AS ISO 15225—2003
ISO 15225:2000

Australian Standard™

Nomenclature—Specification for a nomenclature system for medical devices for the purpose of regulatory data exchange

Standards Australia

This Australian Standard was prepared by Committee HE-023, Processing of medical and surgical instruments and Committee HE-009, Hypodermic Equipment—General Medical. It was approved on behalf of the Council of Standards Australia on 28 May 2003 and published on 30 June 2003.

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This Standard was issued in draft form for comment as DR 03180.

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First published as AS ISO 15225—2003.

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Published by Standards Australia International Ltd
GPO Box 5420, Sydney, NSW 2001, Australia

ISBN 0 7337 5363 9

PREFACE

This Standard was prepared by the Australian members of the Joint Standards Australia/ Standards New Zealand Committees HE-023, Processing of Medical and Surgical Instruments and HE-009, Hypodermic Equipment—General Medical. 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.

This Standard is identical with and has been reproduced from ISO 15225:2000, *Nomenclature—Specification for a nomenclature system for medical devices for the purpose of regulatory data exchange.* ISO 15225 was prepared by the European Committee for Standardization (CEN) Technical Committee TC 257, Symbols and information provided with medical devices and nomenclature for regulatory data exchange, in collaboration with ISO Technical Committee TC 210, Quality management and corresponding general aspects for medical devices, in accordance with the Vienna Agreement on technical cooperation between ISO and CEN.

The objective of this Standard is to specify requirements and guidance for the construction of a nomenclature for medical devices in order to facilitate co-operation and exchange of regulatory data between interested parties such as regulatory authorities, manufacturers, suppliers, health care providers, and end users.

The terms ‘normative’ and ‘informative’ are used to define the application of the annex to which they apply. A normative annex is an integral part of a standard, whereas an informative annex is only for information and guidance.

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.

References to International Standards should be replaced by references to Australian or Australian/New Zealand Standards as follows:

Reference to International Standard		*Australian Standard*	
ISO/IEC		AS	
2382	Information technology—Vocabulary	1189	Data processing—Vocabulary
2382-1	Part 1: Fundamental terms	1189.1	Part 1: Fundamental terms
2382-4	Part 4: Organization of data	1189.4	Part 4: Organization of data

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INTRODUCTION

This European Standard gives rules and guidelines for the construction of a nomenclature system for medical devices in order to enable Competent Authorities, Notified Bodies and manufacturers to meet the requirements of Council Directives on medical devices. It is also intended to assist in the implementation of community sectoral legislation and to facilitate co-operation and exchange of information within the European Community and at international level. It is intended that this assistance and facilitation could be extended to other relevant parties such as Regulatory Bodies and Health Care Providers.

This European Standard also gives the requirements for a minimum data set and relating to this data system its structure. These requirements are provided for system designers setting up databases utilizing the nomenclature system described herein. It is intended that the information covered by this standard should be available in the public domain.

The requirements contained in this standard are applicable to the development and updating of a European Nomenclature for medical devices.

This European Standard provides rules and guidelines for nomenclature design, which will ensure that nomenclatures built upon this standard will be simple to use, rational, applicable by all grades and professions of users and suitable for both computerized systems and printed matter.

In order to avoid the proliferation of nomenclature systems, even though each may be in conformity with this standard, it is desirable that a control body be set up to administer and maintain the European Nomenclature system. This standard has been prepared with the needs of such a body in mind and to provide ease of management at reasonable cost.

It is anticipated that the European Gatekeeper will liaise with other bodies responsible for maintaining nomenclatures in other regulatory environments, with a view to appropriate international harmonization.

AUSTRALIAN STANDARD

Nomenclature—Specification for a nomenclature system for medical devices for the purpose of regulatory data exchange

1 Scope

This European Standard specifies requirements and guidance for the construction of a nomenclature for medical devices in order to facilitate co-operation and exchange of regulatory data on an international level between interested parties such as: Regulatory Authorities, Manufacturers, Suppliers, Health Care Providers, and End Users.

> NOTE 1: This European Standard includes guidelines for a minimum data set and its structure. These guidelines are provided for system designers setting up databases utilizing the nomenclature system described herein.

The requirements contained in this standard are applicable to the development and maintenance of a European nomenclature for medical device identification.

> NOTE 2: This European Standard will not include the nomenclature itself. The nomenclature will be supplied as a separate document.

> NOTE 3: It is intended to complement the specific requirements of the EC Directives on medical devices in the context of specifying means by which common identification can be achieved between bodies required to exchange data in conformity with the requirements of the Directives.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possiblity of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 1087 : 1990	Terminology - Vocabulary
ISO/IEC 8859-1 : 1998	Information processing - 8-bit single-byte coded graphic character sets
ISO/IEC 2382-1 : 1993	Information technology - Vocabulary - Part 1: Fundamental terms
ISO 2382-4 : 1987	Information processing systems - Vocabulary - Part 4: Organization of data
ISO/IEC 2382-17 : 1996	Information technology - Vocabulary - Part 17: Databases

> NOTE: Other documents which may be useful for the understanding of this standard are listed in the Bibliography.

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