BRITISH STANDARD

BS EN
1041:1998

Information supplied by the manufacturer with medical devices

The European Standard EN 1041:1998 has the status of a British Standard

ICS 01.110; 11.040.01; 11.120.01

National foreword

This British Standard is the English language version of EN 1041:1998.

The UK participation in its preparation was entrusted to Technical Committee CH/68, General terminology, symbols and information provided with 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 16, an inside back cover and a back cover.

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Descriptors: Medical equipment, information, manufacturers, vocabulary, symbols

English version

Information supplied by the manufacturer with medical devices

Informations fournies par le fabricant avec les dispositifs médicaux

Bereitstellung von Informationen durch den Hersteller eines Medizinprodukts

This European Standard was approved by CEN on 18 January 1998.

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.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

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 1041:1998 E

Foreword

This European Standard has been prepared by Technical Committee CEN/TC 257, Symbols and information provided with medical devices and nomenclature for regulatory data exchange, the Secretariat of which is held by SFS.

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 August 1998, and conflicting national standards shall be withdrawn at the latest by August 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 annexes ZA and ZB, which are integral parts of this standard.

This standard is intended to complement the specific requirements of the EU Directives on medical devices relating to the information supplied by the manufacturer for different categories of medical devices.

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.

Contents

Introduction

This standard is applicable to medical devices generally, but it should be noted that other European Standards may specify additional information requirements for particular types of medical devices.

The requirements of this standard are given in clause **4**. Additional information and guidance are given in the annexes.

Annex A gives a short bibliography of documents related to information, including labelling, supplied by the manufacturer. Annexes B and C reproduce, for convenience of use, the relevant text of the EU Directives relating to active implantable medical devices, and to medical devices, respectively. Guidance is given in annexes B and C to assist manufacturers to achieve compliance with the requirements of those texts.

For ease of use, a two column system of presentation has been adopted for annexes B and C. The first column reproduces verbatim the information requirements as given in annex 1 of the Council Directives concerning medical devices. The second column contains, where appropriate, further guidance for manufacturers as to ways in which compliance with the particular information requirements of the Directives may be achieved. This guidance is not to be considered as the obligatory or only way of achieving compliance with the requirements of the Directive; alternative ways may be acceptable.

In order to facilitate the presentation of information and to reduce the need for translation into numerous languages, consideration should always be given to using appropriate symbols.

1 Scope

This standard specifies requirements for the information to be supplied by a manufacturer for different categories of medical devices, as required by the relevant EU Directives. It does not specify the language to be used for such information. It is intended to complement the specific requirements of the EU Directives on medical devices in the context of specifying means by which certain requirements can be met. If these means are followed by a manufacturer, they will provide presumption of conformity with the relevant essential requirements regarding information to be supplied.

2 Normative references

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

ISO 31 (all parts), *Quantities and units.*

EN 28601, *Data elements and interchange formats — Information interchange — Representation of dates and times.* (ISO 8601, 1st edition 1988 and technical corrigendum 1:1991).

3 Definitions

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

3.1

batch; lot

a defined quantity of starting material, packaging material or product processed in one process or series of processes

3.2

batch code; lot number; batch number; lot code

a distinctive combination of numbers and/or letters which specifically identifies a batch

NOTE This definition is as given for batch or lot number in the Rules Governing Medicinal Products in the European Community, Volume IV, Guide to Good Manufacturing Practice for Medicinal Products.

3.3

information supplied by the manufacturer with the medical device

all written, printed or graphic matter:

a) on a medical device or any of its containers or wrappers; or

b) accompanying a medical device;

relating to the identification, technical description and use of the medical device, but excluding shipping documentation and promotional material.

The information comprises the details on the label and the data in the instructions for use. The instructions for use may be included on the label.

3.4

medical device

any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

— diagnosis, prevention, monitoring, treatment or alleviation of disease;

— diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;

— investigation, replacement or modification of the anatomy or of a physiological process;

— control of conception;

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means

[EN 46001]

NOTE This definition is as given in the Council Directive concerning medical devices (93/42/EEC), Article 1, paragraph 2 (a).

