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EUROPÄISCHE NORM

EN 1041:2008+A1

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English version

Information supplied by the manufacturer of medical devices

Informations fournies par le fabricant de dispositifs médicaux

Bereitstellung von Informationen durch den Hersteller von Medizinprodukten

This European Standard was approved by CEN on 4 July 2008 and includes Amendment 1 approved by CEN on 11 July 2013.

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Foreword

This document (EN 1041:2008+A1:2013) has been prepared by Technical Committee CEN/CLC/TC 3 “Quality management and corresponding general aspects for medical devices”, the secretariat of which is held by NEN.

This European Standard ⟨A1⟩ *deleted text* ⟨A1⟩ shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by March 2014 and conflicting national standards shall be withdrawn at the latest by March 2014.

⟨A1⟩ Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights. ⟨A1⟩

This document includes Amendment 1 approved by CEN on 11 July 2013.

This document supersedes ⟨A1⟩ EN 1041:2008 ⟨A1⟩.

The start and finish of text introduced or altered by amendment is indicated in the text by tags ⟨A1⟩ ⟨A1⟩.

This document 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 93/42/EEC and 90/385/EEC, as amended, with the exception of 3.3 and Annex B.

Annex A provides practical guidance about the implementation of the essential requirements of the applicable Directives.

For relationship with EU Directives, see informative Annexes ZA and ZB, which are integral parts of this document.

According to the CEN/CENELEC Internal Regulations, the national standards organisations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Introduction

The first edition of this standard was drafted in a period when the Active Implantable Medical Device Directive (AIMDD) (90/385/EEC) and the Medical Device Directive (MDD) (93/42/EEC) were relatively new and the In Vitro Diagnostic Medical Device Directive (IVDD) (98/79/EEC) was not in existence. In addition, at the time the previous edition of this standard was adopted, the established method of providing information on, with, or otherwise in association with a device was by hard copy. Predominantly, this was printed copy on substrates such as paper, card, or plastic.

Since the time of approval of the first edition of this standard on 18 January 1998, the MDD and AIMDD have been amended. In addition, other methods of provision of information have become freely available and widely used.

The intention of this second edition is to make available guidance for manufacturers of medical devices that is appropriate regardless of the means used to disseminate that information as well as to update the requirements to reflect the changes to Directives 90/385/EEC and 93/42/EEC. In this standard, Directives 90/385/EEC and 93/42/EEC refer to the versions amended in 2007. The guidance reflects the desire to take into account different methods of provision of information, and it is intended that it should, as far as possible, be suitable for future methods of provision of information.

The requirements and guidance will provide manufacturers with appropriate means to ensure that their provision of information is relevant to all intended recipients and is in compliance with the Essential Requirements of the Directives. The requirements may also provide means by which compliance can be tested by regulatory and inspection agencies.

The possibility of providing information by alternative means is foreseen in Directives 93/42/EEC and 90/385/EEC. Annex B provides guidance on alternative labelling.

1 Scope

This [A1] European Standard [A1] specifies requirements for information to be supplied by a manufacturer for medical devices regulated by Council Directive 90/385/EEC relating to active implantable medical devices and Council Directive 93/42/EEC concerning medical devices. It does not specify the language to be used for such information, nor does it specify the means by which the information is to be supplied. It is also intended to complement the specific requirements of the cited EU Directives on medical devices by providing guidance on means by which certain requirements can be met. If a manufacturer follows these means, they will provide a presumption of conformity with the relevant Essential Requirements regarding information to be supplied.

This standard does not cover requirements for provision of information for in vitro diagnostic medical devices, which are covered by other labelling standards (see Bibliography).

NOTE When national transpositions of the Directives specify the means by which information shall be supplied, this standard does not provide derogation from these requirements for that country.

