INTERNATIONAL STANDARD

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# Medical devices — Risk management —

# Part 1:
Application of risk analysis

*Dispositifs médicaux — Gestion du risque —*

*Partie 1: Application de l'analyse du risque*

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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.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

International Standard ISO 14971-1 was prepared jointly by Technical Committee ISO/TC 210, *Quality management and corresponding general aspects for medical devices*, and IEC/SC 62A, *Common aspects of electrical equipment in medical practice*.

ISO 14971 consists on the following parts, under the general title *Medical devices — Risk management*:

— *Part 1: Application of risk analysis*

Annexes A to F of this part of ISO 14971 are for information only.

## Introduction

Judgements relating to safety, including the acceptability of risks, are necessary in order to determine the suitability of a medical device for its intended use. Factors influencing the perception of safety include the socio-economic and educational background of the society concerned, and the actual and projected situation and status of the patient. Such judgements must take into account the intended use, performance, risks and benefits of the device, and the risks and benefits associated with the clinical procedure.

The overall process for the control of risks is referred to as "risk management". This part of ISO 14971 describes techniques for risk analysis based on quantitative or qualitative estimation of the probability of possible consequences of a postulated event relating to the application of a medical device. Risk analysis is the initial step in the overall process referred to as risk management. Elements of risk evaluation and risk control are included in the flow diagram (figure 1) for purposes of completeness. The relationship between risk analysis, risk evaluation and risk control is illustrated in annex E. Further work is under consideration.