

Australian Standard™

**Quality systems—Medical devices—
Particular requirements for the
application of ISO 9003**



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.

The following are represented on Committee QR-008:

Australian Chamber of Commerce and Industry
Australian Electrical and Electronic Manufacturers Association
Australian Industry Group
Australian Information Industry Association
Australian Institute of Petroleum
Australian Organisation for Quality
Boiler and Pressure Vessel Manufacturers Association of Australia
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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 EN 46003:1999, *Quality systems - Medical devices — Particular requirements for the application of EN ISO 9003*.

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 9003.

Users in Australia should be aware that, where reference is made to EN 29001, EN 29002 and/or EN 29003, they are identical with the 1994 editions of AS/NZS ISO 9001, AS/NZS ISO 9002 and AS/NZS ISO 9003 respectively. These Standards provide three quality assurance models that represent three distinct forms of quality system requirements suitable for the purpose of a supplier demonstrating its capability, and for the assessment of the capability of a supplier by external parties.

At the time of publication, the 1994 editions of AS/NZS ISO 9001, AS/NZS ISO 9002 and AS/NZS ISO 9003 have been superseded by AS/NZS ISO 9001:2000, *Quality management systems — Requirements*, but will remain available as superseded standards until December 2003. The use of the superseded standards and their EN equivalents beyond that date is endorsed for applications covered by the Australian Medical Device legislation.

As this Standard is reproduced from a European 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 European 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

EN ISO 9003 : 1994 is intended to be a general standard defining quality system requirements. EN 46003 provides particular requirements for **suppliers** of **medical devices** that are more specific than the general requirements specified in EN ISO 9003 : 1994.

In conjunction with EN ISO 9003 : 1994, this European Standard defines requirements for quality systems relating to final inspection and test of **medical devices**. It can only be used in combination with EN ISO 9003 : 1994 and is not a "stand alone" standard.

There is a wide variety of **medical devices** and some of the particular requirements of this standard only apply to named groups of **medical devices**. These groups are described in clause 3, Definitions.

Particular requirements in a number of clauses of this standard are covered in detail in other European Standards. **Suppliers** should review the requirements and consider using national standards implementing harmonized European Standards in these areas.