2 Normative references

[A1] The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies. [A1]

[A1] *deleted text* [A1]

EN ISO 3166-1,[A1] [1)] [A1] *Codes for the representation of names of countries and their subdivisions — Part 1: Country codes (ISO 3166-1:2006)*

ISO 639-1, *Codes for the representation of names of languages — Part 1: Alpha-2 Code*

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

ISO 8601, *Data elements and interchange formats — Information interchange — Representation of dates and times*

CEN/TR 15133, *Nomenclature — Collective terms and codes for groups of medical devices*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
batch; lot
defined amount of material or a number of devices, including finished product and accessories, that is processed in one process or a series of related processes

NOTE The defined amount of material or number of devices will normally be associated with a unique statement of conformity to a defined quality specification.

[A1]

1) EN ISO 3166-1 is currently impacted by the corrigendum EN ISO 3166-1:2006/AC:2008, *Codes for the representation of names of countries and their subdivisions — Part 1: Country codes (ISO 3166-1:2006/Cor 1:2007)*. [A1]

3.2
batch code; lot number; batch number; lot code
unique identifier associated with a single batch or lot (see 3.1)

3.3
alternative labelling
any form of electronically accessible information supplied by the manufacturer (see 3.4) related to a medical device such as CD/DVD-ROM, Internet or other mode

3.4
information supplied by the manufacturer
all material, however provided, relating to the identification, technical description and use of a medical device that is intended to ensure the safe, effective and compliant use of the device

NOTE Shipping documents and promotional material are excluded from this definition when identification, technical description and use of a medical device are not intended to ensure the safe, effective and compliant use of the device.

3.5
medical device
any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and 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

[Council Directive concerning medical devices (93/42/EEC), Article 1, paragraph 2 (a)]

3.6
user
any person, legal or natural, for whom the information supplied (see 3.4) is intended

4 Requirements

4.1 General

Product information and labelling shall be part of risk management procedures.

NOTE 1 Due consideration should be given to the guidance provided in Annex A.

NOTE 2 Product-related standards may require additional information to be supplied.

4.2 Units, symbols and colours

Units used shall be SI units as specified in ISO 1000 or any other legal units.

[A1] Symbols and safety-related identification colours shall be explained in the information supplied unless they are taken from harmonised standards. [A1]

4.3 Language and country identifiers

If the manufacturer decides to identify the language used in the information provided, for example to indicate to users the appropriate language in a multilingual document, this shall be done using the language codes given in ISO 639-1 and/or the plain text of the language (e.g. “English”).

If the manufacturer decides to identify the country in the information provided, for example to indicate to users the appropriate customer service contact details for their country, this shall be done using the country codes given in EN ISO 3166-1 and/or the plain name of the country (e.g. “France”).

4.4 Dates

Any human-readable date shall be expressed in the format YYYY-MM-DD, YYYY-MM or YYYY, in accordance with ISO 8601.

NOTE The choice of format will be determined by the requirements of the relevant Directives and the specific nature of the devices concerned.

4.5 Device nomenclature

4.5.1 Identifiers of nomenclature

When it is required to include the identification of the generic device group or the device category in the information supplied with the device, this may be done using a nomenclature that is in compliance with EN ISO 15225.

NOTE For details of nomenclatures claimed to be in compliance with EN ISO 15225, see the Bibliography.

4.5.2 Device common terms

When it is appropriate to identify collective terms for medical devices in the information supplied, for example common technology or common materials of construction, this shall be done using the terms and codes set out in CEN/TR 15133.

4.5.3 Batch code; lot number; batch number; lot code

These shall consist of alphanumeric characters but may also be presented by other means, for example by using machine-readable codes.

5 Requirements for provision of information

5.1 General

5.1.1 ▌A1⟩ Safe and effective use of the device ⟨A1▐

Any means of provision of information with medical devices shall take into account the intended users, the conditions of use and any issues specific to individual device types that are necessary for the safe and effective use of the device. This shall apply regardless of whether the specific requirements listed below apply to the device.

The appropriate way of providing information shall be based on a risk assessment and in line with the training, experience and education of the intended users.