4 Requirements for information to be supplied by the manufacturer

NOTE The medical devices Directives stipulate the legal requirements for information supplied by the manufacturer. These are reproduced verbatim in the informative annex B for active implantable devices and informative annex C for medical devices. Due consideration should be given to the guidance in these annexes.

Product related standards may require additional information to be supplied. Product area standards may also require additional information, e.g. clause 6 of the various parts of EN 60601 for medical electrical equipment.

4.1 Requirements

4.1.1 Information supplied by the manufacturer and intended for direct visual recognition shall be legible when viewed under an illumination of 215 lx using normal vision, corrected if necessary, at a distance which takes into account the specifics and size of the individual medical device.

NOTE 1 The information presented should be understandable by the intended user and/or other persons, where appropriate.

NOTE 2 If there is insufficient space on the container or the device, the relevant information may be given on an insert, accompanying document or on the next layer of packaging, as applicable.

The recognition of certain markings on small or specialized devices may require the use of methods other than visual, for example, electronic.

4.1.2 Any symbols used in the information supplied by the manufacturer with the medical devices shall either:

a) conform to those specified in harmonized standards, or

b) in areas for which no harmonized standards exist, have their meanings explained in the information supplied by the manufacturer with the device.

NOTE Examples of harmonized standards are EN 980 and EN 60601.

4.1.3 Any identification colours used in the information supplied by the manufacturer with the medical devices shall either:

a) conform to those specified in relevant harmonized standards, e.g. medical gas cylinders; or

b) where no harmonized standard exists, be described together with their meanings in the information supplied by the manufacturer with the device.

NOTE Reference to standards which include colour coding is given in annex A.

4.1.4 The information supplied by the manufacturer shall not be presented in such a manner that it obscures other essential information.

NOTE The information supplied by the manufacturer should not be presented in such a manner that it may be confused with other essential information.

4.1.5 Any units of measurement shall be expressed in SI units as specified in ISO 31, or other legal units.

NOTE 1 Attention is drawn to Council Directive 80/181/EEC as amended, see annex A, and to ISO 1000 which gives further guidance on the application of SI units.

NOTE 2 This requirement does not preclude the additional use of other units as allowed by harmonized standards.

4.1.6 As far as is practicable and appropriate, the information needed to use the device safely shall be set out on the device itself and/or on the packaging for each unit, or, where appropriate, on the sales packaging. If individual packaging of each unit is not practicable, the information shall be set out in the leaflet supplied with the device(s).

4.1.7 User adjustable controls shall have their function clearly specified.

4.1.8 Any detachable component, intended by the manufacturer to be used separately from the original device, shall be identified by its batch code, or by other appropriate means.

4.1.9 The address of the manufacturer shall be provided in sufficient detail to enable contact to be established.

NOTE Specific legal requirements apply to devices imported into the European Union, see annex C, **13.3**a).

4.1.10 Any date shall be expressed in the format YYYY-MM-DD, or YYYY-MM, or YYYY, in accordance with EN 28601.

NOTE The choice of format will be determined by the requirements of the relevant Directive(s) and the specific nature of the device itself.

Annex A (informative)

Bibliography

EN 556, *Sterilization of medical devices — Requirements for medical devices to be labelled "Sterile".*

EN 980, *Graphical symbols for use in the labelling of medical devices.*

EN 1089-3, *Transportable gas cylinders — Cylinder identification — Part 3: Colour coding.*

prEN 1733, *Suction catheters for use in the respiratory tract.*

EN 20780, *Packaging — Pictorial marking for handling of goods.* (ISO 780:1985)

EN ISO 9001, *Quality systems — Model for quality assurance in design/development, production, installation and servicing.* (ISO 9001:1994)

EN ISO 9002, *Quality systems — Model for quality assurance in production, installation and servicing.* (ISO 9002:1994)

