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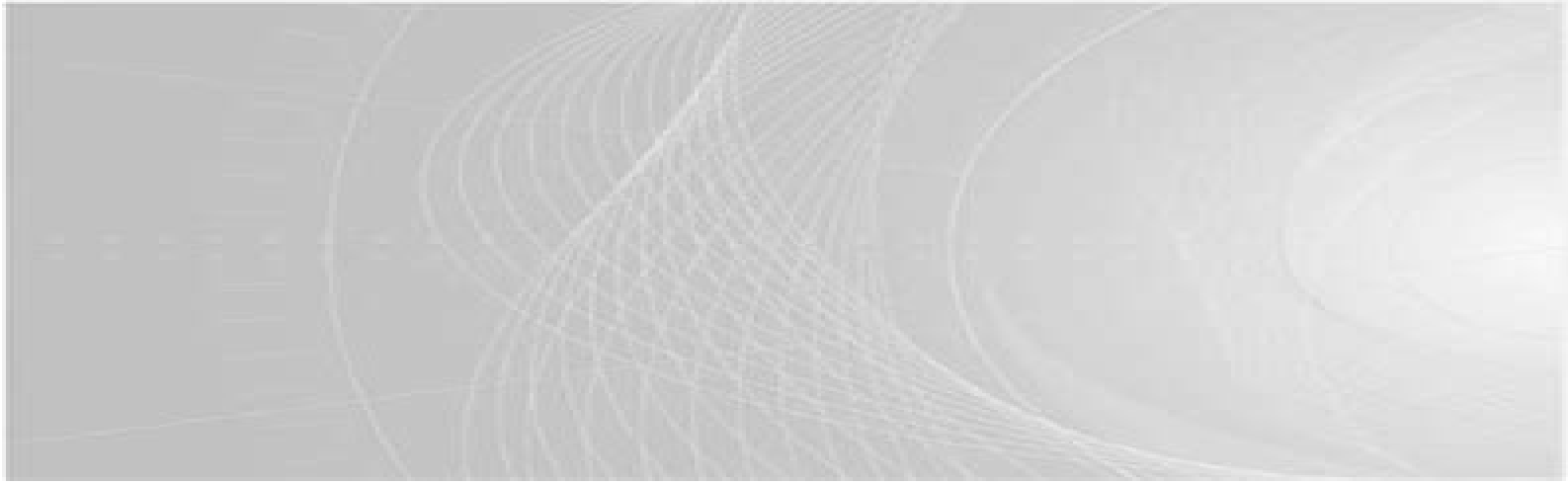

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Camilla Rothe

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and standards Provides readers with a global perspective on medical device regulations Concise and comprehensive information on how to design medical devices to ensure they meet regulations and standards Includes a useful case study demonstrating the design and approval process **Modelo de diseño tecnológico interdisciplinario centrado en las personas para la fisioterapia respiratoria** Aguilar-Zambrano, Jaime A.,Asencio-Santofimio, Helberg,2025-04-25 Ubicu es una historia que trasciende fronteras de disciplinas y h lices academia empresa Estado sociedad civil y defensa del ambiente A lo largo de sus p ginas el lector descubrir c mo un grupo de visionarios de diversas reas del conocimiento se uni para crear un dispositivo m dico desde cero enfrentando desaf os t cnicos culturales y econ micos en el contexto latinoamericano Este modelo de dise o colaborativo no solo busca innovar desde la ingenier a y la ciencia sino tambi n empoderar a las comunidades locales rompiendo las barreras que hist ricamente han limitado el acceso a la salud y creando soluciones sostenibles y apropiadas para la regi n y entornos similares Los primeros cap tulos est n dedicados al an lisis de las dificultades que enfrentan pacientes y fisioterapeutas en el proceso de rehabilitaci n de afecciones pulmonares desaf os que se intensificaron con la pandemia de COVID 19 El libro contin a explicando c mo se desarrolla una tecnolog a orientada a su comercializaci n un prop sito que exige altos niveles de colaboraci n entre m ltiples entidades la participaci n activa de los usuarios de la tecnolog a y un riguroso proceso de dise o descrito en detalle La ltima secci n presenta los componentes de hardware y software que conforman este dispositivo gamificado para la fisioterapia respiratoria con incentivos y seguimiento remoto y c mo cada uno contribuye a una promesa de valor en la que la tecnolog a se convierte en un motor de cambio social y bienestar **DIN EN 60601-1-2 (VDE 0750-1-2), Medizinische elektrische Geräte. Teil 1-2, Allgemeine Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale - Ergänzungsnorm: elektromagnetische Störgrößen - Anforderungen und Prüfungen (IEC 60601-1-2:2014 + A1:2020)** ,2022 **Amendment 1 to ANSI/AAMI/IEC 60601-1-2:2001, Medical Electrical Equipment, Part 1: General Requirements for Safety. 2. Collateral Standard** American National Standards Institute,Association for the Advancement of Medical Instrumentation,2004-01-01 Medical Electrical Equipment - Part 1 ,2002 **Medical Electrical Equipment** Malaysia. Jabatan Standard,2007 **Medical Electrical Equipment - Part 1** ,2002 DIN EN IEC 60601-2-21 (VDE 0750-2-21), Medizinische elektrische Geräte. Teil 2-21, Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Säuglingswärmestrahlern (IEC 60601-2-21:2020 + AMD1:2023) ,2024 *Medizinische elektrische Geräte* ,2016 **Allgemeine Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale** ,2016 *DIN EN 60601-1 (VDE 0750-1), Medizinische elektrische Geräte. Teil 1, Allgemeine Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale (IEC 60601-1:2005 + Cor1:2006 + Cor2:2007 + A1:2012 + A1:2012/Cor1:2014 + A2:2020)* ,2022 **DIN EN IEC 60601-2-35 (VDE 0750-2-35), Medizinische elektrische Geräte. Teil 2-35, Besondere Festlegungen für die Sicherheit einschließlich**

der wesentlichen Leistungsmerkmale von Decken, Matten und Matratzen zur Erwärmung von Patienten in der medizinischen Anwendung (IEC 60601-2-35:2020 + AMD1:2023) ,2024 **DIN EN IEC 60601-2-1 (VDE 0750-2-1), Medizinische elektrische Geräte. Teil 2-1, Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Elektronenbeschleunigern im Bereich von 1 MeV bis 50 MeV (IEC 60601-2-1:2020)** ,2022 **DIN EN IEC 60601-2-50 (VDE 0750-2-50), Medizinische elektrische Geräte. Teil 2-50, Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Säuglings-Phototherapiegeräten (IEC 60601-2-50:2020 + AMD1:2023)** ,2024 *DIN EN IEC 60601-2-21 (VDE 0750-2-21), Medizinische elektrische Geräte. Teil 2-21, Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Säuglingswärmestrahlern (IEC 60601-2-21:2020)* ,2022 **DIN EN IEC 60601-2-20 (VDE 0750-2-20), Medizinische elektrische Geräte. Teil 2-20, Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Säuglings-Transportinkubatoren (IEC 60601-2-20:2020 + AMD1:2023)** ,2024 **DIN EN IEC 60601-2-76 (VDE 0750-2-76), Medizinische elektrische Geräte. Teil 2-76, Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Niedrigenergie-Ionengas-Hämostasegeräten (IEC 60601-2-76:2018 + AMD1:2023)** ,2024 **DIN EN IEC 60601-2-35 (VDE 0750-2-35), Medizinische elektrische Geräte. Teil 2-35, Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Decken, Matten und Matratzen zur Erwärmung von Patienten in der medizinischen Anwendung (IEC 60601-2-35:2020)** ,2022

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