5.1.2 ▌A1⟩ Address required under medical devices directives

All medical devices which are placed on the market and put into service within the Community, shall contain the name or trade name and address of the manufacturer in the information supplied by the manufacturer. When the

manufacturer does not have a registered place of business in the Community, the information shall contain in addition the name and address of the authorised representative.

For devices covered by the MDD, the name or the trade name and address of the manufacturer shall appear on the label and in the instruction for use if provided with the device. When the manufacturer does not have a registered place of business in the Community, the label, or the outer packaging, or instructions for use shall contain, in addition, the name and address of the authorised representative.

For devices covered by the AIMDD, the name and address of the manufacturer shall appear on the sterile pack and the sales packaging and in the instruction for use. When the manufacturer does not have a registered place of business in the Community, the sales packaging and the instructions for use shall contain, in addition, the name and address of the authorised representative.

The address to be used shall be the same as the address of the manufacturer and/or the authorised representative as their registered place of business. The address shall be the same as the address used on the declaration of conformity, in relevant certificates and in the European database for medical devices.

The full address used shall contain the following elements insofar as they are available in the address system of the country where the relevant entity (manufacturer or authorised representative) is registered:

— street/road;

— number/house/floor;

— postal code;

— city;

— state/region; and

— country.

The information regarding street/road and number/house/floor may be omitted if a postal code dedicated to the manufacturer (corporate postal code) or authorised representative is used which fully replaces the indication of street/road and number/house/floor, and is not a PO box number. 〈A1▌

5.2 Specific requirements

5.2.1 Applicability

These specific requirements shall be applicable to all devices to the extent that they are applicable to the specific device type concerned and to the means of provision of the relevant information. For example, the requirement to allow for a “use by” date is not applicable to devices that do not bear a “use by” date.

5.2.2 Accessibility

The information presented with a device shall be accessible to intended users taking into account their age, education, knowledge and training.

When appropriate, a specific means of provision may be restricted to users to whom it is particularly applicable.

NOTE This requirement may result in more than one means of provision being necessary.

5.2.3 Legibility

Information intended for visual recognition shall be easily legible when viewed using normal vision, corrected if necessary, taking into account the specific size and conditions of use of the particular device.

5.2.4 Availability

Information shall be available as long as reasonably necessary, taking the lifetime of the device into consideration.

5.2.5 Security

As far as practicably possible, the medium of information provision shall be protected from corruption, degradation and deliberate change by those other than the manufacturer, whether malicious or not.

If the user can readily identify faulty information, for example by virtue of damaged labels, advice on the action to take shall be provided.

Where the damage to information is not readily apparent and/or the consequences of damage are not obvious, guidance shall be provided on how to maintain the security of the information and limit any adverse consequences.

NOTE When appropriate and relevant, manufacturers should consider if there are any preventative measures that can be taken to maintain information security in relation to customer service.

5.2.6 Changes to information provided

Any changes to information provided for existing users shall be clearly communicated if they are important for patient safety.

6 Documentation

Documentation relating to information provided shall be maintained in the technical documentation(s) relating to the device(s) that are the subject of the information. This may take the form of a specific section holding all the documentation or, alternatively, references to parts of a larger document where the information may be found, such as a quality manual.

Annex A
(informative)

Requirements and guidance for Directives 93/42/EEC and 90/385/EEC, as amended

NOTE This annex covers those non-active and active medical devices to which Council Directives 93/42/EEC and 90/385/EEC apply, hereinafter called medical devices.

A.1 Requirements and guidance for medical devices (Directive 93/42/EEC)

NOTE 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 I. The right hand column gives guidance and further explanation, as appropriate. Where no guidance is given, the Essential Requirements are not reproduced below.

