International Organization for Standardization

ISO 14971:2007

Preview

Medical devices -- Application of risk management to medical devices

This standard was last reviewed and confirmed in 2010. Therefore this version remains current.

ISO 14971:2007 specifies a process for a manufacturer to identify the hazards associated with medical devices, including *in vitro* diagnostic (IVD) medical devices, to estimate and evaluate the associated risks, to control these risks, and to monitor the effectiveness of the controls.

The requirements of ISO 14971:2007 are applicable to all stages of the life-cycle of a medical device.

General information

Current status : Published
Publication date : 2007-03
Corrected version (en) : 2007-09
Corrected version (fr) : 2007-09

Edition : 2
Number of pages : 82

Buy this standard

	Format	Language
✔	PDF + ePub	English
	Paper	English
	PDF	Russian

CHF 198

Buy

Got a question?

Check out our FAQs

Customer care

+41 22 749 08 88

Technical Committee : ISO/TC 210 Quality management and corresponding general aspects for medical devices

ICS : 11.040.01 Medical equipment in general

customerservice@iso.org

Opening hours:
Monday to Friday - 09:00-12:00, 14:00-17:00 (UTC+1)

Life cycle

A standard is reviewed every 5 years

00 | **10** | **20** | **30** | **40** | **50** | **60** | **90.92** Review | **95**

Revisions / Corrigenda

Previously
⊘ ISO 14971:2000
⊘ ISO 14971:2000/Amd 1:2003

Now under review
⊙ ISO 14971:2007

Will be replaced by
⊙ ISO/DIS 14971
⊙ ISO/DTR 24971

You may be interested in:

By Elizabeth Gasiorowski on 2 May 2013

By you

We asked you through our social media channels Facebook, LinkedIn,

Keep up to date with ISO

Google+ and Twitter to tell us what you thought were the benefits of standards, and how they helped you in your daily life. We received contributions from around the world. Here is a selection of the best.