

Medical devices — Risk analysis

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British Standard

ICS 11.040.01

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Summary of pages

This document comprises a front cover, an inside front cover, the EN title page, pages 2 to 10, an inside back cover and a back cover.

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English version

Medical devices — Risk analysis

Dispositifs médicaux — Analyse des risques

Medizinprodukte — Risikoanalyse

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CEN

European Committee for Standardization
Comité Européen de Normalisation
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Foreword

This European Standard has been prepared by BTS 3 /WG 1, Risk assessment of medical devices, of CEN/CS.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by April 1998, and conflicting national standards shall be withdrawn at the latest by April 1998.

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directives.

For relationship with EU Directives, see informative annex ZA which is an integral part of this standard.

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Annexes A, B, C, D and E are informative.

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Introduction

Judgements relating to safety, including the acceptability of risks, are necessary in order to determine the suitability for use of a medical device. 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 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 risk is referred to as risk management. During the design phase of a medical device a manufacturer will need to analyse the hazards and risks associated with the use of a device. This standard addresses that phase of the risk management process.

Relevant standards mentioned within this standard include harmonized European Standards, the references to which have been published in the Official Journal of the European Communities.

1 Scope

This standard specifies a procedure for the manufacturer to investigate, using available information, the safety of a medical device, including in vitro diagnostic devices or accessories, by identifying hazards and estimating the risks associated with the device. It is of particular assistance in areas where relevant standards are not available or not used.

This standard does not stipulate levels of acceptability, which because they are determined by a multiplicity of factors, cannot by their nature be set down in such a standard.

This standard is not intended to give detailed guidance on management of risks. Furthermore, it is not intended to cover decision-making processes regarding assessment of the indications and contra-indications for the use of a particular device.

2 Definitions

For the purposes of this standard, the following definitions apply.

2.1 harm

Physical injury and/or damage to health or property.
[ISO/IEC Guide 51 : 1990]

2.2 hazard

A potential source of harm.
[ISO/IEC Guide 51 : 1990]

2.3 risk

The probable rate of occurrence of a hazard causing harm and the degree of severity of the harm.
[ISO/IEC Guide 51 : 1990]

2.4 risk analysis

The investigation of available information to identify hazards and to estimate risks.

2.5 safety

Freedom from unacceptable risk of harm.
[ISO/IEC Guide 51 : 1990]

3 Procedure

3.1 General (step 1 of figure 1)

The risk analysis procedure, as described in 3.2 to 3.9 and illustrated in the flow diagram given in figure 1 shall be followed and the conduct and results of the risk analysis procedure shall be documented and maintained by the manufacturer.

NOTE 1. Risk analysis can be carried out as part of a quality system.

NOTE 2. The documentation of the conduct and results of the risk analysis procedure should include at least the following:

- a complete description and identification of the devices or the accessory under consideration;
- a list of possible hazards as identified under 3.3;
- an indication of the way in which the risk has been reduced to acceptable levels;
- identification of which party carried out the risk analysis.