Zertifikat

The certification body of TÜV Informationstechnik GmbH hereby awards this certificate to the company

Philips Deutschland GmbH
Lübeckertordamm 5
20099 Hamburg, Germany

to confirm that its software product

IMKB-Berechnung Version 1.2.2 für Philips PDMS

fulfils all requirements of the standard

ISO/IEC 25051:2006.

The requirements are summarized in the appendix to this certificate.

The appendix is part of the certificate and consists of 6 pages.

The certificate is valid only in conjunction with the corresponding evaluation report until 2016-04-30.

ISO/IEC 25051 PQ6125.14 TÜVIT® 2014 Trusted Product

Voluntary Validation

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Certificate-Registration-No.:
TUVIT-PQ6125.14

Essen, 2014-04-30

Dr. Christoph Sutter
Head of Certification Body

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Member of
TÜV NORD GROUP

TÜV®

Certification System

The certification body of TÜV Informationstechnik GmbH performs its certification on the basis of the following product certification system:

- German document: "Zertifizierungsschema für TÜViT Trusted-Zertifikate der Zertifizierungsstelle TÜV Informationstechnik GmbH", version 1.0 as of 2010-05-18, TÜV Informationstechnik GmbH

Evaluation Report

- German document: "Prüfung IMKB-Berechnung Version 1.2.2 für Philips PDMS auf Konformität mit ISO/IEC 25051:2006 – Prüfbericht", version 1.6 as of 2014-04-29, Evaluation Lab for IT Usability of TÜV Informationstechnik GmbH

Evaluation Requirements

- "ISO/IEC 25051: Software-Engineering – Software product Quality Requirements and Evaluation (SQuaRE) – Requirements for quality of Commercial Off-The-Shelf (COTS) software product and instructions for testing" (2006)
- Product-specific requirements (see below)

The evaluation requirements are summarized at the end.

Evaluation Target

Target of evaluation is the software product:

"Intensivmedizinische Komplexbehandlung (IMKB), Version 1.2.2 für Philips Patientendatenmanagementsystem Release E (ICIP) oder Release F (ICCA)", short "IMKB-Berechnung Version 1.2.2 für Philips PDMS"

the corresponding product description:

German document: “Produktbeschreibung IMKB – Lastenheft“, Version 2.6 vom 16.04.2014, Philips GmbH, Unternehmensbereich Healthcare

and the user documentation required for the operation:

German document: “Benutzerdokumentation IMKB“, Version 1.3 vom 16.04.2014, Philips GmbH, Unternehmens-bereich Healthcare.

The software product consists of a stateless set of database rules that are applied to records of the patient data management system and that generate new records out of it.

Evaluation Result

- The evaluation target consisting of product, product description and user documentation fulfils the requirements of the standard ISO/IEC 25051:2006.
- The product-specific requirements are fulfilled.
- The constraints of the evaluation report have to be regarded.

Summary of the product-specific requirements

The following product-specific requirements are defined in the product description are basis of the certification and have been checked:

1 Statements on functionality

From the documentation in the electronic patient chart the product correctly and automatically calculates effort points for complex intensive care treatment (IMKB) according to the Operation Procedure Codes 2013 (OPS2013) and the German Coding Rules (DKR).

2 Statements on reliability

The reliability of the calculation is given, if the documentation in the electronic patient chart is done regularly and technical resources (servers, processes, databases etc.) necessary for calculations are available. After temporary failure of technical resources recalculation takes place that correctly treats data from the previous days. (configurable period)

3 Statements on usability

The product does not contain a user interface. Therefore, the aspect, statements on usability, is not applicable.

4 Statements on efficiency

The calculation of effort points is done so that the results are available the next day.

5 Statements on maintainability

The manufacturer will adapt the product on customer demand or due to legal changes of the calculation basis. The maintainability is given.

6 Statements on portability

The product requires the specified environment and must be operated together with the Philips Patient Data Management System Release E (ICIP) or Release F (ICCA).

7 Statements on the quality in use

The product description contains statements relating to economic efficiency, potential cost savings and fulfilment of future guidelines and parameters.

The complete product-specific requirements are defined in the product description (see item evaluation target).

Summary of the Evaluation Requirements

The standard ISO/IEC 25051:2006 contains the following requirements:

1 Requirements on the product description (clause 5.1)

The product description is available for potential acquirers and users and contains information about the product properties. It is free of inconsistencies and contains testable / verifiable statements. It contains information for product identification and hints and makes statements on functionality, reliability, usability, efficiency, maintainability, portability and quality in use.

2 Requirements on the user documentation (clause 5.2)

The user documentation is complete, correct, consistent and understandable, contains necessary information on how to use the software and is operable.

3 Requirements on the quality of the software (clause 5.3)

The quality of the software complies with the statements of the product description and user documentation in terms of functionality, reliability, usability, efficiency, portability and quality in use.

4 General requirements for test documentation (clause 6.1)

The test documentation demonstrates that the requirements on the quality of the software (clause 5.3) are fulfilled. It is free of inconsistencies, contains a test plan, a test description and test results.

5 Requirements of the test plan (clause 6.2)

The test plan contains at least one test case for each quality characteristics of the product description, for each require-

ment on the quality of the software (clause 5.3), and for each function described in the user documentation. The test cases demonstrate the conformity of the software to the statements in the user documentation. Furthermore, the test plan contains test cases for all installation procedures and operational limits. The criteria used to decide if the test results demonstrate the conformity of the software to the product description and user description are indicated. The test environment and time schedule are described in the test plan.

6 Requirements for the testing description (clause 6.3)

For each test case, the testing description includes the test objective, a unique identifier, the input data and test boundaries, the detailed test steps to perform, expected results, criteria for result interpretation as well as criteria to decide whether the test result is positive or negative.

The test procedures include the following points: preparation, action necessary steps to carry out and record the test results as well as the conditions and actions to stop and eventually restart the tests. They are sufficiently detailed to provide for repeatability and reproducibility of the tests. Following correction, a procedure for re-test of the affected functions exists.

7 Requirements for the test results (clause 6.4)

The summary of the test results is recorded in an execution report. It demonstrates that all test cases have been executed according to the test plan. The summary of the anomalies are listed in the anomaly report. Any anomaly is described and it is explained how this was corrected. The assessment of the execution report and anomaly report

demonstrates that all expected behaviours were obtained within the specified limits.