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Questions (those relating to new/ revised requirements are in italics) Documented? Need to be? Y or N In Use? Effective? Y or N (comments) ISO 9001:2000 Checklist

ISO 13485 2016 Translated into Plain English

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ISO 13485 2016 is an international quality management standard for medical devices. This page presents an overview of ISO 13485 2016 and provides a PDF sample of our approach.

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