INTERNATIONAL STANDARD

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Anaesthetic and respiratory equipment — User-applied labels for syringes containing drugs used during anaesthesia — Colours, design and performance

Matériel d'anesthésie et de réanimation respiratoire — Étiquettes apposées par l'utilisateur sur les seringues contenant des médicaments utilisés pendant l'anesthésie — Couleurs, aspect et propriétés

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ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. 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.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 26825 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 1, *Breathing attachments and anaesthetic machines*.

Anaesthetic and respiratory equipment — User-applied labels for syringes containing drugs used during anaesthesia — Colours, design and performance

IMPORTANT — The electronic file of this document contains colours which are considered to be useful for the correct understanding of the document. Users should therefore consider printing this document using a colour printer.

1 Scope

This International Standard gives requirements for labels which the user attaches to syringes so that the contents can be identified just before use during anaesthesia. It covers the colour, size, design and general properties of the label and the typographical characteristics of the wording for the drug name.

This International Standard does not give requirements for labels applied to a syringe or cartridge by the drug manufacturer.

NOTE National or regional regulations might require additional labelling, which can include bar coding. No requirements for this additional labelling are given.

CAUTION — The use of colours is intended only as an aid in the identification of drug groups and does not absolve the user from the duty of reading the label and correctly identifying the drug prior to use.

2 General

2.1 The label shall be self-adhesive and shall withstand the following test:

a) Apply the label to a 10 ml or 12 ml polyethylene syringe for at least 12 h at (23 ± 2) °C.

NOTE Polyethylene was chosen as the material of the test syringe because it has poor adhesion properties and represents the ‘worst case’.

b) Immerse the syringe and label in a 50 % solution (volume fraction) of isopropanol in water for 5 min.

c) After immersion, remove the syringe from the liquid, hold vertically and allow it to air dry for 5 min.

d) The label shall not move, curl or lift at the edge when touched by hand.

2.2 If the labels are provided as a tape, the location where the tape shall be cut between labels shall be perforated or clearly marked. If there is backing material, the label shall be easily separable from it and from adjacent labels.

2.3 The material of the label shall be suitable for the user to write additional information upon it, e.g. the concentration of the drug, using a ball-point pen, without smudging or blurring.

2.4 The label package shall be marked with the number and date of this International Standard, i.e., ISO 26825:2008.