EESTI STANDARD EVS-EN ISO 6009:1999

Nahaalusteks süsteteks mõeldud ühekordselt kasutatavad nõelad. Identifitseerimiseks kasutatav värvuskodeerimine

Hypodermic needles for single use - Colour coding for identification

EESTI STANDARDIKESKUS

EESTI STANDARDI EESSÕNA **NATIONAL FOREWORD**

Käesolev Eesti standard EVS-EN ISO 6009:1999 sisaldab Euroopa standardi EN ISO 6009:1994 ingliskeelset teksti. Käesolev dokument on jõustatud 12.12.1999 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes. Standard on kättesaadav Eesti standardiorganisatsioonist.	This Estonian standard EVS-EN ISO 6009:1999 consists of the English text of the European standard EN ISO 6009:1994. This document is endorsed on 12.12.1999 with the notification being published in the official publication of the Estonian national standardisation organisation. The standard is available from Estonian standardisation organisation.

Käsitlusala: Standard kehtestab värvuskoodi ühekordselt kasutatavate nahaalusteks süsteteks mõeldud nõelte, mille välisdiameeter jääb vahemikku 0,3 – 3,4 mm, identifitseerimiseks. Standard on kohaldatav normaalpaksusega, õhukese ja üliõhukese seinaga nõeltele ning läbipaistmatutele ja poolläbipaistvatele värvidele.	**Scope:**

ICS 11.040.20

Võtmesõnad: identifitseerimismeetodid, meditsiiniaparatuur, nahaalusteks süsteteks mõeldud nõelad, värvuskoodid, värvusmarkeering

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 6009

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Descriptors: Medical equipment, hypodermic needle, single-use article, colour code.

English version

Hypodermic needles for single use

Colour coding for identification
(ISO 6009:1992)

Aiguilles hypodermiques non réutilisables; code de couleurs pour l'identification (ISO 6009:1992)

Medizinische Einmalkanülen; Farbcodierung zur Identifizierung (ISO 6009:1992)

This European Standard was approved by CEN on 1994-07-27 and is identical to the ISO Standard as referred to.

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, 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

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Foreword

International Standard

ISO 6009:1992 Hypodermic needles for single use; colour coding for identification

has been taken over by Technical Committee CEN/TC 205 'Non-active medical devices' from the work of ISO/TC 84 'Medical devices for injections' of the International Organization for Standardization.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, and conflicting national standards withdrawn, by January 1995 at the latest.

In accordance with the CEN/CENELEC Internal Regulations, the following countries are bound to implement this European Standard:

Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

Endorsement notice

The text of the International Standard ISO 6009:1992 was approved by CEN as a European Standard without any modification.

Introduction

The intention of this International Standard is to specify colours to enable rapid visual identification of the outside diameter of single-use hypodermic needles. The presence of colour coding on a needle or package does not absolve the user of the responsibility to check the marked size of the needle.

The colours used to code needles may be applied in either opaque or transparent form, and the colour code is equally applicable to normal-walled, thin-walled and extra-thin-walled needles. The nominal outside diameters of needles listed in this International Standard for which colours are given are those specified in ISO 9626. This does not imply that hypodermic needles of all the listed nominal outside diameters are currently manufactured.

This International Standard establishes a colour code but does not specify that needles are to be colour-coded or to what portion of the needle and/or packaging the colour is to be applied. Such requirements may be given in the relevant product standards such as ISO 7864.

The Technical Committee responsible for the preparation of this International Standard has reviewed the use of instrumentally determined colour zones (chromaticity and luminance index) as used in previous editions to specify opaque colours and has decided that instrumental measurement is not practicable. The measurement of the colour zone of an opaque colour, especially of an item of the size and shape of the hub of a needle, is a complex procedure requiring apparatus and expertise that is to be found in relatively few laboratories and test houses. It may therefore be inconvenient, difficult or impossible for a manufacturer or purchaser routinely to assess compliance of a product with colour zone values. Such difficulties are compounded in the case of translucent colours, which are being used increasingly by needle manufacturers to allow air bubbles inside the hub to be seen and eliminated before injection.

As a consequence, the colours in this International Standard are specified by name, accepting that this inevitably introduces a certain amount of subjectivity in the assessment of compliance. This subjectivity may be minimized by viewing the hubs under controlled lighting conditions (e.g. "daylight" (D_{65}) illumination at 1 000 lx to 1 500 lx) and by the use of assessors of medically-demonstrated correct colour vision. Visual comparison of the colour of a product with a reference colour sample is simple and quick, and is therefore a useful routine method of product assessment. Accordingly, reference colour samples have been made available. These take the form of sets of needle hubs of colours complying with this International Standard. Details are given in annex B and it should be noted that only those diameters of needle currently having coloured hubs are included (i.e. 0,3 mm to 1,2 mm nominal outside diameter). It is expected that the range of diameters included in the reference colour samples will be extended in due course.