Requirements **Information Requirements from the Council Directive concerning Medical Devices given in the Essential Requirements in Annex I**	**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 symbols as given in EN 980 or the word stating this condition. Sterile devices should be prominently labelled by the appropriate symbols as given in EN 980. The definitions of sterile as given in EN 556-1 and EN 556-2 apply. 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.
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 4.2, 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 on 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).
13. Information supplied by the manufacturer	
13.1. Each device must be accompanied by the information needed to use it safely and properly, taking account of the training and knowledge of the potential users, and to identify the manufacturer.	Any information should be made available in a way that is understandable to the intended user and/or patient. For complex equipment a user-friendly guide on how to check and operate the device in an emergency will be of

Requirements **Information Requirements from the Council Directive concerning Medical Devices given in the Essential Requirements in Annex I**	**Guidance**
	benefit in addition to instructions of use.
This information comprises the details on the label and the data in the instructions for use. As far as 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 one or more devices.	When instructions for use are provided by means of a leaflet, the number of leaflets in a multiple pack is determined by the manufacturer, taking into consideration the use of the device. Information may also be provided by electronic means (see Annex B). 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 labelling, 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.	
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 4.2 requirements, of this standard.
13.3. The label must bear the following particulars:	National regulations may require the information referred to in sections 13.3 and 13.6 of Annex I of the medical devices directive 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 that conform to harmonized standards will mean that there is no 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 the authorized representative where the manufacturer does not have a registered place of business in the Community;	The full postal addresses may not be necessary if the information is sufficient to contact them, e.g., name or trade name, post code, country. However, the address needs to be sufficient to contact the physical location of the manufacturer and/or the authorized representative, if applicable. The post box alone is not sufficient.
(b) the details strictly necessary to identify the device and the contents of the packaging especially for the users;	For many devices, the identity will be clearly evident to the intended user. Unpackaged devices, devices with transparent packaging or those provided only with transit or storage containers may not require further identification. For more complex devices, the identity of the product can be indicated on the device itself or on the packaging or instructions for use, as appropriate. It may be appropriate to list contents and quantity,

Requirements Information Requirements from the Council Directive concerning Medical Devices given in the Essential Requirements in Annex I	Guidance
	especially for the users.
(c) where appropriate, the word "STERILE";	The word “sterile” by itself is not a symbol and translation may be required. Instead STERILE as given in EN 980 is a symbol and therefore does not require translation. The method of sterilization should also be given, if appropriate, by using the proper symbols. The definitions of “sterile” as given in EN 556-1 and EN 556-2 apply. 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. The symbol LOT can be used to identify batch codes and 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 the date of manufacture using the symbol given in EN 980 in the form YYYY-MM. The latter may be incorporated in the lot number (e.g. LOT 2006-07 1234).
(f) where appropriate, an indication that the device is for single use. A manufacturer's indication of single use must be consistent across the Community;	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

Requirements **Information Requirements from the Council Directive concerning Medical Devices given in the Essential Requirements in Annex I**	**Guidance**
	instructions and hazard warnings (see EN ISO 780). Normal storage conditions of devices are assumed unless otherwise specified.
(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), particularly for patients at home or undergoing self-treatment, and any novel or unfamiliar features or mode of operation that may not be self-evident. Internationally recognized symbols may be used as appropriate.
(k) any warnings and/or precautions to take;	Refer as appropriate to risks with which the intended user may not be expected to be familiar and that 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 2006-1234, or in the serial number, e.g. SN 2006-1234.
(m) where applicable, 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.
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. Any detachable component should be identified by its batch code or by other appropriate means.
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 I 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, clause 4, paragraph 4). The use of symbols that conform to harmonized standards will mean that there is no 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".

