BRITISH STANDARD

BS EN
1441 : 1998

Medical devices — Risk analysis

The European Standard EN 1441 : 1997 has the status of a British Standard

ICS 11.040.01

National foreword

This British Standard is the English language version of EN 1441 : 1997.

The UK participation in its preparation was entrusted to Technical Committee CH/5, Risk assessment of medical devices, which has the responsibility to:

- aid enquirers to understand the text;
- present to the responsible European committee any enquiries on the interpretation, or proposals for change, and keep the UK interests informed;
- monitor related international and European developments and promulgate them in the UK.

A list of organizations represented on this committee can be obtained on request to its secretary.

Cross-references

The British Standards which implement international or European publications referred to in this document may be found in the BSI Standards Catalogue under the section entitled 'International Standards Correspondence Index', or by using the 'Find' facility of the BSI Standards Electronic Catalogue.

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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.

This British Standard, having been prepared under the direction of the Health and Environment Sector Board, was published under the authority of the Standards Board and comes into effect on 15 March 1998

ISBN 0 580 28876 5

Amendments issued since publication

Amd. No.	Date	Text affected

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN 1441

October 1997

ICS 11.040.01

Descriptors: Medical equipment, safety, accident prevention, hazards, statistical analysis, estimation, acceptability, specifications, information

English version

Medical devices — Risk analysis

Dispositifs médicaux — Analyse des risques

Medizinprodukte — Risikoanalyse

This European Standard was approved by CEN on 13 September 1997.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Central Secretariat has the same status as the official versions.

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CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

Central Secretariat: rue de Stassart 36, B-1050 Brussels

Ref. No. EN 1441 : 1997 E

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.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

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

Contents

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) a complete description and identification of the devices or the accessory under consideration;

b) a list of possible hazards as identified under **3.3**;

c) an indication of the way in which the risk has been reduced to acceptable levels;

d) identification of which party carried out the risk analysis.