EN ISO 9004-1, *Quality management and quality system elements — Part 1: Guidelines.* (ISO 9004-1:1994)

EN 45502-1, *Active implantable medical devices — Part 1: General requirements for safety, marking and information to be provided by the manufacturer.*

EN 46001, *Quality systems — Medical devices — Particular requirements for the application of EN ISO 9001.*

EN 46002, *Quality systems — Medical devices — Particular requirements for the application of EN ISO 9002.*

EN 60601, *Medical electrical equipment.*

EN ISO 6009, *Hypodermic needles for single use — Colour coding for identification.* (ISO 6009:1992)

ISO 1000, *SI units and recommendations for the use of their multiples and of certain other units.*

ISO 7000, *Graphical symbols for use on equipment — Index and synopsis.*

IEC 1258, *Guidelines for the development and use of medical electrical equipment educational materials.*

93/42/EEC, Council Directive concerning medical devices. Council of European Communities.

90/385/EEC, Council Directive on the approximation of the laws of the Member States relating to active implantable medical devices. Council of European Communities.

80/181/EEC, Council Directive on the approximation of the laws of the Member States relating to units of measurement. Council of European Communities.

89/336/EEC, Council Directive on the approximation of the laws of the Member States relating to electromagnetic compatibility. Council of European Communities, Rules Governing Medicinal Products in the EEC, Volume IV, GMP for Medicinal Products Council of European Communities.

93/465/EEC, Council Decision on CE-Mark. Council of European Communities.

89/618/EURATOM, Council Directive on informing the general public about health protection measures to be applied and steps to be taken in the event of a radiological emergency. Council of European Communities.

Annex B (informative)

Requirements and guidance for active implantable medical devices

NOTE The left-hand column reproduces verbatim the requirements for information to be supplied by the manufacturer from Directive 90/385/EEC relating to active implantable medical devices given in the essential requirements in annex 1. The right-hand column gives guidance and further explanation as appropriate.

Information requirements from the Council Directive relating to active implantable medical devices given in the essential requirements in annex 1	**Guidance**
11. The devices and, if appropriate, their component parts, must be identified to allow any necessary measure to be taken following the discovery of a potential risk in connection with the devices and their component parts.	Such identification will facilitate recall if necessary.
12. Devices must bear a code by which they and their manufacturer can be unequivocally identified (particularly with regard to the type of device and year of manufacture); it must be possible to read this code, if necessary, without the need for a surgical operation.	An example of a means by which this code can be read without the need for a surgical operation would be by provision of radio-opaque symbols on the device, with/without further telemetry appropriate to the particular device, to obtain further identification details.
13. When a device or its accessories bear instructions required for the operation of the device or indicate operating or adjustment parameters, by means of a visual system, such information must be understandable to the user and, as appropriate, the patient.	When a device is put into service, national regulations may require the information described in sections 13, 14 and 15 of annex 1 of the Directive to be in their national language(s) (90/385/EEC, article 4, paragraph 4). Consideration should be given to making this information available to the patient and a copy being retained by the implanting medical practitioner.
14. Every device must bear, legibly and indelibly, the following particulars, where appropriate in the form of generally recognized symbols:	Apart from the code referred to under essential requirement 12 above, no information is put on the device itself. (See **4.1.2** of this standard.)
14.1 On the sterile pack:	
— the method of sterilization;	This refers to the method of sterilization used by the manufacturer. The appropriate symbol as specified in EN 980 may be used, and if so it will not be necessary in addition to use the symbol for sterile.
— an indication permitting this packaging to be recognized as such;	The word "sterile" by itself is not a symbol and translation will be required. STERILE as given in EN 980 is a symbol and therefore does not require translation. If the symbol is used, the word "sterile" is not needed.
— the name and address of the manufacturer;	Name, or trade name, and an address to allow the manufacturer to be contacted. The full postal address may not be necessary provided that the address is of sufficient detail that the manufacturer can be contacted, for example name or trade name, postcode and country.
— a description of the device;	For many devices, the identity will be clearly evident to the intended user. Unpackaged devices or those provided only with transit or storage containers may not require further identification. Transparent packaging may reduce the requirement for detailed descriptions. For more complex devices, the identity of the product can be indicated on the device itself or on the packaging or accompanying information, as appropriate. It may be appropriate to list contents and a quantity.

