

Developing an IVDR-compliant web application

„In infoteam, we have found the partner we were looking for to develop, maintain and enhance our regulations-compliant web application Proclarix® Risk Calculator: reliable, experienced and with the perfect balance between customer focus and independence.“

Christian Brühlmann, Chief Business Officer & Co-Founder
Proteomedix AG

For our client:

 **Proteomedix**

Web application | IVDR | C# | ASP.NET | HTML

MVC | MS SQL | Cyber security | SBOM

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Initial situation

- Customer has an algorithm that calculates a risk assessment for prostate diseases based on specific biomarkers
- Request: Website to offer evaluation software as a commercial application for laboratories and doctors
- Requirement: Conformity with applicable regulations for software safety class C
- Requirement: Technical maintenance and enhancement of the application, including implementation of the higher requirements found in the IVDR, in particular cyber security

Solution

2017: Start of the collaboration

- Development of a web application (frontend and backend) based on ASP.NET – parameter input, evaluation, report generation
- Included implementation of database staging and data-protection-compliant user administration with login function
- IVDD-compliant documentation for approval
- Regular software maintenance and adjustments

Since 2022: Updates in accordance with IVDR requirements and feature updates

- Extended risk assessment and threat analysis in accordance with the IVDR
- Evaluation and elimination of the vulnerabilities found in the penetration test
- Automated software component analysis, incl. vulnerability scans*; also in place as part of post-market surveillance
- Adding further language packs

*Search for known security vulnerabilities in the software bill of materials (SBOM)



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