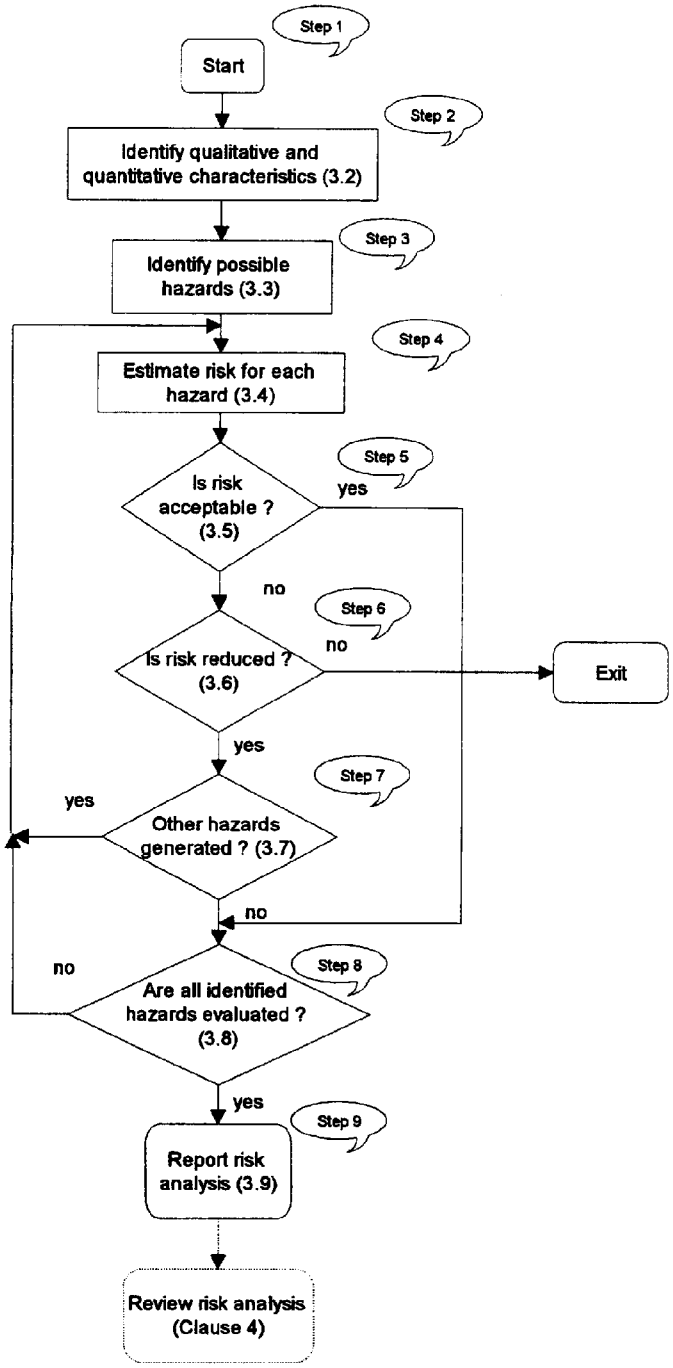

Figure 1. Flow diagram of risk analysis procedure

3.2 Identification of qualitative and quantitative characteristics related to medical devices (step 2 of figure 1)

For the particular device or accessory being considered, list all those characteristics that can affect its safety and, where appropriate, list their defined limits.

NOTE 1. Additional guidance on risk analysis procedures for in vitro diagnostic devices is given in annex A.

NOTE 2. Additional guidance on risk analysis procedures for toxicological hazards is given in annex B.

NOTE 3. The following questions can serve as a useful guide in drawing up such a list.

a) What is the intended use and how is the device to be used?

Factors that should be considered include the intended user, the required skill and training of the user, in which environment it is to be used, by whom it will be installed and whether the patient can influence the use of the device. Special attention should be paid to users with special needs like handicapped persons, the elderly and children. Their special needs might include assistance by another person to enable the use of a device.

b) Is the device intended to contact the patient or other persons?

Factors that should be considered include intended contact, surface contact, invasive contact, implantation and, respectively, the period and frequency of contact.

c) What materials and/or components are incorporated in the device or are used?

Factors that should be considered include whether the characteristics relevant to safety are known.

d) Is energy delivered to and/or extracted from the patient?

Factors that should be considered include the type of energy transferred and its control, quality, quantity and time function.

e) Are substances delivered to and/or extracted from the patient?

Factors that should be considered include whether the substance is delivered or extracted, whether it is a single substance or range of substances, the maximum and minimum transfer rates and control thereof.

f) Are biological materials processed by the device for subsequent re-use?

Factors that should be considered include the type of process and substance(s) processed, e.g. auto-transfusion, dialyzers.

g) Is the device supplied sterile or intended to be sterilized by the user or are other microbiological controls applicable?

Factors that should be considered include whether the device is intended for single use or to be re-usable, any packaging, the shelf life and any limitation on the number of re-use cycles or type of sterilization process to be used.

h) Is the device intended to modify the patient environment?

Factors that should be considered include temperature, humidity, atmospheric gas composition and pressure.

i) Are measurements made?

Factors that should be considered include the variables measured and the accuracy and the precision thereof.

j) Is the device interpretative?

Factors that should be considered include whether conclusions are presented by the device from input or acquired data, the algorithms used and confidence limits.

k) Is the device intended to control or to interact with other devices or drugs?

Factors that should be considered include identifying other devices and drugs which can be involved and the potential problems associated with such interactions.

l) Are there unwanted outputs of energy or substances?

Energy-related factors that should be considered include noise and vibration, heat, radiation (including ionizing, non-ionizing and ultraviolet/visible/infrared radiation), contact temperatures, leakage currents and electrical and/or magnetic fields.

Substance-related factors that should be considered include discharge of chemicals, waste products and body fluids.

m) Is the device susceptible to environmental influences?

Factors that should be considered include the operational, transport and storage environment, including spillage, and power and cooling supplies.

n) Are there essential consumables or accessories associated with the device?

Factors that should be considered include specifications for such consumables or accessories and any restrictions placed upon users in their selection of these.

o) Is maintenance and/or calibration necessary?

Factors that should be considered include whether maintenance and/or calibration are to be carried out by the operator or user or by a specialist.

p) Does the device contain software?