Information requirements from the Council Directive relating to active implantable medical devices given in the essential requirements in annex 1	Guidance
— if the device is intended for clinical investigations, the words: "exclusively for clinical investigations";	National language versions of the Directive also translate the words in quotes.
— if the device is custom-made, the words: "custom-made device";	National language versions of the Directive also translate the words in quotes.
— a declaration that the implantable device is in a sterile condition;	STERILE as given in EN 980 is a symbol and therefore does not require translation. If the symbol is used, the word "sterile" is not needed. The definition of "sterile" as given in **3.4** of EN 556:1994 applies.
— the month and year of manufacture;	The symbol for "date of manufacture" is given in EN 980.
— an indication of the time limit for implanting a device safely.	The symbol to identify "use by" is given in EN 980. This indicates the last month during which the device is intended to be implanted.
14.2 On the sales packaging:	The sales packaging may also be the storage packaging.
— the name and address of the manufacturer;	Name, or trade name, and an address to allow the manufacturer to be contacted. The full postal address may not be necessary provided that the address is of sufficient detail that the manufacturer can be contacted, for example name or trade name, postcode and country.
— a description of the device;	For many devices, the identity will be clearly evident to the intended user. Unpackaged devices or those provided only with transit or storage containers may not require further identification. Transparent packaging may reduce the requirement for detailed descriptions. For more complex devices, the identity of the product can be indicated on the device itself or on the packaging or accompanying information, as appropriate. It may be appropriate to list contents and a quantity.
— the purpose of the device;	This information may be given in an abbreviated form provided that full details are given in the accompanying documentation. If it is not obvious from the device description, additional information and relevant characteristics should be included, as necessary, to completely identify the device.
— the relevant characteristics for its use;	
— the conditions for transporting and storing the device.	Particulars need only be provided for unusual requirements for storage and handling conditions other than those that would normally be expected by the intended user. Information should also be given if storage or handling conditions are critical for the safe and proper performance of the device. Thus, it would be generally understood without specific labelling that devices should be protected from extremes of temperature, from weather and from electro-magnetic radiation. However, if a device is required to be stored within a particular range of relative humidity and temperature, this should be specifically indicated. Internationally recognized symbols may be used, as appropriate, for storage, handling or transport instructions and hazard warnings (see EN 20780). Normal storage conditions of devices are assumed unless specified.

Information requirements from the Council Directive relating to active implantable medical devices given in the essential requirements in annex 1	**Guidance**
15. When placed on the market, each device must be accompanied by instructions for use giving the following particulars:	
— details referred to in 14.1 and 14.2 with the exception of the use before date and the month and year of manufacture;	These are: the identity of the manufacturer, identity of the product, the word "sterile", single use, custom-made device or for clinical investigation only, as appropriate; storage and handling instructions; any warnings, instructions for use and limitations of use. This information may be given in the form of symbols.
— the performances referred to in section 2 and any undesirable side effects;	This refers to the performances referred to in annex 1, essential requirement 2 of Council Directive 90/385/EEC.
— information allowing the physician to select a suitable device and the corresponding software and accessories;	
— information constituting the instructions for use allowing the physician and, where appropriate, the patient to use the device, its accessories and software correctly, as well as information on the nature, scope and times for operating controls and trials and, where appropriate, maintenance measures;	
— information allowing, if appropriate, certain risks in connection with implantation of the device to be avoided;	Any special operating instructions, any warnings and/or cautions should be given. The manufacturer should decide the type and level of information required, taking into consideration such factors as the assumed technical knowledge and skill of the intended user and any novel or unfamiliar features or mode of operation which may not be self-evident. Internationally recognized symbols may be used.
— information regarding risks of reciprocal interference in connection with the presence of the device during specific investigations or treatment;	
— the necessary instructions in the event of the sterile pack being damaged and, where appropriate, details of appropriate methods of resterilization;	The manufacturer may wish to make clear that the device is not sterile and should not be used if the sterile package is found to be open or damaged.
— an indication, if appropriate, that a device can be reused only if it is reconditioned under the responsibility of the manufacturer to comply with the essential requirements.	
The instruction leaflet must also include details allowing the physician to brief the patient on the contra-indications and the precautions to be taken. These details should cover in particular:	If the information is not necessary to brief the patient it need not be included.
— information allowing the lifetime of the energy source to be established;	
— precautions to be taken should changes occur in the device's performance;	
— precautions to be taken as regards exposure, in reasonably foreseeable environmental conditions, to magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure, accelerations, etc.;	
— adequate information regarding the medicinal products which the device in question is designed to administer.	

