1. Record Nr. UNINA9911006741103321 Autore Wirth Axel Titolo Medical Device Cybersecurity for Engineers and Manufacturers, Second Edition Pubbl/distr/stampa Norwood:,: Artech House,, 2024 ©2024 **ISBN** 9781523162598 1523162597 9781630819927 1630819921 Edizione [2nd ed.] Descrizione fisica 1 online resource (481 pages) Altri autori (Persone) GatesChristopher SmithJason Soggetti Computer security - Standards Medical instruments and apparatus Lingua di pubblicazione Inglese **Formato** Materiale a stampa Livello bibliografico Monografia Medical Device Cybersecurityfor Engineers and Manufacturers, Nota di contenuto Second Edition -- Contents -- Foreword to the First Edition --Foreword to the Second Edition -- 1 Why Secure Medical Devices? -- 1.1The Inspiration for This Book: The Original First Edition Introduction -- 1.2Why a Second Edition? -- 1.3The Evolution of Cybersecurity in Healthcare -- 1.4The Unique Role of Medical Devices -- 1.5Regulatory Environment --1.6Looking Ahead -- References -- 2 Establishing a Cybersecurity Focus Within Medical Device Manufacturers -- 2.1Governance and Organization -- 2.2Building a Security-Capable Organization --2.2.1Implementation and Oversight --2.2.2A Lifecycle Approach to Cybersecurity --2.2.3Design and Implementation of Best Practices and Principles --2.2.4Security 2.2.5PostMarket Management --Testing --2.2.6Internal Training for Non-Cybersecurity Engineers and Managers -- 2.3 Communicating Cybersecurity Needs, Costs, and Risks to Senior

Leadership -- 2.3.1Lack of Common Understanding of

Cybersecurity Risks -- 2.3.2Lack of Context for the Risk and Its Tradeoffs -- 2.3.3Talking to the Wrong Leader, That Is, Not the Decision-Maker -- 2.4Security and Lifecycle Management Overview -- 2.4.1Coordination Between the Four Lifecycles -- 2.5 Organizational Roles and Responsibilities -- 2.5.1Roles and Responsibilities: Overview and Rationale -- 2.5.2Role-Specific Training and Education

Sommario/riassunto

This book focuses on the cybersecurity challenges and solutions relevant to medical device engineering and manufacturing. It provides a comprehensive guide to establishing secure practices throughout the lifecycle of medical devices, from design and development to deployment and postmarket management. Authored by Axel Wirth, Christopher Gates, and Jason Smith, the book emphasizes the importance of adhering to global regulations and standards, addressing supply chain risks, and implementing robust incident response plans. The second edition includes updates on the evolving cybersecurity landscape in healthcare, offering best practices for engineers, manufacturers, and regulatory professionals. It is intended for a professional audience, including medical device developers, security specialists, and compliance managers, aiming to enhance the security and safety of medical technologies.