Factors that should be considered include whether software is intended to be installed, modified or exchanged by the user and/or operator.

q) Does the device have a restricted shelf life?

Factors that should be considered include labelling or indicators and the disposal of such devices.

r) Possible delayed and/or long term use effects?

Factors that should be considered include ergonomic and cumulative effects.

s) To what mechanical forces will the device be subjected?

Factors that should be considered include whether the forces to which the device will be subjected are under the control of the user or controlled by interaction with other persons.

t) What determines the lifetime of the device?

Factors that should be considered include ageing.

u) Is the device intended for single use or re-use?

3.3 Identification of possible hazards (step 3 of figure 1)

Using the examples of possible hazards listed in annex C as an aide-memoire, compile a list of potential hazards associated with the device in both normal and fault conditions.

3.4 Estimation of the risks for each hazard (step 4 of figure 1)

For each of the possible hazards identified under **3.3**, estimate the risks in both normal and fault conditions using available information/data.

NOTE 1. In order to better analyse the risks, their components, i.e. consequences and probability, should be analysed separately. This includes answering the following questions.

- Does the hazard occur in the absence of a failure?
- Does the hazard occur in a failure mode?
- Does the hazard occur only in a multiple failure condition?

Annex D gives information on some risk analysis techniques that can be used.

NOTE 2. Information/data can be obtained, for example, from:

- relevant standards;
- scientific data;
- field data from similar devices including published reported incidents;
- clinical evidence;
- results of appropriate investigations.

3.5 Acceptability of risk (step 5 of figure 1)

If a risk for a given hazard is appropriately addressed by compliance with a relevant standard or acceptability is demonstrated by other means, proceed to **3.8**. If the risk for a given hazard estimated in accordance with **3.4** exceeds the levels of acceptability defined through the application of relevant standards or by other means, proceed to **3.6**.

NOTE. If the risk is judged to be outside acceptable limits only in failure mode, the likelihood of a fault occurring should be analysed. In doing this, the following questions should be addressed.

- Can a failure be detected by the user before the hazard occurs?
- Can the failure be eliminated by more effective manufacturing controls or by preventive maintenance?
- Will misuse increase the likelihood of failure?
- Can alarms be added?

3.6 Risk reduction (step 6 of figure 1)

If the risk is reduced appropriately, proceed to **3.7**.

NOTE. If any risk is judged unacceptable, it should be reduced to acceptable levels by appropriate means in a staged process:

a) direct safety means (design);

b) indirect safety means (safeguarding). Examples of safeguarding are:

- restricting accessibility, e.g. for radiation hazards;
- shielding from the hazard, e.g. by means of a protective cover;

c) descriptive safety means, e.g. restricting period or frequency of use of the device, restricting application, lifetime, or environment;

d) redefining the intended use.

3.7 Generation of other hazards (step 7 of figure 1)

Determine whether the risk reduction procedure has introduced new hazards.

3.8 Evaluation of all identified hazards (step 8 of figure 1)

If risks have been estimated for all identified hazards proceed to **3.9**, if not, return to **3.4**.

3.9 Risk analysis report (step 9 of figure 1)

Document the results of the risk analysis in accordance with **3.1** so that a decision can be taken as to whether the remaining risks associated with the identified hazards are acceptable, having regard to the intended application and use of the device.

NOTE. Techniques that can be used for the analysis of the risks include failure mode effect analysis (FMEA), fault tree analysis (FTA) and hazard and operability (HAZOP) studies. The need for, selection of and use of such techniques can depend on the nature of the device and is outside the scope of this standard. Annex D gives a short summary of some of the techniques that can be used. See annex E for a bibliography.

4 Review of risk analysis

In the light of new data a review of the risk analysis will be required.

NOTE. A review of risk analysis will be required if risks change over time. Rapidly changing technology can eliminate, increase or decrease the risk for any given hazard. New risks can arise or be identified for the first time.

