chemgineering

ERES Certificate

Software: SoftMax Pro GxP
Version: 7.1

MOLECULAR DEVICES

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Assessment objective: Compliance check against the Electronic Records and Electronic Signatures (ERES) requirements of FDA 21 CFR Part 11 and EudraLex, Volume 4, Annex 11 for SoftMax Pro GxP 7.1

Object description: Software to process preconfigured protocols and custom assay workflows for microplate data acquisition and analysis.

Approach: The functions and properties of the above software system are audited against the ERES requirements of 21 CFR Part 11 and EU GMP Annex 11 with its current interpretations. The assessment is guided by a requirements checklist, which is based on the respective 21 CFR Part 11 and Annex 11 paragraphs.

Assessment results:

- **Operator responsibility**
  ERES compliance requires an appropriate operational environment.
  It is the operations responsibility to provide a compliant environment regarding:
  - Technical environment, data management
  - Training
  - Administration
  - Standard Operating Procedures (SOP).

- **Summary**
  The software is compliant with the following ERES requirements:

21 CFR Part 11:	11.10 (b), (d), (f), (g), (h); 11.50, 11.70; 11.300 (a)
EU GMP Annex 11:	Paragraphs: 4.8, 6, 8, 9, 12, 14b, 14c

  The software is compliant with the following ERES requirements with support of the operator:

21 CFR Part 11:	11.10 (a), (c), (e), (i), (j), (k); 11.100 (a), (b); 11.200 (a); 11.300 (b), (c), (d)
EU GMP Annex 11:	Paragraphs: Principles, 1 to 4.7, 7, 9, 10, 14a, 17

  The software supports electronic signature.

Sieghard Wagner