
Klinične raziskave medicinskih pripomočkov za ljudi - Dobre klinične prakse - Tehnični popravek 1 (ISO 14155:2011/Cor 1:2011)

Clinical investigation of medical devices for human subjects - Good clinical practice - Technical Corrigendum 1 (ISO 14155:2011/Cor 1:2011)

Klinische Prüfung von Medizinprodukten an Menschen - Gute klinische Praxis (ISO 14155:2011/Cor 1:2011)

Investigation clinique des dispositifs médicaux pour sujets humains - Bonnes pratiques cliniques - Rectificatif technique 1 (ISO 14155:2011/Cor 1:2011)

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Ta slovenski standard je istoveten z: EN ISO 14155:2011/AC:2011

ICS:

11.040.01	Medicinska oprema na splošno	Medical equipment in general
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SIST EN ISO 14155:2011/AC:2011 **en**

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EUROPEAN STANDARD

EN ISO 14155:2011/AC

NORME EUROPÉENNE

July 2011

EUROPÄISCHE NORM

Juillet 2011

Juli 2011

ICS 11.100.20

English version
Version Française
Deutsche Fassung

Clinical investigation of medical devices for human subjects - Good clinical practice - Technical Corrigendum 1 (ISO 14155:2011/Cor 1:2011)

Investigation clinique des dispositifs médicaux pour sujets humains - Bonnes pratiques cliniques - Rectificatif technique 1 (ISO 14155:2011/Cor 1:2011)

Klinische Prüfung von Medizinprodukten an Menschen - Gute klinische Praxis (ISO 14155:2011/Cor 1:2011)

This corrigendum becomes effective on 15 July 2011 for incorporation in the three official language versions of the EN.

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Ce corrigendum prendra effet le 15 juillet 2011 pour incorporation dans les trois versions linguistiques officielles de la EN.

Die Berichtigung tritt am 15. Juli 2011 zur Einarbeitung in die drei offiziellen Sprachfassungen der EN in Kraft.

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

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Foreword

This document (EN ISO 14155:2011/AC: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.

Endorsement notice

The text of ISO 14155:2011/Cor 1:2011 has been approved by CEN as a EN ISO 14155:2011/AC:2011 without any modification.

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INTERNATIONAL STANDARD ISO 14155:2011
TECHNICAL CORRIGENDUM 1

Published 2011-07-15

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION • МЕЖДУНАРОДНАЯ ОРГАНИЗАЦИЯ ПО СТАНДАРТИЗАЦИИ • ORGANISATION INTERNATIONALE DE NORMALISATION

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

TECHNICAL CORRIGENDUM 1

Investigation clinique des dispositifs médicaux pour sujets humains — Bonnes pratiques cliniques

RECTIFICATIF TECHNIQUE 1

iTeh STANDARD PREVIEW

Technical Corrigendum 1 to ISO 14155:2011 was prepared by Technical Committee ISO/TC 194, *Biological evaluation of medical devices*.

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Page 12, 4.7.4

Replace “a) Potential benefits” with “b) Potential benefits”.

Amend the rest of the list accordingly.

Page 21, 7.3

In the first sentence, replace the word “evaluation” with “investigation”.