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GD210: ISO 13485:2003 Quality Management System Audits ... 13485:2003 Quality Management System (QMS) Audits Under The Canadian Medical Devices Conformity Assessment System (CMDCAS). This Guidance Document Has Been Revised To Reflect CAN/CSA-ISO 13485:03, Medical Devices – Quality Management Systems – Requirements For Regulatory Purposes, And 1th, 2024 QUALITY MANAGEMENT SYSTEM ISO 13485:2003 13485:2003 For The Following Scope: For And On Behalf Of BSI: VP Regulatory Affairs, BSI Group America, Inc. Originally Registered: 10/22/2013 Effective Date: 04/22/2015 Expiry Date: 12/23/2017 Page: 1 Of 4 QU 2th, 2024 FUTURE OF ISO 13485 AND UPDATE ON ISO 14971 REVISION OF ISO 14971 Notes On ISO/IEC Guide 63:2019 • Guide Is Intended For Writers Of Standards For Medical Devices, When Developing/revising Standards • Current Edition (2012) Was Based On ISO 14971:2007 • Edition 3 Is Basis For ISO 14971:2019 And For Other Standards • Def 2th, 2024.

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Must Show That Quality Systems Are Properly Implemented And Maintained. A Third-  
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Column In Green Shade Follows The Format Of ISO 13485:2016 (8-section Format,  
Based Upon ISO 9001:2008) To Help Identify And Locate Where In The  
Requirements Are Relevant. In The Green Shaded Right-hand Column, The ISO

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