

Medical Safety Design

The safe and economical use of medical products in diagnostics and therapy require optimal risk management and high usability. The standards IEC 60601-1-6 and IEC 62366 oblige manufacturers of medical products to conduct a usability engineering process and risk management that is documented according to standards. We assist you from the product idea via the development to the submission of the usability engineering file and risk management file at the certifying bodies.

WHAT IS MEDICAL SAFETY DESIGN?

Until recently, usability has „only“ been a sales argument. The collateral standard IEC 60601-1-6 and IEC 62366, however, requires the manufacturers of medical devices to assume a new duty: The measures for more usability must pass a usability engineering cycle and be documented in a usability engineering file. Additionally, a risk management file must be prepared.

AN EXTENSIVE RANGE OF SERVICES

The employees of User Interface Design GmbH (UID) and Jörg Stockhardt consulting & more (c&m) offer you an extensive range of services:

- We consult you on the usability engineering process and design your product according to usability criteria
- Risk management according to ISO 14971:2007
- We prepare the accompanying and final documentation of the usability engineering process in a usability engineering file according to IEC 60601-1-6 and IEC 62366
- We prepare your risk management file according to ISO 14971:2007

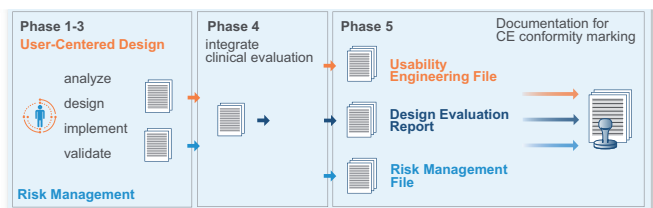
We integrate the results of the independent evaluation of the medical product in our documentation. Finally, you receive a complete documentation for the submission at the notified bodies.

YOUR USABILITY CONTACT PERSON



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YOUR WAY TO SAFE MEDICAL PRODUCTS



YOUR BENEFIT

- User-friendly products allow to strengthen your position and meet requirements for medical devices and in-vitro diagnostics. You can act faster and considerably distinguish yourself from your competitors.
- A number of standards play a role when developing safe medical products. We help you to keep an overview – efficiently and successfully.
- In the usability engineering process, the user is the focus of the development, which influences the variety of functions, increases acceptance, and reduces costs.

THE TEAM BEHIND MEDICAL SAFETY DESIGN

Due to the collaboration of UID and c&m, you can benefit from a package of services that is unique in Germany. In your interest, we offer you usability engineering and risk management from a single source. The know-how of experienced medical usability engineers meets the long experience in consulting of Jörg Stockhardt as regards projects on conformity assessment, quality and risk management. In total, UID and c&m have successfully been managing projects for 25 years.

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