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Australian Standard™

Medical devices—Quality management systems—Requirements for regulatory purposes

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This Australian Standard was prepared by Committee HE-028, Quality Management and Corresponding General Aspects for Medical Devices. It was approved on behalf of the Council of Standards Australia on 24 Dec 2003 and published on 31 December 2003.

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PREFACE

This Standard was prepared by the Standards Australia Committee HE-028, Quality Management and Corresponding General Aspects for Medical Devices.

This Standard is identical with and has been reproduced from ISO 13485:2003, *Medical devices—Quality management systems—Requirements for regulatory purposes.*

This Standard cancels and replaces AS ISO 13485—2002, *Quality systems—Medical devices—Particular requirements for the application of ISO 9001*, and AS ISO 13488—2002, *Quality systems—Medical devices—Particular requirements for the application of ISO 9002*).

The objective of this Standard is to specify requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer requirements and regulatory requirements applicable to medical devices and related services. The primary objective is to facilitate harmonized medical device regulatory requirements for quality management systems. As a result, it includes some particular requirements for medical devices and excludes some of the requirements of ISO 9001 that are not appropriate as regulatory requirements. Because of these exclusions, organizations whose quality management systems conform to this International Standard cannot claim conformity to ISO 9001 unless their quality management systems conform to all the requirements of ISO 9001.

The terms ‘normative’ and ‘informative’ are used to define the application of the annex to which they apply. A normative annex is an integral part of a standard, whereas an informative annex is only for information and guidance.

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9000	Quality management systems—Fundamentals and vocabulary	9000	Quality management systems—Fundamentals and vocabulary

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