SLOVENSKI STANDARD

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Kliniļne raziskave medicinskih pripomoļkov za ljudi ï 1. del: Sploġne zahteve (ISO 14155-1:2003)

Clinical investigation of medical devices for human subjects - Part 1: General requirements (ISO 14155-1:2003)

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

Investigation clinique des dispositifs médicaux pour sujets humains - Partie 1: Exigences générales (ISO 14155-1:2003)

Ta slovenski standard je istoveten z: **EN ISO 14155-1:2003**

ICS:

11.040.01	Medicinska oprema na splošno	Medical equipment in general

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

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ICS 11.100

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English version

Clinical investigation of medical devices for human subjects - Part 1: General requirements (ISO 14155-1:2003)

Investigation clinique des dispositifs médicaux pour sujets humains - Partie 1: Exigences générales (ISO 14155-1:2003)

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

This European Standard was approved by CEN on 7 February 2003.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Slovak Republic, Spain, Sweden, Switzerland and United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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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.

Annex ZA
(informative)

Clauses of this European Standard addressing essential requirements or other provisions of EU Directives

This European standard has been prepared under a mandate given to CEN/CENELEC by the European Commission and the European Free Trade Association and supports essential requirements of EU Directives 90/385/EEC and 93/42/EEC.

WARNING : Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

The clauses of this standard are likely in support of annex X of Directive 90/385/EEC and annex VII of Directive 93/42/EEC.

Compliance with these clauses of this standard provides one means of conforming with the specific provisions of the Directives concerned and associated EFTA regulations.

INTERNATIONAL STANDARD

ISO 14155-1

First edition
2003-02-15

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.