Annex C (informative)

Requirements and guidance for medical devices

NOTE 1 This annex covers those active and non-active medical devices to which the Council Directive concerning medical devices (93/42/EEC) applies, hereinafter called medical devices.

NOTE 2 The left-hand column reproduces verbatim the requirements for information to be supplied by the manufacturer from Directive 93/42/EEC concerning medical devices given in the essential requirements in annex 1. The right-hand column gives guidance and further explanation, as appropriate.

Information requirements from the Council Directive concerning medical devices given in the essential requirements in annex 1	**Guidance**
General	
8.7 The packaging and/or label of the device must distinguish between identical or similar products sold in both sterile and non-sterile condition.	In accordance with this standard, sterile devices are identified as such, preferably by the symbol STERILE as given in EN 980 or the word stating this condition. Sterile devices should be prominently labelled by the symbol STERILE. The definition of sterile as given in **3.4** of EN 556:1994 applies. Where both sterile and non-sterile versions of the same device from the same manufacturer are available in similar packaging and where, in such cases, the non-sterile device could be mistaken as sterile, it may be necessary, for the safety of the patient, to provide a prominent statement of non-sterility. The similarity can either originate in the device itself or its packaging.
9.1 If the device is intended for use in combination with other devices or equipment, the whole combination, including the connection system, must be safe and must not impair the specified performances of the devices. Any restrictions on use must be indicated on the label or in the instructions for use.	
10.3 The measurements made by devices with a measuring function must be expressed in legal units conforming to the provisions of Council Directive 80/181/EEC.	See **4.1.5**, requirements, of this standard.
11.4.1 The operating instructions for devices emitting radiation must give detailed information as to the nature of the emitted radiation, means of protecting the patient and user and ways of avoiding misuse and of eliminating the risks inherent in installation.	Radiation is not limited to ionizing radiation. Other examples of radiation include heat and laser radiation (see also 89/618/Euratom).
12.9 The function of the controls and indicators must be clearly specified on the devices. Where a device bears instructions required for its operation or indicates operating or adjustment parameters by means of a visual system, such information must be understandable to the user and, as appropriate, the patient.	This applies only to user adjustable controls.
13. Information supplied by the manufacturer	
13.1 Each device must be accompanied by the information needed to use it safely and to identify the manufacturer, taking account of the training and knowledge of the potential users.	Any information should be given in a way that is understandable to the intended user and/or patient. For complex equipment a simple guide on how to check and operate the device in an emergency may be of benefit in addition to instructions of use.

