RELEASE 3.5.0

SOFTWARE VALIDATION SUMMARY

Validaide B.V. hereby confirms that the Validaide software application Release 3.5.0 has been developed in accordance with the Standard Operating Procedures as defined in the company's current version of the Quality Management System. The software is classified as category 3 according to GAMP5 and the Release 3.5.0 has been validated according to GAMP5 and FDA 21 CFR Part 11 guidelines.

Summary of Design & Operational Qualification

The development process started with capturing the user requirements as User Stories. User stories incorporated in the specified release are documented as electronic records and developed in accordance with our Software Development Standard Operating Procedure.

Automated functional test cases have been developed and/or maintained for each User Story in accordance with our Software Testing Standard Operating Procedure, with traceability between User Stories and test cases documented in electronic records.

Prior to the implementation of this Release, the functional tests for new and existing functionality in Validaide have been performed and successfully passed. In total, 2653 test cases were successfully executed and passed on 17/12/2020.

All known problems or issues are documented in the development support system.

Summary of IT Infrastructure Qualification

Validaide Release 3.5.0 has been implemented into the production environment on 17/12/2020 in accordance with the current Release Management Standard Operating Procedure. A post-release evaluation has been performed, the results for which have been documented.

Validaide Release 3.5.0 is hosted in a production environment for which an IT Infrastructure Qualification has been performed. The results of the IT Infrastructure Qualification have been documented, and include a description of the physical security, data security, back-up processes, service level agreements and server monitoring processes.

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Mark Bijl CTO	Eelco de Jong Managing Director	Petra Cseh Quality Manager