Annex A (informative)

Guidance on risk analysis procedure for in vitro diagnostic devices

A.1 General

This annex provides additional guidance on the risk analysis of in vitro diagnostic medical devices, taking into account the particularities and specific aspects of these devices. The use of in vitro diagnostic medical devices does not create any direct risk to the patient or the person subjected to the examination, as they are not applied in or on the human body. Under certain circumstances, however, indirect risks may result from device-associated hazards leading or contributing to erroneous decisions. In addition, user-related hazards and their associated risks should also be considered.

A.2 Identification of hazards

In addition to those aspects mentioned in annex C, the following aspects should be considered in identifying potential hazards for the patient or the person subjected to examination:

- batch inhomogeneity, batch-to-batch inconsistency;
- common interfering factors;
- carry-over effects;
- sample identification errors;
- stability problems (in storage, in shipping, in use, after first opening of the container);
- problems related to taking, preparation and stability of specimens;
- inadequate specification of prerequisites.

Potential hazards for the user can arise from radioactive, infectious, toxic or otherwise hazardous ingredients of reagents and from the packaging design. For instruments, the problem of potential contamination during handling, operation and maintenance should be considered in addition to the non-specific instrument-related hazards (e.g. energy hazards).

A.3 Risk estimation

In estimating the risk for each hazard the following aspects should be taken into account:

- extent of reliance on the analytical result (contribution to the medical decision);
- plausibility checks;
- availability and use of controls;
- quality assurance measures applied in medical laboratories;
- detectability of deficiencies/errors;
- situations of use, e.g. emergency cases;
- professional use/non-professional use.

Annex B (informative)

Guidance on risk analysis procedure for toxicological hazards

B.1 General

This annex provides guidance on the procedure to be followed in carrying out **3.3** and **3.4** of the risk analysis procedure, see steps 3 and 4 in figure 1, with respect to toxicological hazards. Toxicological hazards are due to chemical constituents causing biological harm. prEN ISO 10993-1 sets out the general principles for the biological evaluation of materials/devices.

Efforts should be made to avoid unnecessary testing using animals; attention is drawn to prEN ISO 10993-2 on animal welfare requirements, the EU Directive on Animal Protection (86/609/EEC) and to relevant national legislation.

A test may be omitted if the omission can be scientifically justified.

B.2 Estimation of toxicological risks

B.2.1 *Introduction*

The toxicological risk analysis should take account of:

- the chemical nature of the materials;
- prior use of the materials;
- biological safety test data.

The amount of data required and the depth of the investigation will vary with the intended use and are dependent upon the nature and duration of patient contact. Data requirements are usually less stringent for packaging materials, devices contacting intact skin and any component of a device which does not come into direct contact with body tissues, infusible liquids, mucous membranes or compromised skin.

Current knowledge of the material/ device provided by scientific literature, previous clinical experience and other relevant data should be reviewed to establish any need for additional data. In some cases it can become necessary to obtain formulation data, residue data (e.g. from sterilization processes, monomers), biological test data, etc.

B.2.2 *The chemical nature of the materials*

Information characterizing the chemical identity and biological response of materials is useful in assessing a medical device for its intended use. Some factors which can affect the biocompatibility of the material include:

- the identity, concentration, availability and toxicity of all constituents, e.g. additives, processing aids, monomers, catalysts, reaction products, etc.;
- the influence of biodegradation and corrosion on the material.

Where reactive or hazardous ingredients have been used in, or can be formed by, the production, processing, storage or degradation of a material, the possibility of exposure to residues should be considered. Information on residue concentration and/or leaching can be necessary. This can take the form of experimental data or information on the chemistry of the materials involved.

Where complete formulation data are not available to a manufacturer due to confidentiality, verification should be obtained that an assessment has been carried out of the suitability of the material for use in the proposed application.

B.2.3 *Prior use*

Available information on previous use of each material or intended additive and on any adverse reactions encountered should be reviewed. However, previous use of an ingredient or material does not necessarily assure its suitability in similar applications. Account should be taken of the intended use, the concentration of the ingredients and current toxicological information.

B.2.4 *Biological safety test data*

prEN ISO 10993-1 gives guidance on which tests should be considered for particular applications. The need for testing should be reviewed on a case-by-case basis in the light of existing data, so that unnecessary testing is avoided.