Information requirements from the Council Directive concerning medical devices given in the essential requirements in annex 1	**Guidance**
This information comprises the details on the label and the data in the instructions for use.	
As far as is practicable and appropriate, the information needed to use the device safely must be set out on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging. If individual packaging of each unit is not practicable, the information must be set out in the leaflet supplied with the device(s).	A leaflet can be a manual. When instructions for use are provided by means of a leaflet, the number of leaflets in a multiple pack is determined by the manufacturer considering the use of the device. Many devices, particularly active devices and many non-active Class I devices, will not be supplied with packaging, apart from transit containers. In the absence of suitable packaging, any information should be supplied on attachments, accompanying documentation, or marking of the device, as necessary.
Instructions for use must be included in the packaging for every device. By way of exception, no such instructions for use are needed for devices in Class I or Class IIa if they can be used safely without any such instructions.	It may be impractical and indeed undesirable to include such instructions for use within a sterile package which needs to be opened in order to read them.
13.2 Where appropriate, this information should take the form of symbols. Any symbol or identification colour used must conform to harmonized standards. In areas for which no standards exist, the symbols and colours must be described in the documentation supplied with the device.	Documentation can be the label and/or instructions for use. See **4.1.3**b), requirements, of this standard.
13.3 The label must bear the following particulars:	National regulations may require the information referred to in points 13.3 and 13.6 of annex 1 of the medical device directives to be in their national language(s) or in another Community language when a device reaches the final user, regardless of whether it is for professional or other use (93/42/EEC, article 4, paragraph 4). The use of symbols which conform to harmonized standards will obviate the need to translate certain information.
a) the name or trade name and address of the manufacturer. For devices imported into the Community, in view of their distribution in the Community, the label, or the outer packaging, or instructions for use, shall contain in addition the name and address of either the person responsible referred to in Article 14.2 or of the authorized representative of the manufacturer established within the Community or of the importer established within the Community, as appropriate;	The full postal address may not be necessary provided that the address is of sufficient detail that the manufacturer, or if the device is imported into the community, the person responsible, the authorized representative, or the importer can be contacted, e.g. name or trade name, postcode and country. The trademark or logo may be sufficient in the country of sale to identify the manufacturer.
b) the details strictly necessary for the user to identify the device and the contents of the packaging;	For many devices, the identity will be clearly evident to the intended user. Unpackaged devices or those provided only with transit or storage containers may not require further identification. Transparent packaging may reduce the requirement for detailed descriptions. For more complex devices, the identity of the product can be indicated on the device itself or on the packaging or accompanying information, as appropriate. It may be appropriate to list contents and a quantity.

Information requirements from the Council Directive concerning medical devices given in the essential requirements in annex 1	Guidance
c) where appropriate, the word "STERILE";	The word "sterile" by itself is not a symbol and translation may be required. STERILE as given in EN 980 is a symbol and therefore does not require translation. If the symbol is used, the word "sterile" is not needed. The definition of "sterile" as given in **3.4** of EN 556:1994 applies. The symbol STERILE should be prominent. Where only parts of the device are intended to be sterile, this should be stated e.g. sterile fluid path.
d) where appropriate, the batch code, preceded by the word "LOT", or the serial number;	The word "lot" by itself is not a symbol and translation may be required. LOT as given in EN 980 is a symbol and therefore does not require translation. If the symbol is used the word is not needed. The symbol LOT can be used to identify batch codes or the symbol SN to identify serial numbers.
e) where appropriate, an indication of the date by which the device should be used in safety, expressed as the year and month;	The symbol to identify the "use by" date is given in EN 980. This indicates the last month during which the device is intended to be used. If it is not necessary to give a "use by" date, it may be appropriate to give either the date of manufacture using the symbol given in EN 980, or the date of sterilization, in the form YYYY-MM. The latter may be incorporated in the lot number (e.g. LOT 1991-07 1234).
f) where appropriate, an indication that the device is for single use;	The symbol ISO 7000/1051 for "Do not re-use" is reproduced in EN 980.
g) if the device is custom-made, the words "custom-made device";	National language versions of the Directive also translate the words in quotes.
h) if the device is intended for clinical investigations, the words "exclusively for clinical investigations";	National language versions of the Directive also translate the words in quotes.
i) any special storage and/or handling conditions;	Particulars need only be provided for unusual requirements for storage and handling conditions other than those that would normally be expected by the intended user. Information should also be given if storage or handling conditions are critical for the safe and proper performance of the device. Thus, it would be generally understood without specific labelling that devices should be protected from extremes of temperature, from weather and from electro-magnetic radiation. However, if a device is required to be stored within a particular range of relative humidity and temperature, this should be specifically indicated. Internationally recognized symbols may be used, as appropriate, for storage, handling or transport instructions and hazard warnings (see EN 20780). Normal storage conditions of devices are assumed unless otherwise specified.

