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**Simboli za označevanje medicinskih pripomočkov - Zahteve za označevanje medicinskih pripomočkov, ki vsebujejo ftalate**

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

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

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

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**Ta slovenski standard je istoveten z: EN 15986:2011**

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**ICS:**

01.080.20	Grafični simboli za posebno opremo	Graphical symbols for use on specific equipment
11.040.01	Medicinska oprema na splošno	Medical equipment in general

**SIST EN 15986:2011**

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EUROPEAN STANDARD

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## 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

This European Standard was approved by CEN on 22 January 2011.

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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 and CENELEC member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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of an identical text or by endorsement, at the latest by September 2011, and conflicting national standards shall be withdrawn at the latest by September 2011.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

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## 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, 2<sup>nd</sup> 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 1<sup>st</sup> and of the 3<sup>rd</sup> 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,

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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".

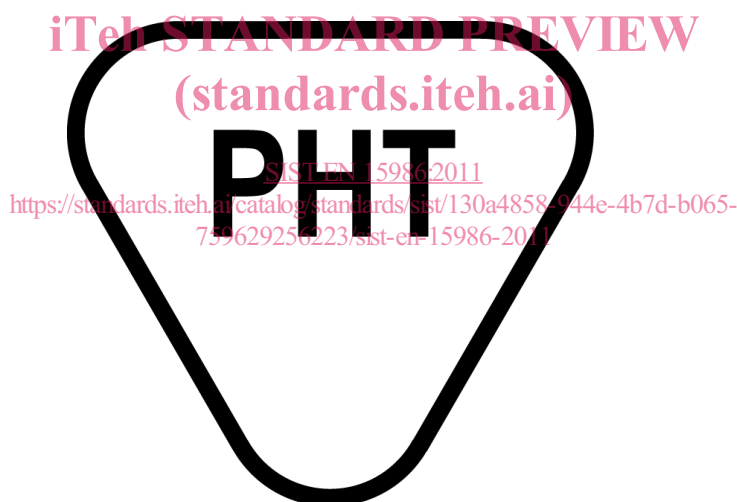
3.2 The meaning of the symbol in 4.2 shall be explained in the information supplied by the manufacturer.

## 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"