

Clinical investigation of medical devices for human subjects —

Part 1: General requirements

The European Standard EN ISO 14155-1:2003 has the status of a
British Standard

ICS 11.100

National foreword

This British Standard is the official English language version of EN ISO 14155-1:2003. It is identical with ISO 14155-1:2003. It supersedes BS EN 540:1993 which is withdrawn

The UK participation in its preparation was entrusted to Technical Committee CH/194, Biological evaluation of medical devices, which has the responsibility to:

- aid enquirers to understand the text;
- present to the responsible international/European committee any enquiries on the interpretation, or proposals for change, and keep the UK interests informed;
- monitor related international and European developments and promulgate them in the UK.

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Summary of pages

This document comprises a front cover, an inside front cover, the EN ISO title page, the EN ISO foreword page, the ISO title page, pages ii to vi, pages 1 to 21, the Annex ZA page, an inside back cover and a back cover.

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Part 1: General requirements (ISO 14155-1:2003)

Investigation clinique des dispositifs médicaux pour sujets
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1:2003)

Klinische Prüfung von Medizinprodukten an Menschen -
Teil 1: Allgemeine Anforderungen (ISO 14155-1:2003)

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Foreword

This document (EN ISO 14155-1:2003) has been prepared by Technical Committee ISO/TC 194 "Biological evaluation of medical devices" in collaboration with Technical Committee CEN/TC 258 "Clinical investigation of medical devices", the secretariat of which is held by AFNOR.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by August 2003, and conflicting national standards shall be withdrawn at the latest by August 2003.

This document supersedes EN 540:1993.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative annex ZA, which is an integral part of this document.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Slovakia, Spain, Sweden, Switzerland and the United Kingdom.

Endorsement notice

The text of ISO 14155-1:2003 has been approved by CEN as EN ISO 14155-1:2003 without any modifications.

INTERNATIONAL STANDARD

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Clinical investigation of medical devices for human subjects —

Part 1: General requirements

*Investigation clinique des dispositifs médicaux pour sujets humains —
Partie 1: Exigences générales*



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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 14155-1 was prepared by Technical Committee ISO/TC 194, *Biological evaluation of medical devices*.

This first edition of ISO 14155-1, together with ISO 14155-2, cancels and replace ISO 14155:1996, which has been technically revised.

ISO 14155 consists of the following parts, under the general title *Clinical investigation of medical devices for human subjects*:

- *Part 1: General requirements*
- *Part 2: Clinical investigation plans*

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.

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*