Information requirements from the Council Directive concerning medical devices given in the essential requirements in annex 1	**Guidance**
j) any special operating instructions;	The manufacturer should decide the type and level of information required, taking into consideration such factors as the assumed technical and clinical knowledge and skill of the intended user(s) and any novel or unfamiliar features or mode of operation which may not be self-evident. Internationally recognized symbols may be used as appropriate.
k) any warnings and/or precautions to be taken;	Refer as appropriate to risks with which the intended user may not be expected to be familiar and which would not be self-evident. Internationally recognized symbols may be used as appropriate.
l) year of manufacture for active devices other than those covered by e). This indication may be included in the batch or serial number;	If the "use by" date is not given, the year of manufacture should be given in the form of YYYY accompanied by the symbol for the date of manufacture, as given in EN 980, or may be incorporated into the batch number provided that the year of manufacture can be recognized as such e.g. LOT 1991-1234, or in the serial number, e.g. SN 1991-1234.
m) where applicable, the method of sterilization.	This refers to the method of sterilization used by the manufacturer. The appropriate symbol as specified in EN 980 may be used, and it will then not be necessary in addition to use the symbol for "sterile".
13.4 If the intended purpose of the device is not obvious to the user, the manufacturer must clearly state it on the label and in the instructions for use.	For many devices, the intended purpose will be self-evident to the user. Unpackaged devices, or those provided only with transit or storage containers, may not require identification of their intended purpose. Transparent packaging may reduce the requirements for description.
13.5 Wherever reasonable and practicable, the devices and detachable components must be identified, where appropriate in terms of batches, to allow all appropriate action to detect any potential risk posed by the devices and detachable components.	Such identification will facilitate recall of the device. See also **4.1.8**, requirements, of this standard.
13.6 Where appropriate, the instructions for use must contain the following particulars:	National regulations may require the information referred to in sections 13.3 and 13.6 of annex 1 to be in their national language(s) when a device reaches the user, regardless of whether it is for professional or other use (93/42/EEC, article 4, paragraph 4). The use of symbols which conform to harmonized standards will obviate the need to translate certain information.
a) the details referred to in section 13.3, with the exception of d) and e);	The exceptions of d) (batch code) and e) (use by date) are not exhaustive. Section 13.6 makes it clear that the information listed under 13.3 need only be given "where appropriate". It would be neither appropriate nor feasible to include, for example, the date of manufacture [section 13.3l)] in the instructions for use where that date already appears on the label. See the guidance given under this annex, 13.3a), b), c), f), g), h), i), j), k), m) above.

