

**IEC 62304:2006
Certified**



CANTATA 

Cantata has been classified as usable in the development of safety related software, up to SW safety Class C, as defined by the **IEC 62304** standard



Cantata has been certified by **SGS -TÜV Saar GmbH**, an independent third party certification body for functional safety, accredited by Deutsche Akkreditierungsstelle GmbH (DAKKS).

AdaTEST 95 

AdaTEST 95 dynamically proves code with intelligent unit and integration testing, in the most cost effective manner.

AdaTEST 95 has been successfully used by customers worldwide since the 1990s to meet the main international safety-related standards.

Sector Brief: Medical Device

In this sector brief we highlight:

- > The IEC 62304 software standard, which specifies life cycle requirements for the development of medical software and software within medical devices.
- > The FDA guidance document that outlines validation principles for medical device software.
- > How Cantata and AdaTEST 95 support project certification

IEC 62304

IEC 62304, *Medical device software - Software life cycle processes*, is a harmonised standard that is used as a benchmark to comply with regulatory requirements in both the European Union and the United States.

Standard Requirements

Cantata's functionality specifically addresses the following sections of the IEC 62304 standard:

- Clause 5 Software Development Process
- Clause 6 Software Maintenance Process
- Clause 8 Software Configuration Management Process
- Clause 9 Software Problem Resolution Process



Hamilton Intelligent Ventilation

FDA

The guidance document, *General Principles of Software Validation; Final Guidance for Industry and FDA Staff*, outlines general validation principles applicable to the development of medical device software.

Standard Requirements

Cantata specifically addresses the following sections of the guidance document:

- Section 3 Context for Software Validation
- Section 4 Principles of Software Validation
- Section 5 Activities and Tasks
- Section 6 Validation of Automated Process Equipment and Quality System Software



GE Healthcare Critical Care Monitor in Use

Cantata Tool Certification Kit

Medical Device Customers Include:



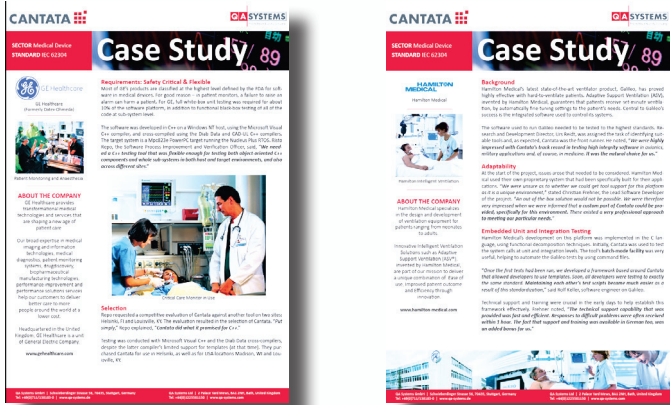
- > The **Safety Manual** provides guidance for how to use Cantata in a safety-related context, and to meet the requirements of independent tool certification
- > The **Standard Briefing** papers are intended to serve as a reference to show how Cantata can be used to satisfy requirements of the IEC 62304 standard and FDA guidance document respectively.
- > The **Certification** of Cantata was undertaken by SGS-TÜV GmbH, an independent third party certification body for functional safety, accredited by Deutsche Akkreditierungsstelle GmbH (DAKKS) [accreditation ID: D-PL-12088-01-01]

Customer Case Studies

Our Customer Case Studies provide more information on how Cantata and AdaTEST 95 were successfully used by various companies worldwide.

"Cantata testing had a positive impact on the way we write the code - reducing coupling between objects and making isolation testing easier!"

- GE Healthcare



Quicklinks

- > Customer Case Study: GE Healthcare
- > Customer Case Study: Hamilton Medical

All Customer Case Studies are available upon request

cellnovo

GE Healthcare

PHILIPS

CareFusion

BREAS

Roche

Dräger

HAMILTON MEDICAL

SIEMENS medical

vitatron

MEDICAL INTELLIGENCE