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Australian STANDARD

Medical devices—Quality management systems—Requirements for regulatory processes

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Australian Digital Health Agency
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Australian Patients Association
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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, to supersede AS ISO 13485:2003, *Medical devices — Quality management systems — Requirements for regulatory purposes*.

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 and applicable regulatory requirements.

This Standard is identical with, and has been reproduced from, ISO 13485:2016, *Medical devices — Quality management systems — Requirements for regulatory purpose.*

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