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PN-EN ISO 14155:2011/AC

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Wprowadza

EN ISO 14155:2011/AC:2011, IDT
ISO 14155:2011/AC1:2011, IDT

Dotyczy

PN-EN ISO 14155:2011

Badania kliniczne wyrobów medycznych na ludziach -- Dobra praktyka kliniczna

Na wniosek Komitetu Technicznego nr 247
ds. Materiałów Medycznych i Biomateriałów

Poprawka do Normy Europejskiej EN ISO 14155:2011/AC:2011 Clinical investigation of medical devices for human subjects - Good clinical practice - Technical Corrigendum 1 (ISO 14155:2011/AC1:2011)

ma status Poprawki do Polskiej Normy

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 14155:2011/AC

July 2011
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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.

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.



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.



INTERNATIONAL STANDARD ISO 14155:2011
TECHNICAL CORRIGENDUM 1

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**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

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

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”.

