

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



# RISK MANAGER



## SUCCESS STORY

### ITV Denpendorf Produktservice GmbH – The experts for textile- based medical implants

„I can recommend the Riskmanager to anyone who needs to  
create a comprehensive risk management file.“

Monika Renardy  
ITV Denpendorf Produktservice GmbH  
Koerschtalstraße 26  
73770 Denpendorf

**BAYOOSOFT**  
MANAGEMENT SOFTWARE

ITV Denkendorf Produktservice GmbH is a company that combines state-of-the-art technology with outstanding quality and extensive expertise. The company has EN ISO 13485 certification and specialises in the development and production of medical implants, most of which are manufactured on a textile basis. In 2005, the company embarked on a search for a digital solution for the risk management of manufactured products, as this was required in a previous audit.

**ITV Denkendorf Produktservice GmbH**

### Challenge: Process-specific risk management

The challenge: ITV Denkendorf's manufacturing and development work covers the entire process, from the molecular level through to the production of almost finished medical products. Its customers only have to take care of the final packaging, sterilisation and market launch. And this is precisely the challenge, because the company does not produce its own products, but is a supplier of preliminary products.

ITV Denkendorf is involved in the production chain right up to the almost finished end product. Risk management must therefore be process-specific and take into account considerations of possible errors in the various manufacturing steps. After all, its customers are ultimately responsible for product-specific risk management, as only they have the contacts to the market and the clinics.

A risk assessment in Microsoft Excel® was out of the question for our contact Monika Renardy, Deputy Manager Development at ITV Denkendorf. A convenient software solution was needed.

"I wanted a product that would enable me to present a clear overview of risk management with as little effort as possible. If possible, the system should enable process-specific analyses," recalls Monika Renardy.



*Our contact person Monika Renardy*

### Decision in favour of the market leader

During her research, Monika Renardy came across BAYOOSOFT Risk Manager. She decided to try out the free trial version and finally purchased the product in 2005. ITV Denkendorf Produktservice GmbH particularly benefited from the product-specific focus at the time.

"The introduction of BAYOOSOFT Risk Manager went well, but as I was a lone fighter in the field of risk management for a long time and learnt by doing, it took some time before I had created the risk management files for the products," reports Monika Renardy. "But the BAYOOSOFT Risk Manager enabled me to create them in a structured way and to keep a good overview."



*Polymerisation reactor at ITV Denkendorf*

## Greater clarity and complete documentation

One advantage that Monika Renardy no longer wants to do without is the clarity and traceability that BAYOOSOFT Risk Manager provides, which makes her work much easier. It is so easy to visualise the process steps in which a particular measure is used.

According to Monika Renardy, the auditors are also always impressed by this. Another advantage of the specialised software solution is that it is audit-proof.

"Some companies are probably still working with Word or Excel files. In our company, three employees now use BAYOOSOFT Risk Manager in parallel". Standardised, clear and complete - risk files like that convince auditors during the audit.

## Support even after the purchase

Even after the successful introduction of BAYOOSOFT Risk Manager, Monika Renardy and her team continue to benefit from the services. The regular updates also offer a constant stream of new features and enhancements for the software solution.

"If I had any difficulties with the operation, I always got help quickly via the hotline right from the start. And Christine Erb (Solution Representative Customer Care), who is always friendly and helpful, has also been looking after us for several years. We are simply convinced all round," emphasises Monika Renardy.







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## 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.

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