Certificate of Compliance

Applicant/Manufacturer: Hangzhou Pangu Automation System Co., Ltd.
Address: No. 509, Longxi North Rd, Fuyang, Hangzhou, Zhejiang, P.R. CHINA
Product Name: Paperless Recorder
Product Type: KT800 Software: DMS
Regulation: U.S. FDA 21 CFR Part 11
Technical File: Doc 11.1410

Product Description:

In conjunction with its PC software components the paperless recorder provides a closed system for electronic recording, saving, and archiving of process data which meets the requirements of FDA 21 CFR Part 11. Its overall appearance is dominated by a 10.4" color display that shows the measured data in various forms of display (numbers, diagram, bar graph, etc.). The integrated security manager ensures that only authorized persons are allowed to operate the device, while the integrated audit trial manager closely documents all operating actions. The measured data is stored electronically and is available for evaluation on site and on the PC.

Conclusion:

This is to certify that the product complies with all relevant provisions of the U.S. FDA 21 CFR Part 11. This certificate is only valid for the technical file, equipment and configuration described above.

Any significant changes in design or construction of the product, or amendments to the Standards referenced above may render this receipt invalid. The product liability rests with the manufacturer or his representative in accordance with U.S. FDA 21 Part 11. While all due care and skill was exercised in caring out this assessment, MTG Shanghai Mantong accept responsibility only for proven gross negligence. This certificate is issued for the date that the product was validated. Conformance to all regulation requirements is the sole responsibility of the manufacturer including the manufacture and quality control of the products. This is not legal document and c[illegible]d as such. This certificate remains the property of MTG Shanghai Mantong to Whom it must be returned on reques[illegible]

MTG FDA REGISTER CORPORATE SEAL CALIFORNIA

Jacky M. Chuang

Executive Director
Date: 11-12-2014

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This certification affirm that the above device and company was registered with U.S. Food and Drug Administration pursuant to section 305 of the United States Public Health and Bioterrorism Preparedness and response Act of 2002, P.L. 107-188, on the date stated above, and makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whole sole benefit it is issued. MTG CO., Inc. assumes no liability to any person or entity in connection with the foregoing. MTG is a private registration agent not affiliated with the U.S. Food and Drug Administration