Evaluation Certificate

IESE Report No. 008.20/E

Fraunhofer IESE

Testo SE & Co. KGaA

Fraunhofer Institute for Experimental Software Engineering IESE

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Evaluation Target

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

- testo 190-T1 logger (Order No. 0572 1901)
- testo 190-T2 logger (Order No. 0572 1902)
- testo 190-T3 logger (Order No. 0572 1903)
- testo 190-T4 logger (Order No. 0572 1904)
- testo 190-P1 logger (Order No. 0572 1900)
- testo 190 Software CFR Version 1.1 (Build 1054) (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 provides functionality to meet the FDA's requirements for the proper use of electronic records and electronic signatures, as defined in U.S. 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 as documented in IESE Report No. 008.20/E. The report provides a detailed description of the target configuration under evaluation, the evaluation criteria, and the evaluation results.

This evaluation statement refers only to the specified evaluation target, as made available to Fraunhofer IESE for inspection. The evaluation was concluded on March 26, 2020.

Kaiserslautern, April 2, 2020

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(Dr.-Ing. Reinhard Schwarz)

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