The market–leading, validated approval accelerator for convenient generation of faultless technical documentation for medical devices

RISK MANAGER

MST INSTRUMENTE GMBH

SUCCESS STORY

Savings in work and time spent on IEC 60601-1

"Especially for manufacturers of medical electrical devices the Risk Manager is in my opinion the first choice. I can only recommend it to everyone!"

Jürgen Müller
MST-Instrumente GmbH
In Breiten 13
78589 Dürbheim

MST-Instrumente GmbH is an ambitious company for the development, production, installation and distribution of human and veterinary medical devices. Since 1992, the company, managed by the two brothers Jürgen and Volker Müller, has been developing medical electrical devices such as high-quality plaster and autopsy saws as well as horse dental rasps.

MST-Instrumente GmbH

Challenge – conversion to IEC 60601-1 Edition 3

As an SME, the challenge for MST-Instrumente GmbH was especially the conversion of IEC 60601-1 to the third edition. Due to the adaptation of the standard, many additional tests on the devices became necessary, which meant immense additional work and time spends with the previous procedure using simple programs for document processing.

The importance of risk analysis increased enormously, so the company from Dürbheim near Tuttlingen was looking for an efficient solution that would at the same time reduce the potential for mistakes in the area of risk observation and assessment.
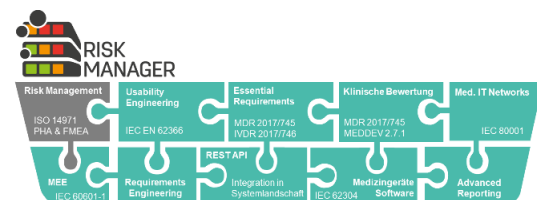
Choosing the Market Leader

The Risk Manager has been used in the company since 2005 to prepare the risk management files. Since it was known that the solution had extension modules, for example for medical electrical devices, the brothers decided to evaluate the full version of Risk Manager first. Thus, all relevant requirements and standards were to be covered in one system in a clear and time-saving way. During the test phase, the company's employees were

MST-Instrumente GmbH - manufacturer of plaster saws, autopsy saws and horse dental rasps

able to find their way around the system quickly. By linking the data and the structured layout, they were quickly convinced that they had found the most efficient approach. A subsequent search for comparable solutions confirmed the considerations, so that MST-Instrumente GmbH decided to use the full version with extensions for Usability and Requirements Engineering as well as for testing the basic requirements in addition to covering IEC 60601-1.
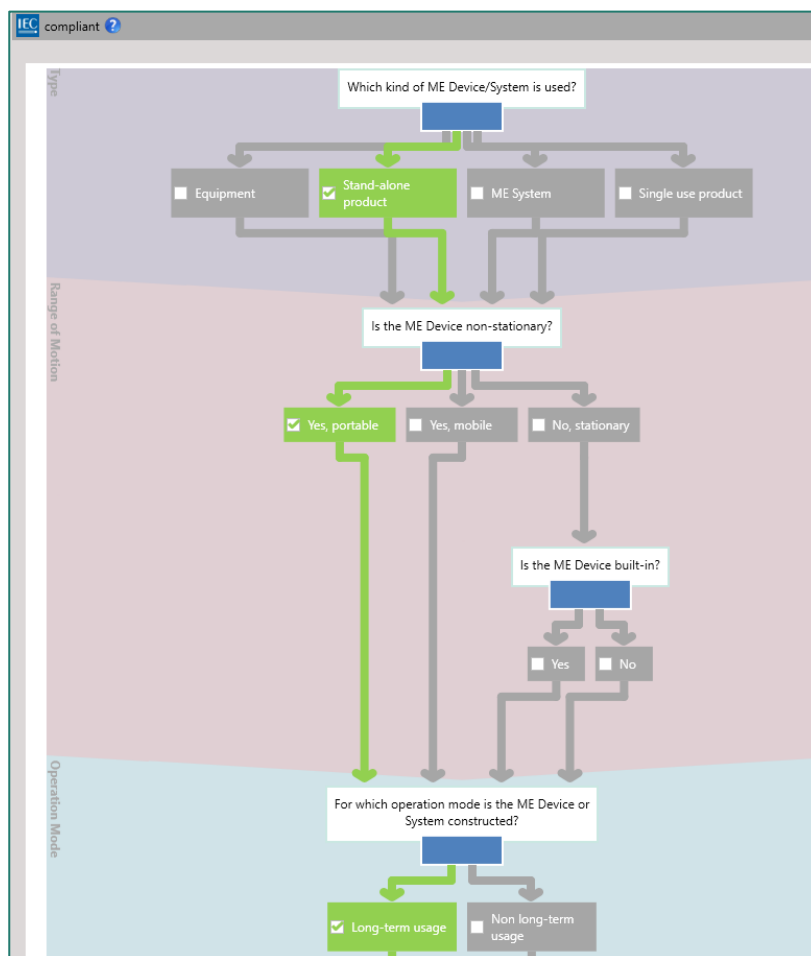
Achieving Cost Savings

After a quick and smooth implementation of the solution, the processing of the documentation could be started immediately. In addition to the efficiency achieved, the user guidance is self-explanatory so that "learning by doing" is possible. Due to the procedure of checklist processing within the framework of IEC 60601-1, only those topics that are really necessary for plaster saws and other medical devices need to be checked. At the same time, all standards and directives are always up to date and their processing is complete in terms of content.

"You find what you are looking for very quickly and you "only" have to concentrate on the content of the documents. Now I can sleep peacefully knowing that there is complete documentation available," Jürgen Müller concludes.

Support even after the purchase

But even after the purchase, MST-Instrumente GmbH will not be forgotten at BAYOONET AG. Customers have the possibility to use a ticket system and always get fast and competent help from a personal contact person. Within the framework of a software update agreement, it is also guaranteed that the customer will be provided with all changes to the integrated standards during the transition period. For Mr. Müller, the Risk Manager is therefore "the first choice for all those who are looking for an integrated solution for technical documentation with few personnel.

Preparation of the conformity report for medical electrical devices according to IEC EN 60601-1 – Risk Manager simplifies the process with an intelligent questionnaire linked to the over 1,500 tests of the standard

RISK MANAGER

The market-leading, validated approval accelerator

BAYOONET AG is a German software company established on the market since 2001 and the manufacturer of the Risk Manager within BAYOOSOFT, our business unit for Management Software. Our solutions are aimed at heavily regulated sectors and critical infrastructures in enterprise environments. Our quality management processes – certified in accordance with ISO 9001 and ISO 13485 by TÜV-Hessen – reflect our passion for sustainable enterprise solutions and distinct customer focus.

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