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SYSTEM ISO 13485:2003/13485:2016 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 Q2th, 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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