Requirements Information Requirements from the Council Directive concerning Medical Devices given in the Essential Requirements in Annex I	Guidance
	It would be neither appropriate nor feasible to include, for example, the date of manufacture (section 13.3 l) in the instructions for use where that date already appears on the label. See the guidance given under this annex, 13.3 a), b), c), f), g), h), i), j), k), m) above.
(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 that 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 when 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 that 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 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 that arise after the device has been implanted. Information is not required about self-evident or trivial risks. As in 13.3 j) and 13.3 k), any special operating instructions, any warnings and/or recommended precautions should be given, taking into consideration such factors as the assumed technical knowledge and skill of the intended user. Internationally recognised symbols may be used.
(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 I;	This requirement relates only to devices intended by the manufacturer to be reusable. It does not relate to devices that a user may decide to reuse outside the manufacturer's recommendations, e.g., those devices marked as "single use". When the device is resterilizable, EN ISO 17664 may be used.

Requirements **Information Requirements from the Council Directive concerning Medical Devices given in the Essential Requirements in Annex I**	**Guidance**
If the device bears an indication that the device is for single use, information on known characteristics and technical factors known to the manufacturer that could pose a risk if the device would be re-used. If in accordance with Section 13.1 no instructions for use are needed, the information must be made available to the user upon request.	This information should be an output of the risk assessment process.
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. 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:	Radiation is not limited to ionizing radiation. Other examples of radiation include microwave and laser radiation. See also 89/618/Euratom. Guidance should be provided so that the physician is able to brief the patient on contra-indications and identified risks related to the device. These risks might come from advances in current technology and, in particular, environmental considerations that may have an effect on the performance of the device. The outcome of the manufacturer's risk management process (in accordance with EN ISO 14971) should be used to determine such warnings and recommendations. If the information is not necessary to brief the patient it need not be included.
(o) medicinal substances or human blood derivates 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.

A.2 Requirements and guidance for active implantable medical devices (Directive 90/385/EEC)

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 I. The right hand column gives guidance and further explanation as appropriate. Where no guidance is given, the Essential Requirements are not reproduced below.

Requirements Information Requirements from the Council Directive relating to Active Implantable Medical Devices given in the Essential Requirements in Annex I	**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 to making a copy available to be 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 4.2 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.
- an indication permitting this packaging to be recognized as such,	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.
- the name and address of the manufacturer,	Name, or trade name, and an address to allow 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, post code 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

Requirements Information Requirements from the Council Directive relating to Active Implantable Medical Devices given in the Essential Requirements in Annex I	Guidance
	can be indicated on the device itself or on the packaging or instructions for use, as appropriate. It may be appropriate to list contents and a quantity.
- 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. The definitions of sterile as given in EN 556-1 and EN 556-2 apply.
- 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〚A1〛 2) 〚A1〛	The sales packaging may also be the storage packaging.
- the name and address of the manufacturer and the name and address of the authorized representative, where the manufacturer does not have a registered place of business in the Community,	Name, or trade name, and an address to allow the manufacturer or the authorized representative to be contacted. The full postal address may not be necessary if the information is sufficient to contact them, e.g., name or trade name, post code, country. However, the address needs to be sufficient to contact the physical location of the manufacturer and/or the authorised representative, if applicable. The post box alone is not sufficient.
- the purpose of the device,	This information may be given in an abbreviated form provided that full details are given in the instructions for use. If not obvious from device description, additional information and relevant characteristics should be included, as necessary, to completely identify the device.
- 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

〚A1〛 2) 〚A1〛 Where the requirement and guidance is the same in 14.1 as in 14.2, the text has not been reproduced in 14.2.

Requirements Information Requirements from the Council Directive relating to Active Implantable Medical Devices given in the Essential Requirements in Annex I	**Guidance**
	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 ISO 780). Normal storage conditions of devices are assumed unless specified.
15. When placed on the market, each device must be accompanied by instructions for use giving the following particulars:	
- the year of authorization to affix the CE mark,	The year of authorization should be adjacent to the CE mark
- details referred to in 14.1 and 14.2 with the exception of (*the use before date and the month and year of manufacture*, *and an indication of the time limit for implanting a device safely*),	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, if appropriate, certain risks in connection with implantation of the device to be avoided,	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 that arise after the device has been implanted. Information is not required about self-evident or trivial risks. Any special operating instructions, any warnings and/or recommended precautions should be given, taking into consideration such factors as the assumed technical knowledge and skill of the intended user. Internationally recognised symbols may be used.
- 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.
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:	Guidance should be provided so that the physician is able to brief the patient on contra-indications and identified risks related to the implantable device. These risks might come from advances in current technology and, in particular, environmental considerations that may have an effect on the performance of the implant. The outcome of the manufacturer's risk management process (in accordance with EN ISO 14971) should be used to determine such warnings and recommendations.
- information allowing the lifetime of the energy source	

