Evaluation Certificate

IESE Report No. 005.19/E

Fraunhofer IESE

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Evaluation Target

testo 190 Software CFR in combination with the testo 190 family of logger devices measuring temperature or pressure, comprising

- testo 190-T1 loggers (Order No. 0572 1901)
- testo 190-T2 loggers (Order No. 0572 1902)
- testo 190-T3 loggers (Order No. 0572 1903)
- testo 190-T4 loggers (Order No. 0572 1904)
- testo 190-P1 loggers (Order No. 0572 1900)
- testo 190 Software CFR (Order No. 0554 1901)

Description

The testo 190 family of data loggers has been designed specifically for temperature and pressure monitoring in autoclaving or freeze-drying processes. The testo 190 Software CFR is an application for collecting, displaying, analyzing, printing, and filing electronic measurement records of such data loggers. It has been designed to meet the FDA's requirements for the proper use of electronic records and electronic signatures, as defined in regulation 21 CFR Part 11.

The evaluation target was evaluated by the Fraunhofer Institute for Experimental Software Engineering IESE with respect to the following requirements:

- product specification
- 21 CFR Part 11, Electronic Records; Electronic Signatures

The evaluation was based on the compliance criteria of the GAMP Special Interest Group 21 CFR Part 11: »Complying with 21 CFR Part 11, Electronic Records and Electronic Signatures«.

The evaluation target complies with the evaluation criteria according to IESE Report No. 005.19/E. The report provides a detailed description of the target configuration under evaluation, the evaluation criteria, and the evaluation results.

This evaluation statement only refers to the specified evaluation target, as made available to Fraunhofer IESE for inspection, in conjunction with testo 190 loggers. The evaluation was successfully concluded on May 29, 2019.

Kaiserslautern, June 26, 2019

Reinhard Schwarz

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(Dr.-Ing. Reinhard Schwarz)