
Podkožne igle za enkratno uporabo - Barvne kode za identifikacijo (ISO 6009:1992)

Hypodermic needles for single use - Colour coding for identification (ISO 6009:1992)

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

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

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Ta slovenski standard je istoveten z: EN ISO 6009:1994

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ICS:

01.070	Barvno kodiranje	Colour coding
11.040.25	Injekcijske brizge, igle in katetri	Syringes, needles and catheters

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EUROPEAN STANDARD

EN ISO 6009

NORME EUROPÉENNE

EUROPÄISCHE NORM

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Descriptors: Medical equipment, hypodermic needles, identification methods, colour marking, colour codes

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)

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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.

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CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

Central Secretariat: rue de Stassart, 36 B-1050 Brussels

Foreword

This European Standard has been taken over by the 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 (ISO).

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of an identical text or by endorsement, at the latest by January 1995, and conflicting national standards shall be withdrawn at the latest by January 1995.

According to 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, United Kingdom.

Endorsement notice

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

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INTERNATIONAL STANDARD

**ISO
6009**

Third edition
1992-12-01

Hypodermic needles for single use — Colour coding for identification

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*Aiguilles hypodermiques non réutilisables — Code de couleurs pour
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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.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

International Standard ISO 6009 was prepared by Technical Committee ISO/TC 84, *Medical devices for injections*, Sub-Committee SC 1, *Syringes, needles and intravascular catheters for single use*.

This third edition cancels and replaces the second edition (ISO 6009:1988), of which it constitutes a technical revision. The major changes are that it covers a wider range of needle sizes, that translucent colours are included, that the colour zones previously used to specify opaque colours are now given only for information, and that mention is made of reference colour samples (i.e. sets of needle hubs of the appropriate colours).

Annexes A, B, C and D of this International Standard are for information only.

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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.

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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 nominal outside diameters in the range 0,3 mm to 3,4 mm. It applies to normal-walled, thin-walled and extra-thin-walled needles and to opaque and translucent colours.

2 Colour code

The colour shall indicate the nominal outside diameter of the tube of the needle, and shall be as given in table 1.

NOTES

1 Attention is drawn to the sets of reference hubs available as reference colour samples (see annex A).

2 The colour zones of opaque colours, and the nearest colour samples in a number of colour atlases are given for information in annexes B and C respectively.

Table 1 — Colour code

Nominal outside diameter of needle mm	Colour
0,3	yellow
0,33	red
0,36	blue-green
0,4	medium grey
0,45	brown
0,5	orange
0,55	medium purple
0,6	deep blue
0,7	black
0,8	deep green
0,9	yellow
1,1	cream
1,2	pink
1,4	red-violet
1,6	white
1,8	blue-grey
2,1	pale green
2,4	purple
2,7	pale blue
3	green-yellow
3,4	olive brown