Requirements Information Requirements from the Council Directive relating to Active Implantable Medical Devices given in the Essential Requirements in Annex I	Guidance
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, acceleration, etc.,	
- adequate information regarding the medicinal products which the device in question is designed to administer,	
Date of issue or the latest revision of the instruction for use.	

Annex B
(informative)

Guidance on alternative labelling for instructions for use (IFU)

Directives 93/42/EEC and 90/385/EEC foresee the possibility that, in the light of technical progress, the information laid down in Annex I, Section 13.1 of the Directive 93/42/EEC and Annex I, Section 15 of the Directive 90/385/EEC may be provided by alternative means in the future. In such circumstances, approval is necessary as described in the regulatory procedure referred to in Article 7(2a) of the Directive 93/42/EEC or Article 9 (10) of the Directive 90/385/EEC.

If alternative labelling is approved, manufacturers should consider the following:

The information provided with a medical device is intended to permit the device to be used safely and for the purposes intended by the manufacturer. This information comprises the details on the label and the data in the instructions for use (IFU). When appropriate for a particular device, e.g., for professional users, the IFU can be provided by alternative means. Examples of ways of delivering alternative labelling include, but are not limited to, physical electronic media such as CD/DVD-ROMs packaged with the device, "help" systems provided with the device, and information delivered over the Internet.

The manufacturer should consider the following questions in the risk analysis:

1) How knowledgeable and experienced is the intended user with the hardware and software needed to display the contents of the alternative labelling?

2) Does the intended user of the medical device have access to the resources (e.g., personal computers connected to the Internet) needed to utilize alternative labelling?

3) If the content of the alternative labelling is to be displayed on the device itself, what information is required in case of a problem with the device that would prevent the contents of the alternative labelling being displayed (e.g., a hardware or software fault)?

4) Are there back-up systems for providing physical labelling when needed or preferred?

B.1 Guidance on alternative labelling for medical devices (Directive 93/42/EEC)

Requirements	Guidance
Medical Device Directive; MDD, 93/42/EEC. 13.1. Each device must be accompanied by the information needed to use it safely and properly, taking account of the training and knowledge of the potential users and to identify the manufacturer. This information comprises the details on the label and the data in the instructions for use. As far as 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 and supplied with one or more devices. 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 IIa if they can be used safely without any such instructions.	The content of the alternative labelling should satisfy all relevant requirements of the MDD. The means for providing information with a device, e.g., by paper, electronically, or a combination of both, should be indicated on or with the package (e.g., on the label or insert). If information is provided electronically, the electronic format and means of access (e.g., web address) should also be indicated. The contents of the alternative labelling should be easy to read on the display device or devices where it is intended to be displayed. The alternative labelling should be organized to enable the user to search for and find critical information quickly. The manufacturer should provide a paper manual promptly and at no charge to any user who requests it. If the alternative labelling is provided on physical media such as CD/DVD-ROM, it should bear all the information necessary for the version of the IFU and the software required. If alternative labelling is provided via Internet: - the user should be able to identify the correct version of the labelling that matches their device; - adequate physical and access security should be provided to ensure a highly resilient service environment with minimal downtime; - the manufacturer should ensure that the alternative labelling on the Internet is current and accurate.

