Irish Standard
I.S. EN ISO 14155-1:2009

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

I.S. EN ISO 14155-1:2009

Incorporating amendments/corrigenda issued since publication:

This document replaces:	*This document is based on:*	*Published:*
EN ISO 14155-1:2003	EN ISO 14155-1:2009	15 July, 2009
	EN ISO 14155-1:2003	16 May, 2003

This document was published under the authority of the NSAI and comes into effect on:
9 September, 2009

ICS number:
11.100.20

NSAI
1 Swift Square,
Northwood, Santry
Dublin 9

T +353 1 807 3800
F +353 1 807 3838
E standards@nsai.ie
W **NSAI.ie**

Sales:
T +353 1 857 6730
F +353 1 857 6729
W standards.ie

Price Code:
J

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I.S. EN ISO 14155-1:2009

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 14155-1

July 2009

ICS 11.100.20

Supersedes EN ISO 14155-1:2003

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 27 June 2009.

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

Management Centre: Avenue Marnix 17, B-1000 Brussels

Ref. No. EN ISO 14155-1:2009: E

Contents

Page

Foreword

The text of ISO 14155-1:2003 has been prepared by Technical Committee ISO/TC 194 “Biological evaluation of medical devices” of the International Organization for Standardization (ISO) and has been taken over as EN ISO 14155-1:2009 by Technical Committee CEN/TC 258 “Clinical investigation of medical devices” the secretariat of which is held by DIN.

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of an identical text or by endorsement, at the latest by January 2010, and conflicting national standards shall be withdrawn at the latest by March 2010.

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

This document supersedes EN ISO 14155-1:2003.

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 EC Directives.

For relationship with EC Directives, see informative Annex ZA and ZB, which are 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, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

Endorsement notice

The text of ISO 14155-1:2003 has been approved by CEN as a EN ISO 14155-1:2009 without any modification.

Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC on Medical Devices

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC on medical devices.

Once this standard is cited in the Official Journal of the European Communities under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this standard given in table ZA confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZA — Correspondence between this European Standard and Directive 93/42/EEC on medical devices

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
A.2.5	Annex X: 1.1.1	This requirement is also addressed in 4.5.1 of EN 14155-2:2003
11	Annex X: 1.1.2	This requirement is also addressed in 4.5.3 of EN 14155-2:2003
	Annex X: 1.1.a)	This requirement is not addressed in this standard
7	Annex X: 1.1.b)	This requirement is partly addressed in this standard
	Annex X: 1.1.c)	This requirement is not addressed in this standard
	Annex X: 1.1.d)	This requirement is not addressed in this standard
5	Annex X: 2.2	
6.3	Annex X: 2.3.1	Entire EN 14155-2
6.4	Annex X: 2.3.2	This requirement is also addressed in 4.7 of EN 14155-2:2003
6.4	Annex X: 2.3.3	This requirement is also addressed in 4.7 of EN 14155-2:2003
	Annex X: 2.3.4	This requirement is not addressed in this standard This requirement is addressed in 4.5.4 of EN 14155-2:2003
8.2 i)	Annex X: 2.3.5	This requirement is also addressed in 4.11 of EN 14155-2:2003
10.2 a)	Annex X: 2.3.6	
11.2	Annex X: 2.3.7	

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

Annex ZB
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 90/385/EEC on Active Implantable Medical Devices

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 90/385/EEC on active implantable medical devices.

Once this standard is cited in the Official Journal of the European Communities under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this standard given in table ZB confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZB — Correspondence between this European Standard and Directive 90/385/EEC on active implantable medical devices

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 90/385/EEC	Qualifying remarks/Notes
A.2.5	Annex 7: 1.1.1	This requirement is also addressed in 4.5.1 of EN 14155-2:2003
11	Annex 7: 1.1.2	This requirement is also addressed in 4.5.3 of EN 14155-2:2003
A.2.5	Annex 7: 1.2	
7	Annex 7: 1.3	
	Annex 7: 1.4	This requirement is not addressed in this standard
	Annex 7: 1.5	This requirement is not addressed in this standard
6.3	Annex 7: 2.3.1	Entire EN 14155
6.4	Annex 7: 2.3.2	This requirement is also addressed in 4.7 of EN 14155-2:2003
6.4	Annex 7: 2.3.3	This requirement is also addressed in 4.7 of EN 14155-2:2003
6.5	Annex 7: 1.6	
	Annex 7: 2.3.4	This requirement is not addressed in this standard This requirement is addressed in 4.5.4 of EN 14155-2:2003
8.2 i)	Annex 7: 2.3.5	This requirement is also addressed in 4.11 of EN 14155-2:2003
10.2 a)	Annex 7: 2.3.6	
11.2	Annex 7: 2.3.7	

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

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I.S. EN ISO 14155-1:2009

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

Reference number
ISO 14155-1:2003(E)

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Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
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Contents

Page

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*