Annex C (informative)

Examples of possible hazards and contributing factors associated with medical devices

C.1 General

Clauses **C.2** to **C.7** give non-exhaustive lists of possible hazards and contributing factors associated with different medical devices. These lists are intended to provide an aide-memoire in identifying possible hazards under **3.3** of the risk analysis procedure (step 3 of figure 1).

C.2 Energy hazards

- electricity;
- heat;
- mechanical force;
- ionizing radiation;
- non-ionizing radiation;
- electromagnetic fields;
- moving parts;
- suspended masses;
- patient support device failure;
- pressure (vessel rupture);
- acoustic pressure;
- vibration;
- magnetic fields, e.g. MRI.

C.3 Biological hazards

- bio-burden;
- bio-contamination;
- bio-incompatibility;
- incorrect output (substance/energy);
- incorrect formulation (chemical composition);
- toxicity;
- (cross-)infection;
- pyrogenicity;
- inability to maintain hygienic safety;
- degradation.

C.4 Environmental hazards

- electromagnetic interference;
- inadequate supply of power or coolant;
- restriction of cooling;
- likelihood of operation outside prescribed environmental conditions;
- incompatibility with other devices;
- accidental mechanical damage;
- contamination due to waste products and/or device disposal.

C.5 Hazards related to the use of the device

- inadequate labelling;
- inadequate operating instructions;
- inadequate specification of accessories;
- inadequate specification of pre-use checks;
- over-complicated operating instructions;
- unavailable or separated operating instructions;
- use by unskilled/untrained personnel;
- reasonably foreseeable misuse;
- insufficient warning of side effects;
- inadequate warning of hazards likely with re-use of single use devices;
- incorrect measurement and other metrological aspects;
- incorrect diagnosis;
- erroneous data transfer;
- mispresentation of results;
- incompatibility with consumables/accessories/other devices.

C.6 Hazards arising from functional failure, maintenance and ageing

- inadequacy of performance characteristics for the intended use;
- lack of, or inadequate specification for maintenance, including inadequate specification of post maintenance functional checks;
- inadequate maintenance;
- lack of adequate determination of end of device life;
- loss of mechanical integrity;
- inadequate packaging (contamination and/or deterioration of the device);
- improper re-use.

Annex D (informative)
Information on risk analysis techniques

D.1 General

This annex provides guidance on some available procedures for probabilistic safety analysis that can be used under **3.4** (step 4 of figure 1). The basic principle is that the possible consequences of a postulated event are analysed step by step.

D.2 Failure mode and effect analysis (FMEA)

FMEA is a primarily qualitative technique, by which the consequences of an individual component fault mode are systematically identified and evaluated. It is an inductive technique using the question 'What happens to the output if...?' Components are analysed one at a time, thus generally looking at a single fault condition. This is done in a 'bottom-up' mode, i.e. following the process to the next higher functional system level.

FMEA can be extended to incorporate an investigation of the degree of severity of the consequences, their respective probabilities of occurrence and their detectability, and become a so-called failure mode effect and criticality analysis (FMECA). In order to perform such an analysis, the construction of the device should be known in some detail.

FMEA can also be a useful technique to deal with human error. It can also be used to identify hazards and thus provide a valuable input to a fault tree analysis (FTA).

Disadvantages of this technique can arise from difficulties in dealing with redundancies and the incorporation of repair or preventive maintenance actions as well as its restriction on single fault conditions.

D.3 Fault tree analysis (FTA)

FTA is primarily a means of analysing hazards identified by other techniques and will start from a postulated undesired consequence, also called 'top event'. In a deductive manner, starting with the top event, the possible causes or fault modes of the next lower functional system level causing the undesired consequence are identified. Following stepwise identification of undesirable system operation to successively lower system levels will lead to the desired system level, which is usually the component fault mode. This will reveal the sequences most likely to lead to the postulated consequence and has therefore proved to be useful for forensic purposes.

The results are represented pictorially in the form of an event tree. The faults identified in the tree can be events that are associated with hardware failures, human errors or any other pertinent event which led to the undesired event and are not limited to the single fault condition.

