AS ISO 14155—2002
ISO 14155:1996

Australian Standard™

Clinical investigation of medical devices

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
Department of Defence (Australia)
Medical Industry Association of Australia Inc
Neurological Society of Australasia
Royal Australasian College of Surgeons
Royal Perth Hospital
The Australian Society for Biomaterials
The University of New South Wales
The University of Sydney

Keeping Standards up-to-date

Standards are living documents which reflect progress in science, technology and systems. To maintain their currency, all Standards are periodically reviewed, and new editions are published. Between editions, amendments may be issued. Standards may also be withdrawn. It is important that readers assure themselves they are using a current Standard, which should include any amendments which may have been published since the Standard was purchased.

Detailed information about Standards can be found by visiting the Standards Australia web site at www.standards.com.au and looking up the relevant Standard in the on-line catalogue.

Alternatively, the printed Catalogue provides information current at 1 January each year, and the monthly magazine, *The Australian Standard*, has a full listing of revisions and amendments published each month.

We also welcome suggestions for improvement in our Standards, and especially encourage readers to notify us immediately of any apparent inaccuracies or ambiguities. Contact us via email at mail@standards.com.au, or write to the Chief Executive, Standards Australia International Ltd, GPO Box 5420, Sydney, NSW 2001.

This Standard was issued in draft form for comment as DR 02203.

Australian Standard™

Clinical investigation of medical devices

First published as AS ISO 14155—2002.

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

ISBN 0 7337 4686 1

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 ISO 14155:1996, *Clinical investigation of medical devices.*

The objective of this Standard is to specify requirements for the conduct of clinical investigation and documentation of medical devices.

As this Standard is reproduced from an international 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 International Standard' should read 'this Australian Standard'.

(c) A full point substitutes for a comma when referring to a decimal marker.

CONTENTS

INTRODUCTION

This International Standard was prepared to assist sponsors, regulatory authorities, and investigators in the conduct and performance of the clinical investigation of medical devices.

The text of this International Standard contains general requirements; it is intended to protect human subjects and ensure the scientific conduct of the investigation.

AUSTRALIAN STANDARD

Clinical investigation of medical devices

1 Scope

This International Standard

a) pertains to the clinical investigation in human subjects of those medical devices whose clinical performance needs assessment;

b) specifies the requirements for the conduct of the clinical investigation and documentation on whether the medical device achieves the performance intended by the sponsor, determines any undesirable side effects under normal conditions of use and permits assessment of the acceptable risks relating to the intended performance of the device;

c) provides the framework for systematic written procedures for the organization, design, implementation, data collection, documentation and conduct of the clinical investigation.

2 Normative reference

The following standard contains provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the edition indicated was valid. All standards are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent edition of the standard indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

World Medical Association's Declaration of Helsinki, *Recommendations guiding physicians in biomedical research involving human subjects* (see annex A).

1) This definition is in accordance with [3] in annex D.

3 Definitions

For the purposes of this International Standard, the following definitions apply.

3.1 clinical investigation: Any systematic study in subjects undertaken to verify the performance of a specific device under normal conditions of intended use.

3.2 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 on human beings for the purpose of

— diagnosis, prevention, monitoring, treatment or alleviation of disease,

— diagnosis, monitoring, treatment, alleviation 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.[1)]

3.3 device (intended for clinical investigation): Any medical device intended for use by an appropriately qualified practitioner when conducting clinical investigations in an adequate clinical environment.

3.4 clinical performance: Effects achieved by a device in relation to its intended use, when correctly applied to appropriate subjects.