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| System Information | | |
| System Name: | Git LFS | |
| **Contact Information (Mark N/A if not applicable)** | | |
| Process Owner | Name:  Himabindu Bhogaraju | Department:  QMS Enterprise and Validated Tools |
| System Owner | Name:  Monika Sankar | Department:  Development |
| **System Description and Intended Use** | | |
| Git Large File Storage (LFS) is an open-source extension for Git that stores larger files outside of the Git repository. It keeps track of their versions and provides a pointer to the location of the large files.  It enables developers to use large file versioning, which provides more repository space. It also provides faster cloning and fetching using the same Git workflow.  Merge Healthcare intends to use Git LFS for versioning and storing large files. | | |

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| Assessment Conclusion | | | | | | | | |
| **Assessment Criteria** | | | | **Assessment Result** | | | | |
| **Validation Determination** – If the answer to any question in section 3.1 or 3.2 is **Yes** select **Yes**, otherwise select **No**. | | | | Yes No | | | | |
| **ERES (21CFR Part 11) Applicability** – If the answer to any question in section 3.2 is “Yes” select **Yes**; otherwise check **No**.  Select Electronic Records if the answer to question 3.2.1.1 or 3.2.1.2 is **Yes**.  Select Electronic Signatures if the answer to question 3.2.1.3 or 3.2.1.4 is **Yes**. | | | | Yes No  Electronic Records  Electronic Signatures | | | | |
| **Risk Level**  Low: 3 to 59  Medium: 60 to 90  High: >90 | | | | Low Medium High  N/A | | | | |
| **System Classification** | | | | Class 1  Class 2  Class 3 | | | | |
| **Required Deliverables** | | | | | | | | |
| User Needs and User Requirements  System Requirements  Configuration Specifications  Design Specifications  Validation Protocol  Verification Protocol  UAT Protocol  Test Plan  Test Report | | | | | | | | |
| **Change Management Level** | | | | | | | | |
| Change Management Required:  Patch level required.  Maintenance release level required.  Rationale: As Git LFS is a Class 2 computer system, require maintenance and major level management will be required. | | | | | | | | |
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| **Additional Information** | | | | | | | | |
| N/A | | | | | | | | |
| Assessment | | | | | | | | |
| **Qualification Determination** | | | | | | | | |
| **Control of Documents, Control of Quality Records, Device History Record** | | | | | | | | |
|  | | Yes  No | Does the system control the review, approval, and/or distribution of quality system documents or records? | | | | | |
|  | | Yes  No | Does the system create or maintain records of changes to quality system documents or records? | | | | | |
| **Quality Management System** | | | | | | | | |
|  | | Yes  No | Does the system automate any processes required under the Merge Health Quality Management System (for example, Training, Internal Audits, Management Review, Change Control, CAPA Management, or Complaint Handling)? | | | | | |
|  | | Yes  No | Does the system create or maintain records or documentation required to support the Merge Health Quality Management System processes? | | | | | |
| **Customer-Related Processes** | | | | | | | | |
| 10. | | Yes  No | Does the system create or maintain records of customer complaints, customer feedback, or issuing notice of field actions? | | | | | |
| **Design and Development** | | | | | | | | |
| 13. | | Yes  No | Does the system automate or create/maintain records, of the design and implementation, verification or validation and transfer phases of offering or product design? | | | | | |
| **Purchasing Controls and Supplier Management** | | | | | | | | |
|  | | Yes  No | Does the system create, maintain or control purchasing data? | | | | | |
|  | | Yes  No | Does the system automate or create/maintain records of supplier audits? | | | | | |
|  | | Yes  No | Does the system automate or create/maintain records of the Supplier Corrective Action Requests (SCAR) process? | | | | | |
| **Manufacturing Process Control** | | | | | | | | |
| 34. | | Yes  No | Does the system create or maintain records of devices manufactured including management or recording of deviations from the manufacturing process? | | | | | |
| **Process Validation (Special, Production Software, and Quality System Software)** | | | | | | | | |
|  | | Yes  No | Does the system create or maintain records ensuring special processes (device quality characteristic that cannot be fully verified in the finished product by inspection or testing) are identified and validated? | | | | | |
