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English version

Symbol for use in the labelling of medical devices - Requirements for labelling of medical devices containing phthalates

Symbole à utiliser pour l'étiquetage des dispositifs médicaux - Exigences relatives à l'étiquetage des dispositifs médicaux contenant des phtalates

Symbol zur Kennzeichnung von Medizinprodukten - Anforderungen zur Kennzeichnung von phthalathaltigen Medizinprodukten

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CEN Management Centre:
Avenue Marnix 17, B-1000 Brussels

CENELEC Central Secretariat:
Avenue Marnix 17, B-1000 Brussels

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Foreword

This document (EN 15986:2011) has been prepared by Technical Committee CEN/CENELEC/TC 3 “Quality management and corresponding general aspects for medical devices”, the secretariat of which is held by NEN.

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of an identical text or by endorsement, at the latest by September 2011, and conflicting national standards shall be withdrawn at the latest by September 2011.

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 Directive 93/42/EEC.

For relationship with EU Directive 93/42/EEC, see informative Annex ZA, which is an integral part of this document.

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.

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

Introduction

This European Standard has been prepared to give expression to the legislative preference within the European Union for the use of symbols to provide information for the safe use of medical devices, and to the legislative requirement for labelling to show the presence of certain phthalates in medical devices.

This European Standard contains requirements for the labelling of medical devices or parts of medical devices containing phthalates requiring labelling, as required by the consolidated Medical Devices Directive 93/42/EEC, as amended by Directive 2007/47/EC.

Labelling of medical devices or parts of medical devices containing particular phthalates is required because some have been classified as CMR 1 & 2, i.e. they could exhibit carcinogenic, mutagenic or reprotoxic/developmental effects. Not all the reproductive and developmental toxicity of phthalates to the human body have been confirmed. However, it has recently been suggested that precautions be taken to limit the exposure of humans particularly that of high risk patient groups.

Phthalates have been extensively used as plasticizers due to the increased flexibility they impart to polyvinyl chloride (PVC), a plastic polymer used in a wide array of products including medical devices.

From a user's point of view, a symbol conveys information in order that the user may assess the suitability of the medical device in order to mitigate risks to the patient. Due to the fact a number of phthalates with known and unknown biological effects exists on the market this European Standard includes only one symbol for medical devices “containing particular phthalates”. The requirements in the consolidated Medical Devices Directive 93/42/EEC, as amended by Directive 2007/47/EC define which medical devices containing phthalates have to be marked with the symbol. When the user has been informed that the product contains those particular phthalates precautionary actions can be found in the instruction for use.

Annex B provides information about the use of the general prohibition symbol.

1 Scope

This European Standard specifies requirements for the labelling of a medical device or parts of a medical device to indicate the presence of phthalates, when required by Annex I of Directive 93/42/EEC Section 7.5, 2nd paragraph. This specifically includes the format of a symbol to be used in the labelling. This European Standard does not specify the requirements for information to be supplied with medical devices, which are addressed by EN 980 and EN 1041.

This European Standard does not specify the requirements of the 1st and of the 3rd paragraphs of Essential Requirement 7.5.

2 Terms and definitions

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

2.1
symbol for use in the labelling of medical devices
object presented on the label and/or on the device itself and/or associated documentation of a medical device, which may utilise symbolic or iconic presentation, that communicates characteristic information without relying on knowledge of the language of a particular nation or people by the giver or receiver of the information

2.2
symbolic presentation
abstract pictorial or graphic representation

[EN 980:2008]

2.3
iconic presentation
pictorial or graphic representation using familiar objects including alphanumeric characters

[EN 980:2008]

2.4
characteristic information
mental representation of a property or properties of an object or set of objects

[EN 12264:2005]

3 Requirements for usage

3.1 If phthalates which are classified as carcinogenic, mutagenic or toxic to reproduction of category 1 or 2 in accordance with table 3.2 of Annex VI of Regulation (EC) No 1272/2008, are part of the formulation and the medical device is:

I) intended to administer and/or remove medicines, or

II) intended to administer and/or remove body liquids, or

III) intended to administer and/or remove other substances to or from the body, or

IV) intended for transport and storage of such body fluids or substances,

the symbol in 4.2 shall be marked on the medical device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging.

NOTE 1 The requirements to label medical devices and for specific patient groups can be found in Directive 93/42/EEC, Annex I, Section 7.5.

NOTE 2 Directive 93/42/EEC Annex I, Section 7.5 refers to Directive 67/548/EEC. Directive 67/548/EEC has been amended and repealed by Regulation (EC) No 1272/2008 of 16 December 2008, therefore this European Standard refers to Regulation (EC) No 1272/2008.

NOTE 3 The term “substances” encompasses “gases”.

3.2 The meaning of the symbol in 4.2 shall be explained in the information supplied by the manufacturer.

4 Symbol labelling phthalates

4.1 General

This clause contains a symbol that neither has been published in previous editions of the European Standard EN 980 nor the ISO standard ISO 15223-1 and may be new or unfamiliar to users.

4.2 Symbol for “CONTAINS OR PRESENCE OF PHTHALATE”

Figure 1 — Symbol for "CONTAINS OR PRESENCE OF PHTHALATE"

This symbol shall be accompanied by the abbreviated designation of the particular phthalate(s) used. The particular phthalate(s) designation shall be located adjacent to the symbol.

