Certifying Medical Image Correction Systems

01 THE CHALLENGE

Guaranteeing the efficiency and security of medical devices is key to providing good healthcare. If the equipment used by healthcare professionals does not deliver accurate results in a timely manner, the consequences can be extremely dangerous.

A Portuguese medical image-processing start-up challenged Critical Software to support the certification activities of their image correction system as a Class IIb medical device. The company required a real-time solution to deblur images used to support arthroscopy procedures.

02 THE SOLUTION

We were responsible for supporting the certification of the image correction device, preparing all the necessary evidences and assisting the company in producing all the required artefacts as set out by European standards.

The Class B software classification assigned to the image processing system under IEC 62304 meant that, to ensure that a CE mark (certifying the system's suitability for use in EU member states) was issued, Critical had to be meticulous in preparing the artefacts through carefully designed processes, gap analysis, and documentation development. The fact that much of this certification activity involved processes that had already been started increased the need for a careful and considered approach to managing the project.

The main tasks consisted of the analysis of the entire system as well as generating the necessary plans needed for its certification, assuring the system's compliance with standards such as ISO 13485, ISO 14971, IEC 60601-1 and IEC 62304, and outlining the minimum requirements for effective quality management systems, risk management practices, device safety, and software lifecycle definition.

Additionally, support to on-site audits was delivered with success, demonstrating a strong relationship between the company and our team.

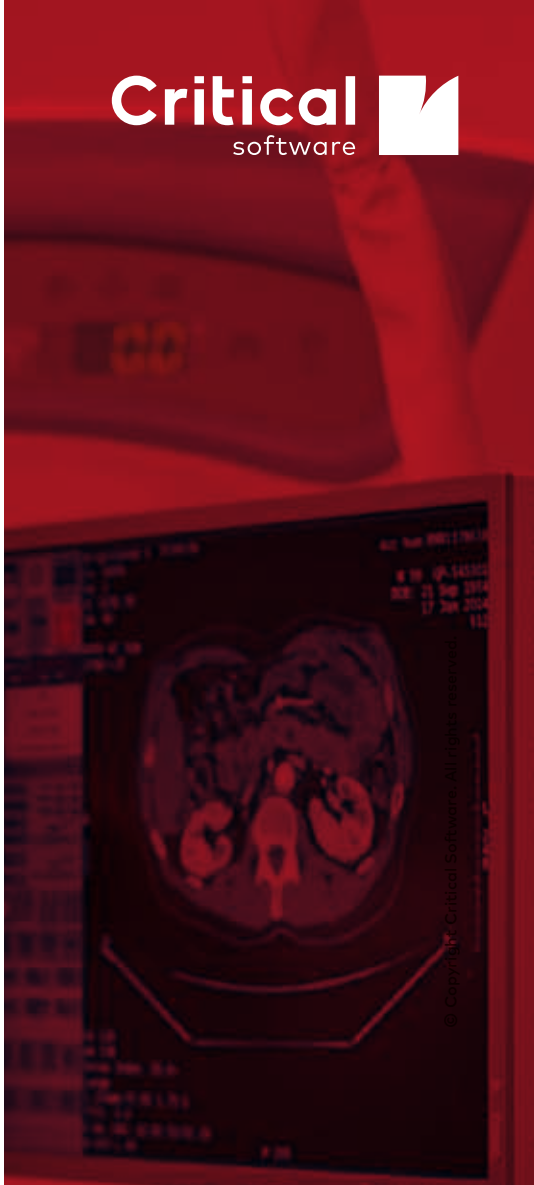
03 THE RESULTS

With our help, the start-up was able to focus its activities on developing and improving the technical capabilities of the image processing system. The clearly defined software development process we implemented also meant that these activities were carried out and completed efficiently, reducing the time-to-market of the system.

04 THE ACTIVITIES

- Verification & validation
- Audit support
- Intelligent video processing
- Augmented reality (AR)
- Documentation for ISO 13485, ISO 14971, IEC 60601-1 and IEC 62304 standard compliance

Critical software



ABOUT CRITICAL SOFTWARE

Critical Software provides systems and software services for safety, mission and business-critical applications. We work closely with our clients, helping them to meet the most demanding standards for performance and reliability.

We were founded in 1998, with NASA our very first client. Today, we work across many international industries and have offices across the globe.

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We are CMMI Maturity Level 5 rated.
For a list of our certifications & standards visit our website.