



Certificate of Compliance

Certificate Number: MT18-80D0

Applicant/Manufacturer: Elitech Technology, Inc.
Address: 1551 McCarthy Blvd, Suite 112, Milpitas, CA, 95035
Product Name: Temperature and/or humidity data logger
Product Type: RC series
Regulation: U.S. FDA 21 CFR Part 11
Technical File: ElitechLog V3.0.0
Technical File: Doc.04.1810

Product Description:

The temperature and/or humidity data logger is mainly used in the fields of medicine, vaccine, blood, food, flowers, laboratory and etc.
 It is especially suitable for cold chain storage and transportations, where high protection grade is required. The data logger can automatically generate data report for viewing after inserting it to the computer. In conjunction with the data management software, Elitechlog, it will provides a closed system for electronic recording, saving and archiving of process data which meets the requirements of FDA 21CFR Part 11.
 The integrated security system ensures that only authorized persons are allowed to operate the device, while the integrated audit trail functions keep recording for all operating actions closely. All measured data store electronically and are available for evaluation on site and from the computer.

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 carrying 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 equipments is the sole responsibility of the manufacturer including the manufacture and quality control of the products. This is not legal document and cannot be used as such. This certificate remains the property of MTG Shanghai Mantong to whom it must be returned on request.



Jacky M. Chuang

Executive Director

Date: 04.28.2018

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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 whose 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