| **Handling, Storage, and Distribution** | | | | | | | | |
|  | | Yes  No | Does the system automate procedures to ensure components, manufacturing materials, in-process devices, finished devices, and returned devices are stored or distributed as per regulatory requirements? | | | | | |
| **Installation and Servicing** | | | | | | | | |
|  | | Yes  No | Does the system create or maintain the installation, inspection, testing, or service records of the device? | | | | | |
| **Analysis of Data/Statistical Techniques** | | | | | | | | |
|  | | Yes  No | Does the system automate or create/maintain records of data analysis for assessing the effectiveness of the quality management system? | | | | | |
| **Device Tracking** | | | | | | | | |
|  | | Yes  No | Does the system track devices or provide device data used in recall or removal processes? | | | | | |
| **Adverse Event Reporting** | | | | | | | | |
|  | | Yes  No | Does the system identify adverse events requiring reporting to the FDA or other competent authorities? | | | | | |
|  | | Yes  No | Does the system process adverse event reports such as Medical Device Reports (MDR) or Vigilance Reports? | | | | | |
| **Clinical Device Usage and Management** | | | | | | | | |
|  | | Yes  No | Does the system automate or create/maintain records of product-related submittals to regulatory bodies? | | | | | |
|  | | Yes  No | Does the system automate, or create/maintain records of the usage and management of medical devices used in clinical studies? | | | | | |
| **Electronic Records Electronic Signatures (ERES) Applicability Assessment** | | | | | | | | |
| **Control of Documents, Control of Quality Records, Device History Record** | | | | | | | | |
|  | | Yes  No | Does the tool create, modify, maintain, archive, retrieve, or transmit electronic records specifically required by any applicable regulation? | | | | | |
|  | | Yes  No | Does the tool contain electronic record(s) that are submitted to the FDA or other regulatory agency in electronic format? | | | | | |
|  | | Yes  No | Does the tool support the application of electronic signatures to records that are required by applicable regulation to be signed? | | | | | |
|  | | Yes  No | Does the tool use electronic signatures that are submitted to any Regulatory Agencies? | | | | | |
| **Risk Assessment – If system does not require validation, then Risk Assessment is not required. Mark fields in the below text boxes N/A as required.** | | | | | | | | |
| **Risk Assessment Determination Questions** | | | | | | | **Assessment Rating** | |
| **System Maturity – Select only one** | | | | | | | | |
|  | Less than 2 years of use in the same or applicable industry (10)  2 to 5 years of use in the same or similar industry (5)  More than 5 years of use in the same or similar industry (1) | | | | | | **1** | |
| **Function Impact – Select only one** | | | | | | | | |
|  | Failure of the system will result in significant impact on the quality management system compliance and integrity (10)  Failure of the system will result in reasonable impact on the quality management system compliance and integrity (5)  Failure of the system will result in minimal impact on the quality management system compliance and integrity (1) | | | | | | **5** | |
| **Product Quality– Select one only** | | | | | | | | |
|  | Failure of the system will result in significant impact on the quality of the product (10)  Failure of the system will result in reasonable impact on the quality of the product (5)  Failure of the system will result minimal impact on the quality of the product (1) | | | | | | **5** | |
| **Risk Assessment Rating** | | | | | | | | |
| Once values are assigned, the following formula will be used to obtain a Risk Rating (Low, Medium, or High). Multiply assessment-rating number for each category by weight and enter the value in the Total column. Sum the Total column for the overall score. | | | | | | | | |
| **Risk Assessment Category** | | | | | **Risk Rating (RR)** | **Weight (W)** | | **Total *(RR x W)*** |
| 3.3.1. System Maturity | | | | | 1 | 3 | | 3 |
| 3.3.2. Function Impact | | | | | 5 | 4 | | 20 |
| 3.3.3. Impact on Product Quality or Subject Safety | | | | | 5 | 5 | | 25 |
| **Overall Risk Rating (å Totals)** | | | | | | | | 48 |
|  | | | | | | | | |

# Document History

| **Revision** | **Author** | **Summary of Changes** |
| --- | --- | --- |
| 1.0 | Sonu Kumar Singh | Initial release |
| 2.0 | Sonu Kumar Singh | As per CSV CR FPTM-3299 ,Document is migrated from the old template to new Merge Healthcare templates. |