Validation Certificate

Easycomp Release 1.1

Validation Process / Change Process

The validation / change process of the Easycomp system is based on the internal SOP for the validation of computerized systems. The SOP describes the risk-based approach according to ISPE GAMP 5 and is in compliance with the EU GMP Guideline - Annex 11 - Computerized Systems (revision 1) and US-FDA 21 CFR Part 11 - Electronic Records; Electronic Signatures.

The Change Request Plans #34 und #35 have been approved on the 03.02.2017 for the process of upgrading the Easycomp system to version 1.1.

Validation Approval / Change Request Approval

Within the cumulative **Change Request Report #35** it has been proven that the process of upgrading the Easycomp system upgrade has been validated to date in accordance with the regulatory requirements of the corresponding validation/change processes.

Date of Approval for the Productive Use
01.12.2017

Operation Phase

Further on the Easycomp system can be used in the operational environment by suitably trained and authorized business personnel at client sites.

It is recognized that continued compliance of the system will need to be maintained after Go-Live in order to fulfill continuously the defined validation requirements for this system.

The Easycomp software is under change control and periodic reviews will be executed continuously.

Statement

The software change process was initiated and monitored by Q-FINITY as external consultant. From the point of view of Q-FINITY the process followed B. Braun's internal procedures and fulfilled B. Braun's organizational and functional requirements.

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Dillingen 2017-07-30
Ort, Datum

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