

Eppendorf Declaration

Conformity statement of the "Enhanced Feature Set GxP" for the epBlue software (epBlue GxP) and software development.

1. Eppendorf declares that the epBlue GxP software for the epMotion® automated liquid handling system has the properties to assist customers by achieving process compliance to the requirements of the following regulations:
 - 21 CFR Part 11 (Electronic Records, Electronic Signatures)
 - EudraLex Vol. 4 Annex 11 (Computerized Systems)
2. Eppendorf as the developer, supplier and legal manufacturer of the epBlue GxP software maintains a quality management system ensuring compliance with the relevant requirements of both ISO 13485 and ISO 9001.
3. The epMotion/epBlue GxP system is classified as GAMP 5 category 4. Conformity with GAMP 5 was verified by an independent third party audit.

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Julia Preu
Head of Quality Management and
Regulatory Affairs R&D

Your local distributor: www.eppendorf.com/contact
Eppendorf SE · Barkhausenweg 1 · 22339 Hamburg · Germany
eppendorf@eppendorf.com

ISO 9001
Certified

ISO 13485
Certified

ISO 14001
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