# INTERNATIONAL STANDARD

# ISO 6009

Third edition
1992-12-01

# Hypodermic needles for single use — Colour coding for identification

*Aiguilles hypodermiques non réutilisables — Code de couleurs pour l'identification*

Reference number
ISO 6009:1992(E)

## 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.