

The market-leading, validated approval accelerator  
for convenient generation of flawless technical  
documentation for medical devices



# RISK MANAGER



Klinikum rechts der Isar  
Technische Universität München

## SUCCESS STORY

### Faultless Documentation and Achievement of the IEC 80001-1 Protection Goals through the BAYOOSOFT Risk Manager

„With the BAYOOSOFT Risk Manager we were able to avoid the time-consuming manual workload. The software guides us through the process without errors, you can't deviate, you can't forget anything and therefore get a perfect result.“

Knut Lauter

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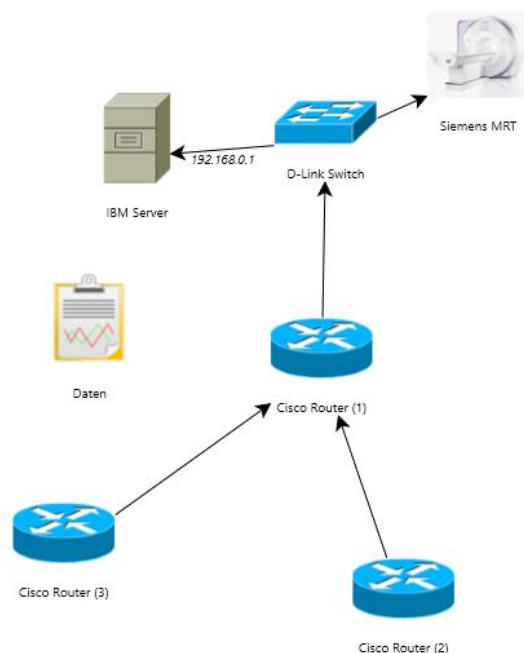
**BAYOOSOFT**  
MANAGEMENT SOFTWARE

Since 1834, the University Hospital rechts der Isar has developed from a district hospital to a supramaximal hospital, which covers the entire spectrum of modern medicine with approx. 1200 beds. With around 30 clinics, 20 interdisciplinary centres and numerous scientific institutes, more than 5500 employees ensure the well-being of patients and the further development of medical research.

#### Klinikum rechts der Isar der Technischen Universität München

### The Path to an automated Risk Management

Previously, the administration of the risk management was done by Excel-Sheets and Word-Documents. A permanent overview of the various risk files could only hardly be guaranteed. Therefore, the project team under leadership of Mr. Lauter decided to look for a functional software solution.



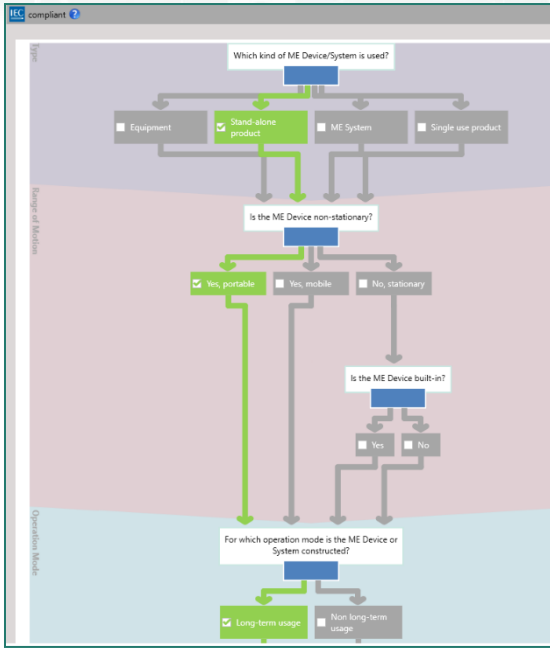
During their research, the project team came across the Darmstadt-based software manufacturer BAYOOSOFT, which has been active on the market since 2001. The BAYOOSOFT Risk Manager is an automated software solution for creating technical

documentations, which not only offers the basic component Risk Management according to ISO 14971, but also the medical device operator solution according to IEC 80001-1. The University Hospital rechts der Isar implemented the modules Medical IT-Networks and Medical Electrical Equipment.

The standard IEC 80001-1 is essential for the operation of medical devices in IT networks. To fulfil this standard, employees are supported by the BAYOOSOFT Risk Manager. Risks can be identified early on, a clear documentation is guaranteed and a central administration is ensured. The well-organized structure of the Risk Manager enables an error-free and traceable documentation for risks within the networks and individual network components. The main focus is to fulfil the protection goals.

### Achieving Time Savings

After the successful implementation of the software with the help of the BAYOOSOFT Service Teams, the employees of the hospital were able to start processing the risk files in the BAYOOSOFT Risk Manager promptly. Thanks to the clearly designed user interface, the trained team was able to quickly find their way around the software and start their daily working of risk management.



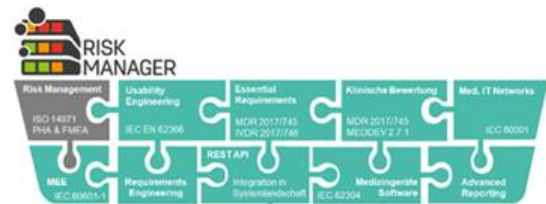
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### After-sales Support

The personal after-sales support is guaranteed by the Solution Engineers of BAYOOSOFT. They accompany the customers from the initial trial onwards, therefore they already know the customer’s system and enables them to support competently and promptly when needed. “We are more than satisfied with the Risk Manager. If we need help, we know the BAYOOSOFT Team will respond as quickly as possible.”, says Mr. Lauter satisfied.

The same number of employees work much more efficient now. There is an enormous saving of time concerning the form of the documents. Content became more important and the focus has shifted to real improvements.

„Before, we used to work with time-consuming Excel-Sheets, where it was easy to lose the overview.”, recalls Mr. Lauter.





# RISK MANAGER

## The market-leading, validated approval accelerator

BAYOOSOFT GmbH was founded in 2022 by spinning off the BAYOOSOFT business unit from BAYOONET AG, which had been established on the market since 2001. It is a German software house and manufacturer of the Access Manager. 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 oriented towards ISO 13485 by TÜV Hessen - reflect our passion for sustainable enterprise solutions and distinct customer focus.

~~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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