Eppendorf Certificate

Conformity of the epBlue GxP software development

Conformity of the software system development

Eppendorf guarantees that the epBlue GxP software system has been developed in a manner that the documentation conforms to the relevant requirements of the following standards and regulations:

- IEC/EN 62304 (Medical device software – Software life cycle processes)
- CFR Title 21, Part 820 (Quality System Regulation)
- GAMP 5 category 3 and category 4 (Good Automated Manufacturing Practice)

The system can be validated in accordance with these requirements.

The manufacturer certifies the positive result of a system audit in accordance with GAMP 5 chapter 7.

Date: April 2014

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