B.2 Guidance on alternative labelling for active implantable medical devices (Directive 90/385/EEC)

Requirements	Guidance
Active Implantable Medical Device Directive (AIMDD), 90/385/EEC 15. When placed on the market, each device must be "accompanied" by instructions for safe use The instruction "leaflet" must also include details allowing the physician to brief the patient on the contra-indications and the precautions to be taken.	The content of the alternative labelling should satisfy all relevant requirements of the AIMDD. The means for providing information with a device, e.g., by paper, electronically, or a combination of both, should be indicated on or with the package (e.g., on the label or insert). If information is provided electronically, the electronic format and means of access (e.g., web address) should also be indicated. The contents of the alternative labelling should be easy to read on the display device or devices where it is intended to be displayed. The alternative labelling should be organized to enable the user to search for and find critical information quickly. The manufacturer should provide a paper manual promptly and at no charge to any user who requests it. If the alternative labelling is provided on physical media such as CD/DVD-ROM, it should bear all the information necessary for the version of the IFU and the software required. If alternative labelling is provided via Internet: - the user should be able to identify the correct version of the labelling that matches their device; - adequate physical and access security should be provided to ensure a highly resilient service environment with minimal downtime; - the manufacturer should ensure that the alternative labelling on the Internet is current and accurate.

Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EC

〈A1〉 NOTE Annexes ZA and ZB:

A recent analysis has shown that, in order to cover the essential requirements of the directives, the manufacturer has to go through Annex A of the standard and make sure that the legal requirements are fulfilled. Since Annex A is an informative annex, it was not included in the current Annexes Z, which now thus appears to be incomplete.

Furthermore, several discrepancies between the content of the Annex A and the requirements of the first Annex of each of the medical devices directives have been noted and need to be remedied. In order to solve these issues, a full revision of the standard will be started directly after publication of this amendment. The standard should, in the meantime, not be used as a means for assuring compliance with requirements of the medical devices directives. Instead the requirements of the directives should be applied directly. 〈A1〉

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide one means of conforming to Essential Requirements of the New Approach Directive 93/42/EC on medical devices.

Once this standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

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

Clause(s)/sub-clause(s) of this European Standard	Essential requirements from Annex I of the Council Directive concerning Medical Devices (93/42/EEC)	Qualifying remarks/Notes
All of this standard, with the exception of 3.3 and Annex B	8.7	Directive 93/42/EEC should be consulted for a comprehensive list of the information required.
	9.1	
	10.3	
	11.4.1	
	12.9	
	13	
	13.1	
	13.2	
	13.3	
	13.4	
	13.5	
	13.6	

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

Annex ZB
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 90/385/EC

〈A1〉 NOTE Annexes ZA and ZB:

A recent analysis has shown that, in order to cover the essential requirements of the directives, the manufacturer has to go through Annex A of the standard and make sure that the legal requirements are fulfilled. Since Annex A is an informative annex, it was not included in the current Annexes Z, which now thus appears to be incomplete.

Furthermore, several discrepancies between the content of the Annex A and the requirements of the first Annex of each of the medical devices directives have been noted and need to be remedied. In order to solve these issues, a full revision of the standard will be started directly after publication of this amendment. The standard should, in the meantime, not be used as a means for assuring compliance with requirements of the medical devices directives. Instead the requirements of the directives should be applied directly. 〈A1〉

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide one means of conforming to Essential Requirements of the New Approach Directive 90/385/EC on medical devices.

Once this standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this standard given in Table ZB.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZB.1 — Correspondence between this European Standard and Directive 90/385/EEC

Clause(s)/sub-clauses of this European Standard	Essential requirements from Annex I of Council Directive concerning Active Implantable Medical Devices (90/385/EEC)	Qualifying remarks/Notes
All of this standard, with the exception of 3.3 and Annex B	11	Directive 90/385/EEC should be consulted for a comprehensive list of the information required.
	12	
	13	
	14	
	14.1	
	14.2	
	15	

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

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A1

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A1

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