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KASUTATAVAD NÕELAD. IDENTIFITSEERIMISEKS
KASUTATAV VÄRVUSKODEERIMINE

Hypodermic needles for single use - Colour coding for
identification (ISO 6009:2016)

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 6009:2016 sisaldab Euroopa standardi EN ISO 6009:2016 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 6009:2016 consists of the English text of the European standard EN ISO 6009:2016.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
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English Version

Hypodermic needles for single use - Colour coding for identification (ISO 6009:2016)

Aiguilles hypodermiques non réutilisables - Code de couleurs pour l'identification (ISO 6009:2016)

Medizinische Einmalkanülen - Farbcodierung zur Identifizierung (ISO 6009:2016)

This European Standard was approved by CEN on 24 August 2016.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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European foreword

This document (EN ISO 6009:2016) has been prepared by Technical Committee ISO/TC 84 "Devices for administration of medicinal products and catheters" in collaboration with Technical Committee CEN/TC 205 "Non-active medical devices" the secretariat of which is held by DIN.

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of an identical text or by endorsement, at the latest by February 2017, and conflicting national standards shall be withdrawn at the latest by February 2017.

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.

This document supersedes EN ISO 6009:1994.

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Endorsement notice

The text of ISO 6009:2016 has been approved by CEN as EN ISO 6009:2016 without any modification.

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: [Foreword - Supplementary information](#).

The committee responsible for this document is ISO/TC 84, *Devices for administration of medicinal products and catheters*.

This fourth edition cancels and replaces the third edition (ISO 6009:1992), which has been technically revised. It also incorporates a Technical Corrigendum ISO 6009:1992/Cor.1:2008.

The main changes to the previous edition of ISO 6009 introduced by this revision are the following:

- a) broadening of the range of needles to designated needle size down to 0,18 mm;
- b) review of 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;
- c) revision of [Annex A](#);
- d) deletion of Annex B.

Introduction

The intention of this International Standard is to specify colours to enable rapid visual identification of the outer 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. This revision defines, in addition, colours for more fine needles to follow the trend in the market.

The colours used to code needles may be applied in either opaque or transparent form, and the colour code is equally applicable to regular walled, thin-walled, extra-thin and ultra-thin walled needles. The nominal outer diameters of needles listed in this International Standard for which colours are given are those specified in ISO 9626.

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 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 only referenced by a colour reference system (RAL) or by Pantone Matching System accepting that this inevitably introduces a certain amount of subjectivity in the assessment of compliance.

Guidance on transition periods for implementing the requirements of this International Standard is given in ISO/TR 19244.

Hypodermic needles for single use — Colour coding for identification

1 Scope

This International Standard establishes a colour code for the identification of single-use hypodermic needles of designated metric size in the range of 0,18 mm (34 Gauge) to 3,4 mm (10 Gauge). It applies to regular-walled, thin-walled, extra-thin-walled and ultra-thin walled needles, and to opaque and translucent colours.

This International Standard is not applicable to pen-needles.

2 Terms and definitions

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

2.1

designated metric size

outer diameter designation of the tubing as defined in [Table 1](#)

Note 1 to entry: It is expressed in millimetres.

2.2

gauge

legacy size designation

Note 1 to entry: A particular gauge size corresponds to a designated metric size defining limits for outer diameters.

3 Colour code

The colour shall indicate the nominal outer diameter of the tube of the needle and shall be as given in [Table 1](#).

[Annex A](#) contains certain guidance to commonly applied colour reference systems for opaque materials.

Table 1 — Colour code

Designated metric size mm	Gauge	Colour
0,18	34	Orange
0,2	33	Black
0,23	32	Deep green
0,25	31	White
0,3	30	Yellow
0,33	29	Red
0,36	28	Blue-green
0,4	27	Medium grey
0,45	26	Brown
0,5	25	Orange
0,55	24	Medium purple