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Medical devices — Guidance on the application of ISO 14971

Dispositifs médicaux — Directives relatives à l'ISO 14971

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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2. www.iso.org/directives

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ISO/TR 24971 was prepared jointly by Technical Committee ISO/TC 210, *Quality management and corresponding general aspects for medical devices*, and Technical Committee IEC/SC 62A, *Common aspects of electrical equipment used in medical practice*. The draft was circulated for voting to the national bodies of both ISO and IEC.

Introduction

Experience indicates that manufacturers have difficulty with practical implementation of some clauses of the risk management International Standard, ISO 14971:2007, *Medical devices — Application of risk management to medical devices*. This Technical Report provides guidance to assist in the development, implementation and maintenance of risk management for medical devices that aim to meet the requirements of ISO 14971. It provides guidance for specific aspects of ISO 14971 for a wide variety of medical devices. These medical devices include active, non-active, implantable, and non-implantable medical devices and *in vitro* diagnostic medical devices.

This Technical Report is not intended to be an overall guidance document on the implementation of ISO 14971 for organizations. It supplements the guidance contained in the informative annexes of ISO 14971 related to the following areas.

— Guidance on the role of international product safety and process standards in risk management

— Guidance on developing the policy for determining the criteria for risk acceptability

— Guidance on how the production and post-production feedback loop can work

— Guidance on the differentiation of information for safety as a risk control measure and disclosure of residual risk

— Guidance on the evaluation of overall residual risk

This Technical Report provides some approaches that an organization can use to implement and maintain some aspects of a risk management system that conforms to ISO 14971. Alternative approaches can be used if these satisfy the requirements of ISO 14971.

When judging the applicability of the guidance in this Technical Report, one should consider the nature of the medical device(s) to which it will apply, the risks associated with the use of these medical devices, and the applicable regulatory requirements.