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Medical devices — Risk management — Part 1: Application of risk analysis

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Descriptors : medical equipment, accident prevention, ergonomics, equipment safety

Reference number : **JIS Q 14971-1 : 2001 (E)**

Foreword

This translation has been made based on the original Japanese Industrial Standard established by the Ministers of Health, Labour and Welfare and Economy, Trade and Industry through deliberations at the Japanese Industrial Standards Committee according to the proposal of establishing a Japanese Industrial Standard form the Japan Federation of Medical Devices Associations (JFMDA), with a draft of Industrial Standard based on the provision of Article 12 Clause 1 of the Industrial Standardization Law.

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In the event of any doubts arising as to the contents,
the original JIS is to be the final authority.

Contents

Medical devices — Risk management — Part 1: Application of risk analysis

Introduction

This Japanese Industrial Standard has been prepared based on ISO 14971-1 *Medical devices—Risk management—Part 1: Application of risk analysis* published in 1998 without modifying the technical contents.

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 JIS Q 14971 describes techniques for risk analysis based on quantitative or qaulitative 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.

Portions underlined with dots are the matters not stated in the original International Standard.