Information requirements from the Council Directive concerning medical devices given in the essential requirements in annex 1	Guidance
b) the performances referred to in section 3 and any undesirable side-effects;	This could take the form of a reference to a relevant published standard which specifies those characteristics.
c) if the device must be installed with or connected to other medical devices or equipment in order to operate as required for its intended purpose, sufficient details of its characteristics to identify the correct devices or equipment to use in order to obtain a safe combination;	Specific information will only be needed about methods of connection or the variety/types of equipment to which the device may properly be connected where these may not be expected to be common knowledge to the intended user, and are not self-evident. Sufficient details of the characteristics (e.g. connections) can be provided by indication of compliance with a relevant published standard which specifies such characteristics.
d) all the information needed to verify whether the device is properly installed and can operate correctly and safely, plus details of the nature and frequency of the maintenance and calibration needed to ensure that the devices operate properly and safely at all times;	This requirement only relates to verification by the user of installation or details of the nature and frequency of maintenance and calibration, rather than the actual steps involved. Information on installation need not be included in the instructions for use supplied to the user, although such information should be separately available if it is not self-evident and it is not intended that installation be done by the manufacturer or his agent.
e) where appropriate, information to avoid certain risks in connection with the implantation of the device;	This clause applies only to the instructions for use for implantable devices, and relates only to risks that are "certain", (i.e. recognized and foreseeable), as opposed to "uncertain" (i.e. unknown and/or improbable). This requirement also only relates to the risks that arise with the process of implantation, rather than those which arise after the device has been implanted. Information is not required about self-evident or trivial risks. As in 13.3j) and 13.3k), any special operating instructions, any warnings and/or recommended precautions should be given. Internationally recognized symbols may be used.
f) information regarding the risks of reciprocal interference posed by the presence of the device during specific investigations or treatment;	
g) the necessary instructions in the event of damage to the sterile packaging and, where appropriate, details of appropriate methods of resterilization;	
h) if the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and, where appropriate, the method of sterilization of the device to be resterilized, and any restriction on the number or reuses. Where devices are supplied with the intention that they be sterilized before use, the instructions for cleaning and sterilization must be such that, if correctly followed, the device will still comply with the requirements in section 1;	This requirement relates only to devices intended by the manufacturer to be reusable. It does not relate to devices which a user may decide to reuse outside the manufacturer's recommendations, e.g. those devices marked as "single use".

Information requirements from the Council Directive concerning medical devices given in the essential requirements in annex 1	**Guidance**
i) details of any further treatment or handling needed before the device can be used (for example, sterilization, final assembly, etc.);	This requirement relates only to cases where the device or its characteristics need to be altered in some way before use (for example, by sterilization, final assembly etc.). It does not require details to be provided for the type of handling which is implicit in normal use, and/or care – e.g., it is not necessary to recommend that a "sterile" device be removed aseptically from its packaging.
j) in the case of devices emitting radiation for medical purposes, details of the nature, type, intensity and distribution of this radiation.	Radiation is not limited to ionizing radiation. Other examples of radiation include heat and laser radiation. See also 89/618/Euratom.
The instructions for use must also include details allowing the medical staff to brief the patient on any contra-indications and any precautions to be taken. These details should cover in particular:	If the information is not necessary to brief the patient it need not be included.
k) precautions to be taken in the event of changes in the performance of the device;	
l) precautions to be taken as regards exposure, in reasonably foreseeable environmental conditions, to magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure, acceleration, thermal ignition sources, etc.;	
m) adequate information regarding the medicinal product or products which the device in question is designed to administer, including any limitations in the choice of substances to be delivered;	
n) precautions to be taken against any special, unusual risks related to the disposal of the device;	
o) medicinal substances incorporated into the device as an integral part in accordance with section 7.4;	INN (International Non-proprietary Names) or other commonly used names should be given.
p) degree of accuracy claimed for devices with a measuring function.	

Annex ZA (informative)

Clauses of this European Standard addressing essential requirements or other provisions of Council Directive 90/385/EEC relating to active implantable medical devices

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 Directive 90/385/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 90/385/EEC.

Compliance with these 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 Directive 90/385/EEC

Clauses of this European Standard	Essential requirements from annex 1 of Council Directive relating to active implantable medical devices (90/385/EEC)
All of this standard	11
	12
	13
	14
	14.1
	14.2
	15

Annex ZB (informative)

Clauses of this European Standard addressing essential requirements or other provisions of Council Directive 93/42/EEC concerning medical devices

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 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 ZB.1, are likely to support requirements of Directive 93/42/EEC.

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

Table ZB.1 — Correspondence between this European Standard and Directive 93/42/EEC

Clauses of this European Standard	Essential requirements from annex 1 of Council Directive concerning medical devices (93/42/EEC)
All of this standard	8.7
	9.1
	10.3
	11.4.1
	12.9
	13
	13.1
	13.2
	13.3
	13.4
	13.5
	13.6

BS EN 1041:1998

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