AS ISO 13488—2002
ISO 13488:1996

Australian Standard™

Quality systems—Medical devices—Particular requirements for the application of ISO 9002

Standards Australia

This Australian Standard was prepared by Committee QR-008, Quality Systems. It was approved on behalf of the Council of Standards Australia on 26 June 2002 and published on 28 June 2002.

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PREFACE

This Standard has been developed to assist in the process of implementation of the Australian Medical Device legislation.

After consultation with stakeholders in both countries, Standards Australia and Standards New Zealand decided to develop this Standard as an Australian, rather than an Australian/New Zealand Standard, through the Joint Standards Australia/Standards New Zealand Committee QR-008 on Quality Systems.

This Standard is identical with and has been reproduced from ISO 13488:1996, *Quality systems — Medical devices — Particular requirements for the application of ISO 9002*.

The objective of this Standard is to specify, for suppliers of medical devices, quality systems requirements that are more specific than those given in ISO 9002.

Users in Australia should be aware that, at the time of publication, the 1994 editions of AS/NZS ISO 9001, AS/NZS ISO 9002 and AS/NZS ISO 9003 have been superseded by AS/NZS ISO 9001:2000, *Quality management systems — Requirements,* but will remain available as superseded standards until December 2003. The use of the superseded standards beyond that date is endorsed for applications covered by the Australian Medical Device legislation.

As this Standard is reproduced from an international Standard, the following applies:

(a) Its number does not appear on each page of text and its identity is shown only on the cover and title page.

(b) In the source text ‘this International Standard’ should read ‘this Australian Standard’.

(c) A full point substitutes for a comma when referring to a decimal marker.

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INTRODUCTION

ISO 9002 is a general standard defining quality system requirements. ISO 13488 provides particular requirements for suppliers of medical devices that are more specific than the general requirements specified in ISO 9002.

In conjunction with ISO 9002, this International Standard defines requirements for quality systems relating to the production, installation and servicing of medical devices. It embraces all the principles of good manufacturing practice (GMP) widely used in the manufacture of medical devices. It can only be used in combination with ISO 9002 and is not an independent standard.

There are a wide variety of medical devices and some of the particular requirements of this International Standard only apply to named groups of medical devices. These groups are described in clause 3.

Other International Standards specify more detailed particular requirements that are additional to those specified here. Suppliers should review the requirements and consider using the relevant International Standards in these areas.

To assist in the understanding of the requirements of this International Standard, an international guidance standard is being prepared.

AUSTRALIAN STANDARD

Quality systems—Medical devices—Particular requirements for the application of ISO 9002

1 Scope

This International Standard specifies, in conjunction with ISO 9002, the quality system requirements for the production and, when relevant, installation and servicing of medical devices.

This International Standard, in conjunction with ISO 9002, is applicable when there is a need to assess a medical device supplier's quality system.

As part of an assessment by a third party for the purpose of regulatory requirements, the supplier may be required to provide access to confidential data in order to demonstrate compliance with this International Standard. The supplier may be required to exhibit these data but is not obliged to provide copies for retention.

NOTE — In this International Standard the term "if appropriate" is used several times. When a requirement is qualified by this phrase, it is deemed to be "appropriate" unless the supplier can document a justification otherwise. A requirement is considered "appropriate" if its non-implementation could result in

— the product not meeting its specified requirements, and/or

— the supplier being unable to carry out corrective action.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 8402:1994, *Quality management and quality assurance — Vocabulary.*

ISO 9002:1994, *Quality systems — Model for quality assurance in production, installation and servicing.*

ISO 11137:1995, *Sterilization of healthcare products — Requirements for validation and routine control — Radiation sterilization.*

3 Definitions

For the purposes of this International Standard, the definitions given in ISO 8402 apply, with the exception that the definition of "product" as given in ISO 9002 applies. In addition, the following definitions apply.

NOTE — These definitions should be regarded as generic, as definitions provided in national regulations may differ slightly.