AS EN 724—2002
EN 724:1994

Australian Standard™

Guidance on the application of EN 29001 and EN 46001 and of EN 29002 and EN 46002 for non-active medical devices

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 724:1994, *Guidance on the application of EN 29001 and EN 46001 and of EN 29002 and EN 46002 for non-active medical devices.*

The objective of this Standard is to provide guidance on the establishment and maintenance of quality systems specified in EN 29001/EN 46001 or EN 29002/ EN 46002 for the manufacture of non-active medical devices.

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At the time of publication, the 1994 editions of AS/NZS ISO 9001, AS/NZS ISO 9002 and AS/NZS ISO 9003 have been superseded by AS/NZS ISO 9001:2000, *Quality management systems — Requirements,* but will remain available as superseded standards until December 2003. The use of the superseded standards and their EN equivalents beyond that date is endorsed for applications covered by the Australian Medical Device legislation.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

This European Standard has been written to give guidance to organizations providing a non-active medical device who wish to ensure that they will comply with EN 29001/EN 29002 and the particular requirements given in EN 46001/EN 46002. It is also intended to provide guidance for certifying and regulatory bodies.The guidance in this standard for the fulfilment of requirements should always be in relation to the products being manufactured and interpreted accordingly.

This standard needs to be read in conjunction with the EN 29000 series of standards with which compliance is sought. This standard is not intended as a replacement for EN 29004 which has its own very distinct relationship with the EN 29000 series of standards.

The combination of EN 29001/EN 46001 and EN 29002/EN 46002 embraces the principles of Good Manufacturing Practices (GMP) which have been in operation in the manufacture of non-active medical devices for a number of years.

This document seeks to assist in the transition from GMP to quality systems by presenting familiar concepts under the relevant paragraphs of EN 29001/EN 46001 and EN 29002/EN 46002.

The references which have been made to EN 29004 are not necessarily exhaustive but seek to identify sections of EN 29004 with particular relevance to the guidance in this document. Consideration of this document alone is not an alternative to understanding EN 29004 and it is therefore recommended that EN 29004 is first read and understood in its entirety. For ease in the use of this standard, references to clauses in EN 29004 have been cited within the framework of EN 29001 and EN 29002.

Annex A to this European Standard provides additional guidance on those elements of quality systems to which particular emphasis should be placed for medical devices which are supplied either sterile or to a defined standard of microbial or particulate cleanliness. The guidance in annex A is intended to be considered in addition to that provided in the body of the standard.

AUSTRALIAN STANDARD

Guidance on the application of EN 29001 and EN 46001 and of EN 29002 and EN 46002 for non-active medical devices

1. Scope

This European Standard provides guidance on the establishment and maintenance of the quality systems specified in EN 29001/EN 46001 or EN 29002/EN 46002 for the manufacture of non-active medical devices. It does not add to, or otherwise change, the requirements of those standards and is not intended to be used for the assessment of a manufacturer's quality system.

This European Standard provides examples of how to meet the requirements, recognising that other methods which achieve the same ends are equally acceptable ; gives general advice on how to meet the requirements; and draws attention to aspects of requirements that may not be readily apparent to those unfamiliar with quality systems for non-active medical devices.

Annex A to this European Standard provides guidance on the elements of quality systems which are relevant to the manufacture of medical devices which are to be supplied either sterile or at a defined level of microbiological or particulate cleanliness.

The adoption of systems other than those described in this European Standard is not to be regarded as a non-compliance with EN 29001 and EN 29002 and/or the specific requirements in EN 46001 and EN 46002.

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