

# SVENSK STANDARD

## SS-EN ISO 14155:2011



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**Klinisk prövning av medicintekniska produkter – God klinisk praxis (ISO 14155:2011)**

**Clinical investigation of medical devices for human subjects – Good clinical practice (ISO 14155:2011)**

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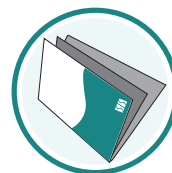
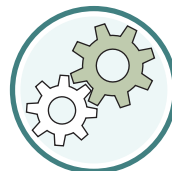
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Europastandarden EN ISO 14155:2011 gäller som svensk standard. Detta dokument innehåller den officiella engelska versionen av EN ISO 14155:2011.

Denna standard ersätter SS-EN ISO 14155:2011, utgåva 1 och SS-EN ISO 14155:2011/AC:2011, utgåva 1.

The European Standard EN ISO 14155:2011 has the status of a Swedish Standard. This document contains the official version of EN ISO 14155:2011.

This standard supersedes the Swedish Standard SS-EN ISO 14155:2011, edition 1 and SS-EN ISO 14155:2011/AC:2011, edition 1.

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EUROPEAN STANDARD

**EN ISO 14155**

NORME EUROPÉENNE

EUROPÄISCHE NORM

October 2011

ICS 11.100.20

Supersedes EN ISO 14155:2011

English Version

## Clinical investigation of medical devices for human subjects - Good clinical practice (ISO 14155:2011)

Investigation clinique des dispositifs médicaux pour sujets  
humains - Bonnes pratiques cliniques (ISO 14155:2011)

Klinische Prüfung von Medizinprodukten an Menschen -  
Gute klinische Praxis (ISO 14155:2011)

This European Standard was approved by CEN on 20 September 2011.

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 CEN-CENELEC Management Centre or to any CEN member.

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## **Foreword**

This document (EN ISO 14155:2011) 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 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 April 2012, and conflicting national standards shall be withdrawn at the latest by April 2012.

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 14155:2011.

This new edition contains revised Annexes ZA and ZB.

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 Directives, see informative Annexes 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, Croatia, 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 14155:2011 has been approved by CEN as EN ISO 14155:2011 without any modification.



# Clinical investigation of medical devices for human subjects — Good clinical practice

## 1 Scope

This International Standard addresses good clinical practice for the design, conduct, recording and reporting of clinical investigations carried out in human subjects to assess the safety or performance of medical devices for regulatory purposes.

The principles set forth in this International Standard also apply to all other clinical investigations and should be followed as far as possible, considering the nature of the clinical investigation and the requirements of national regulations.

This International Standard specifies general requirements intended to

- protect the rights, safety and well-being of human subjects,
- ensure the scientific conduct of the clinical investigation and the credibility of the clinical investigation results,
- define the responsibilities of the sponsor and principal investigator, and
- assist sponsors, investigators, ethics committees, regulatory authorities and other bodies involved in the conformity assessment of medical devices.

It does not apply to *in vitro* diagnostic medical devices.

NOTE Standards developed by ISO/TC 194 are intended to be applied to medical devices. Users of this International Standard will need to consider whether other standards and/or requirements also apply to the investigational device(s) under consideration.

## 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 14971:2007, *Medical devices — Application of risk management to medical devices*