NOTE 1 Phthalates that require labelling by Annex I of Directive 93/42/EEC Section 7.5 are specified in table 3.2 of Annex VI of Regulation (EC) No 1272/2008. Correct abbreviated designations of the particular phthalate(s) used are available at the European Commission Joint Research centre. Institute for Health and Costumer Protection (<http://ecb.jrc.ec.europa.eu/esis/>).

NOTE 2 See Annex A for examples for particular phthalates: DEHP; DBP and BBP.

NOTE 3 The relative sizes of the symbol and the particular phthalates used are not specified.

NOTE 4 This symbol is derived from ISO 7000-2725 (“Contains or presence of”).

Annex A
(informative)

Examples of uses of the symbol given in this European Standard

A.1 General

NOTE These examples are illustrative only and do not represent the only ways in which the requirements of this European Standard can be met.

A.2 Examples of use of the symbol for "contains or presence of phthalate": bis (2-ethylhexyl) phthalate (DEHP)

Figure A.1 — Example of the symbol for "CONTAINS OR PRESENCE OF PHTHALATE"

Figure A.2 — Example of the symbol for "CONTAINS OR PRESENCE OF PHTHALATE"

A.3 Examples of use of the symbol for "contains or presence of phthalate": dibutyl phthalate (DBP)

Figure A.3 — Example of the symbol for "CONTAINS OR PRESENCE OF PHTHALATE"

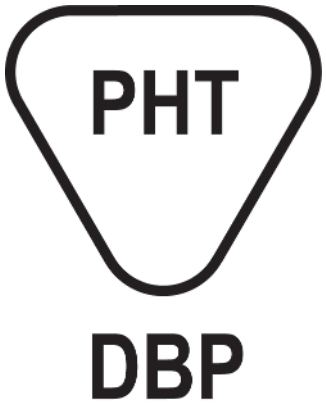

Figure A.4 — Example of the symbol for "CONTAINS OR PRESENCE OF PHTHALATE"

A.4 Examples of use of the symbol for "contains or presence of phthalate": benzyl butyl phthalate (BBP)

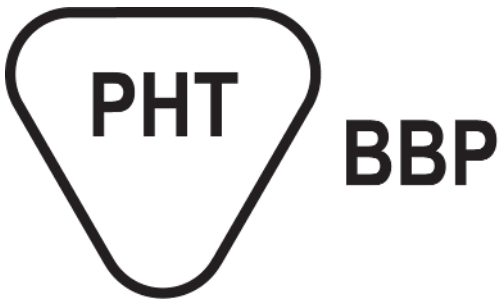

Figure A.5 — Example of the symbol for "CONTAINS OR PRESENCE OF PHTHALATE"

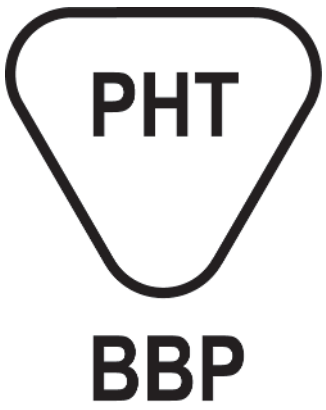

Figure A.6 — Example of the symbol for "CONTAINS OR PRESENCE OF PHTHALATE"

A.5 Examples of use of symbol for "contains or presence of phthalate": combination of bis (2-ethylhexyl) phthalate (DEHP); benzyl butyl phthalate (BBP) and dibutyl phthalate (DBP)

Figure A.7 — Example of the symbol for "CONTAINS OR PRESENCE OF PHTHALATE"

Annex B
(informative)

Use of the negation symbol

Manufacturers wishing to communicate the meaning “does not” or “is not” where a symbol expressing this meaning does not exist, should follow the method set out in EN 80416-3:2002, Clause 7 (for the ‘negation symbol’, a large ‘X’ placed over the symbol). Although it is not generally recommended to use this symbology with the symbol given in this European Standard, the use of the negation symbol is permitted.

Annex ZA
(informative)

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

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC 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)/subclauses of this EN	Essential Requirements (ERs) of the Directive 93/42/EEC	Qualifying remarks
This standard	7.5	Within the limits of the scope of this standard.

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

Bibliography

[1] 93/42/EEC, *Council Directive on the approximation of the laws of the Member States relating to medical devices*. Council of European Communities (OJ No L 169, 12.7.1993, p.1-43), as amended in 2007

[2] 67/548/EEC, *Council Directive on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances*

[3] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (Text with EEA relevance)

[4] ISO 7000, *Graphical symbols for use on equipment — Index and synopsis*

[5] EN 12264:2005, *Health informatics — Categorial structures for systems of concepts*

[6] prEN ISO 15223-1:2009, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements (ISO/DIS 15223-1:2009)*

[7] EN 80416-3:2002, *Basic principles for graphical symbols for use on equipment — Part 3: Guidelines for the application of graphical symbols (IEC 80416-3:2002)*

[8] EN 980:2008, *Symbols for use in the labelling of medical devices*

[9] ISO 15223-1:2007, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

[10] EN 1041, *Information supplied by the manufacturer of medical devices*

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