AS EN 46003—2002
EN 46003:1999

Australian Standard™

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

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At the time of publication, the 1994 editions of AS/NZS ISO 9001, AS/NZS ISO 9002 and AS/NZS ISO 9003 have been superseded by AS/NZS ISO 9001:2000, *Quality management systems — Requirements*, but will remain available as superseded standards until December 2003. The use of the superseded standards and their EN equivalents beyond that date is endorsed for applications covered by the Australian Medical Device legislation.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

AUSTRALIAN STANDARD

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

1 Scope

This European Standard specifies, in conjunction with EN ISO 9003 : 1994, the quality system requirements for the final inspection and test of **medical devices** excluding in vitro diagnostic medical devices and active implantable medical devices, and is applicable when a **medical device supplier's** quality system is assessed in accordance with regulatory requirements.

NOTE: For sterile medical devices the relevant particular clauses in EN 46002 : 1996 apply as this standard alone is not sufficient for manufacturers of sterile medical devices seeking to comply with regulatory requirements.

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 standard. The **supplier** may be required to exhibit these data but is not obliged to provide copies for retention.

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.

EN ISO 8402 : 1995
Quality management and quality assurance – Vocabulary (ISO 8402 : 1994)

EN ISO 9003 : 1994
Quality systems – Model for quality assurance in final inspection and test (ISO 9003:1994)

3 Definitions

For the purposes of this standard, the following definitions apply.

3.1 Medical device: Any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of

- diagnosis, prevention, monitoring, treatment or alleviation of disease;
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;
- investigation, replacement or modification of the anatomy or of a physiological process;
- control of conception;

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

NOTE: Definition **3.1** reproduces the definition given in the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.

3.2 Implantable medical device: Any **device** which is intended:

- to be totally introduced into the human body or;
- to replace an epithelial surface or the surface of the eye

by surgical intervention which is intended to remain in place after the procedure.

Any device intended to be partially introduced into the human body through surgical intervention and intended to remain in place after the procedure for at least 30 days is also considered as implantable device.