Meditsiiniseadmete märgistamiseks kasutatav sümbol. Ftalaate sisaldavate meditsiiniseadmete märgistusnõuded

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

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN 15986:2011 sisaldab Euroopa standardi EN 15986:2011 ingliskeelset teksti.	This Estonian standard EVS-EN 15986:2011 consists of the English text of the European standard EN 15986:2011.
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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

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

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of an identical text or by endorsement, at the latest by September 2011, and conflicting national standards shall be withdrawn at the latest by September 2011.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

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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, 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,