AS EN 50103—2002
EN 50103:1995

Australian Standard™

Guidance on the application of EN 29001 and EN 46001 and of EN 29002 and EN 46002 for the active (including active implantable) medical device industry

Standards Australia

This Australian Standard was prepared by Committee HE-012, Surgical Implants. 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 HE-012:

Australian Chamber of Commerce and Industry

Australian College of Operating Room Nurses

Australian Dental Association

Australian Industry Group

Australian Orthopaedic Association

Commonwealth Department of Health and Ageing

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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 HE-012 on Surgical Implants.

This Standard is identical with and has been reproduced from EN 50103:1995, *Guidance on the application of EN 29001 and EN 46001 and of EN29002 and EN 46002 for the active (including active implantable) medical device industry.*

The objective of this Standard is to provide guidance on concepts and objectives to be considered by a supplier of active medical devices when developing and maintaining a quality system.

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At the time of publication, the 1994 editions of AS/NZS ISO 9001, AS/NZS ISO 9002 and AS/NZS ISO 9003 have been superseded by AS/NZS ISO 9001:2000, *Quality management systems — Requirements,* but will remain available as superseded standards until December 2003. The use of the superseded standards and their EN equivalents beyond that date is endorsed for applications covered by the Australian Medical Device legislation.

This Standard provides for the use of the following Australian/New Zealand Standards as equivalents to the ISO Standards referenced herein:

Reference to International Standard, European Standard or other publication		*Equivalent Australian/New Zealand Standard*	
ISO		AS/NZS ISO	
9001	Quality management systems — Requirements		Quality management systems — Requirements

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

This European Standard gives guidelines for SUPPLIERS OF ACTIVE MEDICAL DEVICES (including ACTIVE IMPLANTABLE MEDICAL DEVICES) who wish to ensure that they comply with EN 46001 *(Quality systems — Medical devices — Particular requirements for the application of EN 29001 for medical devices)* or EN 46002 *(Quality systems — Medical devices — Particular requirements for the application of EN 29002 for medical devices)*. Additionally this European Standard is intended to contribute to a common understanding between SUPPLIERS and third parties.

This European Standard is meaningful only if read in conjunction with EN 29000/ISO 9000 and EN 46000 series of standards. The guidelines are not intended as a replacement or supplement to ISO 9004, which has its own very distinct relationship with the EN 29000/ISO 9000 series of standards.

NOTE 1 The guidance given in this document has been arranged so that the numbers of the subclauses are the same as those of the requirements of EN 29001 and EN 46001, to which the guidance always refers. The respective subclause numbers of EN 29002 and EN 46002 are provided in parentheses.

NOTE 2 Not all requirements of EN 29001 and EN 46001 and of EN 29002 and EN 46002 are addressed in this European Standard. It is, therefore, generally advisable to read these guidelines in parallel with ISO 9004.

NOTE 3 This document provides guidelines both for manufacturers of ACTIVE MEDICAL DEVICES and ACTIVE IMPLANTABLE MEDICAL DEVICES. Most of the wording of this document is drafted to cover both PRODUCT groups: the class ACTIVE MEDICAL DEVICE includes ACTIVE IMPLANTABLE MEDICAL DEVICES by definition. In a few places the guidance applies specifically only to ACTIVE IMPLANTABLE MEDICAL DEVICES or to non-implantable ACTIVE MEDICAL DEVICES: such exceptions are clearly indicated in the text.

AUSTRALIAN STANDARD

Guidance on the application of EN 29001 and EN 46001 and of EN 29002 and EN 46002 for the active (including active implantable) medical device industry

1 Scope

The guidelines contained in this European Standard are applicable to a QUALITY SYSTEM as specified by EN 29001 and EN 46001 or EN 29002 and EN 46002. This European Standard does not add to, or otherwise change the requirements of those standards, and is not intended to be used directly in the assessment of a SUPPLIER'S QUALITY SYSTEM.

The guidelines provide concepts and objectives which should be considered by a SUPPLIER of ACTIVE MEDICAL DEVICES while developing and maintaining his QUALITY SYSTEM.

This European Standard:

— provides examples of how to meet the requirements, while recognizing that other methods which achieve the same ends are equally acceptable;

— gives general advice on how to meet the requirements;

— draws attention to aspects of requirements that may not be readily apparent to those unfamiliar with QUALITY SYSTEMS used in the ACTIVE MEDICAL DEVICE industry.

2 Normative references

This European Standard incorporates by dated or undated reference provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references, the latest edition of the publication referred to applies.

International registration:	Title:	European registration:
ISO 8402: 1994	*Quality management and quality assurance Vocabulary*	—
ISO 9001: 1987	*Quality systems — Model for quality assurance in design/development, production, installation and servicing*	EN 29001:1987
ISO 9002: 1988	*Quality systems — Model for quality assurance in production and installation*	EN 29002:1988
—	*Quality systems — Medical devices — Particular requirements for the application of EN 29001*	EN 46001:1993
—	*Quality systems — Medical devices — Particular requirements for the application of EN 29002*	EN 46002:1993