

Manufacturer's Declaration

Regarding the Compliance with Measures for Assuring the Quality of:

SIMATIC PCS 7, Version 9.0

We state herewith that our standard software product SIMATIC PCS 7 was developed, tested, approved and produced in accordance with the stipulations of valid quality management for the Siemens AG, Process Industries and Drives – Process Automation (PD PA).

The DQS (Deutsche Gesellschaft zur Zertifizierung von Managementsystemen - German society for the certification of quality assurance system) has regularly tested our quality management system since 1993 and has confirmed that our quality management system fulfills the requirements of DIN EN ISO 9001:2008. This is documented in the certificate from the DQS with Reg. No. 000656 QM08.

This quality management system encompasses a life cycle model, which surpasses the requirements of DIN EN ISO 9001:2008. This life cycle model concerning the development of software products also complies with the requirements of the GAMP® 5 Guide "A Risk-Based Approach to Compliant GxP Computerized Systems".

The quality management system is described in:

- Siemens quality management – Mandatory elements
- Management Manual - Process Industries and Drives Division / Process Automation (PD PA)
- PD PA Process House
- Process descriptions and instructions

The product named above are used worldwide. Their application areas also include qualified and/or validated systems in GxP-regulated areas.

This manufacturer's declaration shall not be deemed a guarantee as per Section 443 German Civil Code ("Beschaffenheitsgarantie" as per Section 443 BGB).

Siemens Aktiengesellschaft, September, 21th 2017

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