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Australian Standard™

Clinical investigations of medical devices for human subjects

Part 1: General requirements

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This Australian Standard was prepared by Committee HE-012, Surgical Implants. It was approved on behalf of the Council of Standards Australia on 17 June 2004. This Standard was published on 27 July 2004.

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Australian Dental Association
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Part 1: General requirements

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PREFACE

This Standard was prepared by the Australian members of the Joint Standards Australia/Standards New Zealand Committee HE-012, Surgical Implants, to supersede AS ISO 14155—2002, *Clinical investigation of medical devices.* 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 14155-1:2003, *Clinical investigation of medical devices for human subjects,* Part 1: *General requirements.*

The objective of this Standard is to specify requirements for the conduct of a clinical investigation to establish the performance of medical devices intended to mimic normal clinical use, reveal adverse events under normal conditions of use, and permit assessment of the acceptable risks.

The term 'informative' has been used in this Standard to define the application of the annex to which it applies. An informative annex is only for information and guidance.

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 part of ISO 14155' should read 'this Australian Standard'.

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

(d) The normative reference in Clause 2 has not been adopted as an Australian Standard.

CONTENTS

INTRODUCTION

This part of ISO 14155 is intended to be applied worldwide to clinical investigations of medical devices in order to fulfil the technical aspects of the various national, regional and international regulatory requirements. As the legal regulatory requirements presently differ throughout the world, regulatory specifics have been excluded from the scope of this part of ISO 14155. They are part of national or regional legislative texts and can be referenced in the national or regional forewords, as appropriate.

NOTES

AUSTRALIAN STANDARD

Clinical investigation of medical devices for human subjects —

Part 1:
General requirements

1 Scope

This part of ISO 14155 defines procedures for the conduct and performance of clinical investigations of medical devices. It specifies general requirements intended to

— protect human subjects,

— ensure the scientific conduct of the clinical investigation,

— assist sponsors, monitors, investigators, ethics committees, regulatory authorities and bodies involved in the conformity assessment of medical devices.

This part of ISO 14155

a) specifies requirements for the conduct of a clinical investigation such that it establishes the performance of the medical device during the clinical investigation intended to mimic normal clinical use, reveals adverse events under normal conditions of use, and permits assessment of the acceptable risks having regard to the intended performance of the medical device,

b) specifies requirements for the organization, conduct, monitoring, data collection and documentation of the clinical investigation of a medical device,

c) is applicable to all clinical investigation(s) of medical devices whose clinical performance and safety is being assessed in human subjects.

This part of ISO 14155 is not applicable to *in vitro* diagnostic medical devices.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 14155-2, *Clinical investigation of medical devices for human subjects — Part 2: Clinical investigation plans*