FTA allows a systematic approach, which at the same time is sufficiently flexible to allow analysis of a variety of factors, including human interactions. FTA is primarily used in risk analysis as a tool to provide an estimate of failure probabilities. The pictorial representation leads to an easy understanding of the system behaviour and the factors included, but as the trees become large, processing of fault trees can require the use of sophisticated mathematical methods. This feature makes the verification of the fault tree difficult.

D.4 Hazard and operability study (HAZOP)

HAZOP can be considered to be a form of FMEA. It is a systematic technique for identifying hazards and operability problems, originally developed for use in the chemical process industry. The principles of HAZOP can be applied to process plants in operation or in various stages of design. HAZOP carried out during the initial phase of design can frequently provide a guide to safer detailed design.

The objectives of this technique are:

- to produce a full description of the plant and the process including the intended design conditions;
- to review systematically every part of the process to discover how deviations from the normal operating conditions and the intended design can occur;
- to identify what consequences such deviations will have on the process and its output and to decide whether these deviations can lead to hazards or operability problems.

It is the latter feature which renders HAZOP particularly useful in analysing device risks, where the device characteristics depend on the manufacturing process or other chemical processes.

Annex E (informative)
Bibliography

prEN ISO 10993-1	*Biological evaluation of medical devices — Part 1: Evaluation and testing* (ISO/DIS 10993-1 : 1995)
prEN ISO 10993-2	*Biological evaluation of medical devices — Part 2: Animal welfare requirements* (ISO 10993-2 : 1992)
prEN 12442-1	*Animal tissues and their derivatives utilized in the manufacture of medical devices — Part 1: Analysis and management of risk*
prEN 12442-2	*Animal tissues and their derivatives utilized in the manufacture of medical devices — Part 2: Sourcing, controls, collection and handling*
EN 30993-3 : 1993	*Biological evaluation of medical devices — Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity* (ISO 10993-3 : 1992)
IEC 812 : 1985	*Analysis techniques for system reliability — Procedure for failure mode and effects analysis (FMEA)*
IEC 1025 : 1990	*Fault tree analysis (FTA)*
IEC/TR 513 : 1994	*Fundamental aspects of safety standards for medical electrical equipment*
IEC 300-3-9 : 1995	*Dependability management — Part 3: Application guide — Section 9: Risk analysis of technological systems*
IEC 601-1-4 : 1996	*Medical electrical equipment — Part 1: General requirements for safety — Section 4: Collateral standard: Safety requirements for programmable electronic medical systems*
86/609/EEC	*Council Directive of 24 November 1986 on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes*
ISO/IEC Guide 51 : 1990	*Guidelines for the inclusion of safety aspects in standards*

Annex ZA (informative)
Clauses of this European Standard addressing essential requirements or other provisions of EU Directives

This European Standard has been prepared under a mandate given to CEN/CENELEC by the European Commission and the European Free Trade Association and supports essential requirements of EU Directive 93/42/EEC.

WARNING. Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

The following clauses of this standard, as detailed in table ZA.1, are likely to support requirements of Directive 93/42/EEC.

Compliance with the clauses of this standard provides one means of conforming with the specific essential requirements of the Directive concerned and associated EFTA regulations.

Table ZA.1 Correspondence between this European Standard and EU Directives

Clauses/sub-clauses of this European Standard	Corresponding annexes/paragraphs of Directive 93/42/EEC	Comments
The whole standard	Annex 1, essential requirements: 1, 2, 3, 4, 5, 6, 7.1, 7.2, 7.3, 7.4, 7.5, 7.6, 8.1, 8.2, 9.1, 9.2, 9.3, 10.1, 11.1, 11.2, 11.3, 11.4, 11.5, 12.1, 12.2, 12.3, 12.4, 12.5, 12.6, 12.7, 12.8, 12.9	EN 1441 is intended to be applied in conjunction with relevant product standards where these exist. prEN 12442-1 and prEN 12442-2 cover risk analysis and management, and sourcing, collection and handling issues in relation to medical devices incorporating animal tissues or their derivatives.

BS EN 1441 : 1998

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