase</p> <ul style="list-style-type: none"> 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 <p>XV. Quality and Regulatory Affairs</p> <ul style="list-style-type: none"> a. QMS integration and document control b. NC/CAPA management workflows c. Risk management (ISO 14971) or substantially equivalent d. Regulatory submission documentation (CE/FDA) e. Compliance dashboards <p>XVI. Compliance and Validation</p> <ul style="list-style-type: none"> a. Siemens PLM must be validated to support ISO 13485, 21 CFR Part 11, EU MDR, and FDA QSR or substantially equivalent 		
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	<ul style="list-style-type: none">b. Electronic signature, audit trails, and access control features must be compliant with 21 CFR Part 11 or substantially equivalent.c. CAPA, Complaint Handling, and Post Market Surveillance modules should be customizable and reportable. <p>XVII. Integration Requirements</p> <ul style="list-style-type: none">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. <p>XVIII. Deployment and Support</p> <ul style="list-style-type: none">a. On-premise deployment optionsb. User-based licensing model with role-based accessc. Custom training modules for each departmentd. Post-implementation validation and IQ/OQ/PQ support <p>XIX. User Roles and Access Control</p> <ul style="list-style-type: none">a. Role-based dashboards for R&D, QA, RA, Managementb. Review and approval workflows tailored per departmentc. Secure access for external collaborators (vendors, consultants) <p>XX. Reporting and KPIs</p> <ul style="list-style-type: none">a. Compliance dashboard for ISO 13485 readinessb. Product development KPIs, Design timeline Gantt chartsc. Risk registers and open CAPA dashboards		
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6.	Installation		
7.	<p>Terms and Conditions for Software Supply, Installation, and Support</p> <p>i. Customer References</p> <p>a. The supplier shall provide documented feedback from at least three government institutions that are existing users of the proposed software.</p> <p>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.</p> <p>ii. Training & Documentation</p> <p>a. The supplier shall provide comprehensive hands-on training to all engineers' post- installation. Training must cover all core functionalities of the software.</p> <p>b. Training certificates must be issued for at least 10 personnel.</p> <p>c. Onboarding documentation and three sets of user manuals (in English) must be supplied with the software.</p> <p>iii. Installation & Delivery</p> <p>a. The supplier shall be responsible for the complete installation and commissioning of the system.</p> <p>b. The license key must be delivered within four (4) weeks from the date of the purchase order.</p>		

iv. Warranty & Support

- a. A warranty should be provided for a period of six (6) years from the date of software installation.
- b. Free software updates, including version upgrades, patches, and bug fixes, shall be provided for six (6) year post-commissioning.
- c. Technical support for a period of six (6) 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 six (6) year at no additional cost.
- b. SaaS license support must be ensured for a period of six (6) years.

vi. Timeline

The supplier shall complete the 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.

