cl_general_2023 - Software Validation

1. Information about the Software

Name	cl_general_2023
Version	NA
Location	https://github.com/nishishailesh/cl_general_2023
Processes	All Medical laboratory processes as per ISO15189:2022

2. Intended Use and Use Context

cl_general_2023 is intended to be used for management of Medical laboratory data. It includes examination request, sample collection, sample tracking, barcode printing, interfacing with medical laboratory equipments, result verifications, report generation, QC record keeping, reagent management and accreditation record keeping.

3. Quality Relevance

Criterion	**Y/N**
Is the system used in one or more processes that steer the ISO15189:2022?	Y
Could the conformity of the organization’s medical devices be affected if the system does not work according to its specifications?	Y
Could risks arise for patients, users, third parties or the organization if the system does not work according to its specifications?	Y
Does the software generate or manage data / records that are relevant to the ISO15189:2022 or medical device approval by authorities?	Y
Is the software used to generate electronic signatures on documents?	N

4. General Assessment

4.1 Software Category

- Configurable software (GAMP category 4)

- Custom (self-developed) software (GAMP category 5)

4.2 Risk Assessment

List of Risks:

- Breakdown in hardware and software

List of Risk Mitigation Measures (if necessary):

- Twice a day backup of data and scripts at two other places

4.3 Criticality and Review Schedule

- reviewed upon major changes

5. Validation Plan

5.1 Participants

Role	Name	Task(s)
Programmer	Dr Shaileshkumar Manubhai Patel	All phases and aspects of validation

5.2 Test Environment

- Apache2, php and Mariadb debug environment

5.3 Testing Procedure

- Software system was fed sample data to review output

6. Validation Report and Requirements

6.1 Acceptance Statement

The software validated successfully and works as expected and is approved for use

6.2 Validation of Usage Requirements

ID	Expected	Pass?
U1	User can login with own unique username and password	Yes
U2	User can enter patient demographics and test request and print barcode	Yes
U3	User can search and view requests already entered	Yes
U4	User can verify results and prepare reports	Yes
U5	User can print reports	Yes

ID	Expected	Pass?
U6	User can view QC LJ Chart	Yes
U7	User can enter reagents and consumables record	Yes

6.3 Validation of Technical Requirements

ID	Expected	Pass?
T1	Software can communicate with equipments based on ASTM used by medical equipments	yes
T2	Software can communicate with equipments based on HL7 used by medical equipments	Yes

7. Approval and Release

Date of Approval	**Name of Approver**
2023-06-01	Dr shaileshkumar Manubhai Patel