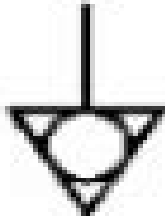
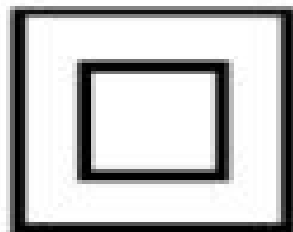


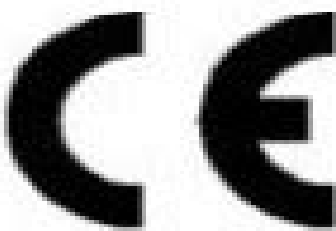
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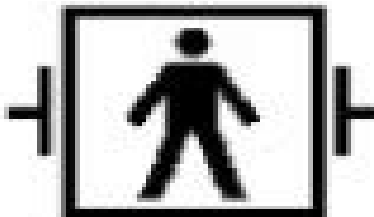
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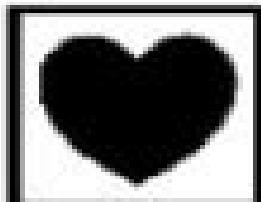
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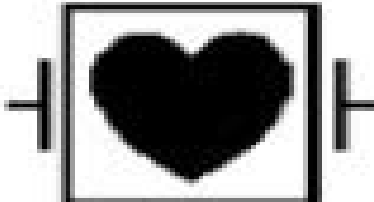
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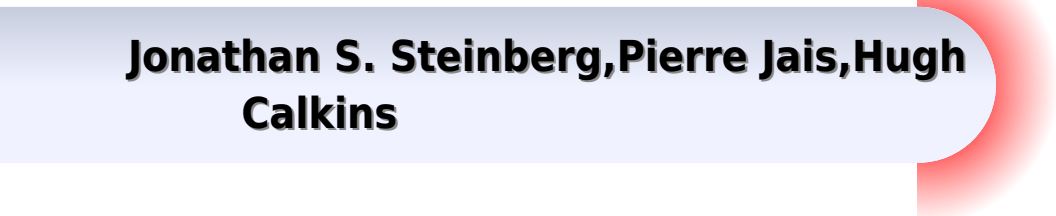
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Federal Register ,2014

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case studies and illustrations **Safety Risk Management for Medical Devices** Bijan Elahi, 2021-11-11 Safety Risk Management for Medical Devices Second Edition teaches the essential safety risk management methodologies for medical devices compliant with the requirements of ISO 14971:2019. Focusing exclusively on safety risk assessment practices required in the MedTech sector, the book outlines sensible, easily comprehensible state-of-the-art methodologies that are rooted in current industry best practices addressing safety risk management of medical devices, thus making it useful for those in the MedTech sector who are responsible for safety risk management or need to understand risk management, including design engineers, product engineers, development engineers, software engineers, Quality Assurance, and regulatory affairs. Graduate-level engineering students with an interest in medical devices will also benefit from this book. The new edition has been fully updated to reflect the state of the art in this fast-changing field. It offers guidance on developing and commercializing medical devices in line with the most current international standards and regulations. Includes new coverage of ISO 14971:2019, ISO TR 24971. Presents the latest information on the history of risk management, lifetime of a medical device, risk management review, production and post-production activities, post-market risk management. Provides practical, easy-to-understand state-of-the-art methodologies that meet the requirements of international regulation. **Applied Human Factors in Medical Device Design** Mary Beth Privitera, 2019-06-15 Applied Human Factors in Medical Device Design describes the contents of a human factors toolbox with in-depth descriptions of both empirical and analytical methodologies. The book begins with an overview of the design control process integrating human factors as directed by AAMI TIR 59 and experienced practice. It then explains each method, describing why each method is important, its potential impact when it's ideal to use, and related challenges. Also discussed are other barriers such as communication breakdowns between users and design teams. This book is an excellent reference for professionals working in human factors, design, engineering, marketing, and regulation. Focuses on meeting agency requirements as it pertains to the application of human factors in the medical device development process in both the US and the European Union (EU). Explains technology development and the application of human factors throughout the development process. Covers FDA and MHRA regulations. Includes case examples with each method.

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