AS EN 540—2002
EN 540:1993

Australian Standard™

Clinical investigation of medical devices for human subjects

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
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Clinical investigation of medical devices for human subjects

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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 HE-012 on Surgical Implants.

This Standard is identical with and has been reproduced from EN 540:1993, *Clinical investigation of medical devices for human subjects*.

The objective of this Standard is to specify the requirements for the conduct of clinical investigations and documentation on the performance of medical devices, to determine any undesirable side effects and permit the assessment of acceptable risks.

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.

CONTENTS

INTRODUCTION

This European Standard was prepared to define procedures to assist manufacturers, regulatory authorities,SPONSORS and CLINICAL INVESTIGATORS on the conduct and performance of the CLINICAL INVESTIGATION of MEDICAL DEVICES.

This European Standard is intended to protect SUBJECTS and ensure the scientific conduct of the CLINICAL INVESTIGATION.

Clinical investigation of medical devices for human subjects

AUSTRALIAN STANDARD

Clinical investigation of medical devices for human subjects

1 Scope

1.1 This European Standard pertains to the CLINICAL INVESTIGATION in human SUBJECTS of those MEDICAL DEVICES whose the clinical PERFORMANCE needs assessment before being placed on the market.

This European standard does not apply to in vitro diagnostic devices.

1.2 This European Standard specifies the requirements :

- for the conduct of CLINICAL INVESTIGATIONS and documentation on whether the MEDICAL DEVICE achieves the performance intended by the SPONSOR,

- to determine any undesirable side effects, under normal conditions of use,

- to permit the assessment of the acceptable risks having regard to the intended PERFORMANCE OF THE MEDICAL DEVICE

1.3 This European Standard provides a framework for the preparation of written procedures for the organisation, design, implementation, data collection and documentation of the CLINICAL INVESTIGATION.

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.

World Medical Association Declaration of Helsinki ; recommendations guiding physicians in biomedical research involving human subjects.

3 Terminology and definitions

For the purpose of this European 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