INTERNATIONAL STANDARD

ISO 15010

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Disposable hanging devices for transfusion and infusion bottles — Requirements and test methods

Dispositifs de suspension à usage unique pour flacons de transfusion et de perfusion — Exigences et méthodes d'essai

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 15010 was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection equipment for medical use*.

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Introduction

This International Standard deals with hanging devices for transfusion bottles in accordance with ISO 1135-1 and infusion bottles in accordance with ISO 8536-1. The intended purpose of hanging devices is to avoid drop-downs of transfusion and infusion bottles during administering of blood or pharmaceutical solutions.

Disposable hanging devices for transfusion and infusion bottles — Requirements and test methods

1 Scope

This International Standard specifies requirements for hanging devices for transfusion bottles in accordance with ISO 1135-1 and infusion bottles in accordance with ISO 8536-1 . The hanging devices are intended for single use only.

The purpose of this International Standard is to establish a safe hanging device for transfusion and infusion bottles during administering of their contents.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 1135-1:1987, *Transfusion equipment for medical use — Part 1: Glass transfusion bottles, closures and caps.*

ISO 2768-1:1989, *General tolerances — Part 1: Tolerances for linear and angular dimensions without individual tolerance indications.*

ISO 8536-1:1991, *Infusion equipment for medical use — Part 1: Infusion glass bottles.*

3 Designation code and test weights

Disposable hanging devices in accordance with the requirements of this International Standard are designated by the description block, followed by a reference to this International Standard, followed by the designation code as specified in table 1.

For example, a hanging device for an infusion bottle in accordance with ISO 8536-1 of nominal capacity 50 ml is designated as follows:

Hanging device ISO 15010 - A 50

Test weights used for the permanent loading test (see 6.2) are also a function of the nominal capacity of the hanging device and are specified in table 1.

Table 1 — Designation code and test weight for permanent loading test

Designation code for disposable hanging device	Nominal capacity ml		Test weight kg
	Transfusion bottle in accordance with ISO 1135-1	Infusion bottle in accordance with ISO 8536-1	
A 50	–	50	3
A 100	120	100	
A 250	–	250	
A 300	300	–	5
A 500	500	500	
A 1000	–	1000	

4 Material

Materials selected for the hanging device shall ensure that all requirements given in clause 5 can be met. The materials shall retain their characteristics when exposed to ultraviolet light or disinfection procedures.

5 Requirements

5.1 Assembly resistance

The disposable hanging device shall not be damaged by a single dismantling and renewed installation. After such manipulation it shall still pass the tests specified in 6.1 and 6.2.

5.2 Gravitational loading

When tested in accordance with 6.1, the disposable hanging device shall not detach from the infusion bottle. It shall not be damaged by the test.

5.3 Permanent loading

When tested in accordance with 6.2, the disposable hanging device shall prevent the transfusion or infusion bottle from falling.

5.4 Surface quality

The surface shall be clean and shall not possess sharp edges or burrs.

5.5 Design

The disposable hanging device shall be designed to ensure that the transfusion or infusion bottle hangs upside down.

6 Testing

6.1 Gravitational test

Attach the disposable hanging device, fitted with a filled infusion bottle in accordance with ISO 8536-1, to the curve of the test hook (see figure 1). Attach one end of a cord to the upper part of the hook, and the other end to a separate fixed point.

Hold the hanging device and hook level with the fixed point and drop the assemblage such that the cord breaks the fall with the hanging device at a vertical distance of 30 cm from the fixed point.

The test is regarded as passed if the hanging device has met the requirements specified in 5.2.

6.2 Permanent loading test

Using a hook of diameter 4 mm, e. g. in accordance with figure 1, load the disposable hanging device for 24 h at (23 ± 2) °C and (50 ± 3) % relative humidity with a test weight in accordance with table 1.

The test is regarded as passed if, after this exposure, the hanging device has met the requirements specified in 5.3.

Dimensions in millimetres

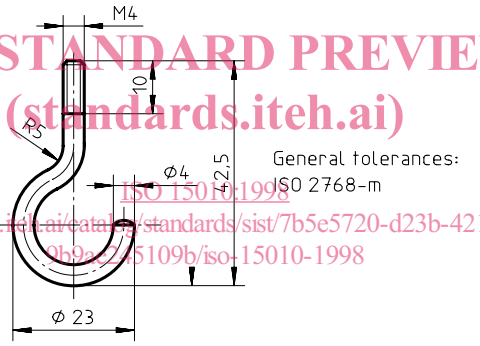

Figure 1 — Test hook

7 Packaging and storage

The packaging and storage conditions shall be selected to ensure that all requirements will continue to be met during the lifetime of the hanging device.

8 Marking

Disposable hanging devices complying with the requirements of this International Standard shall be marked on the packaging with the year of manufacture and the designation in accordance with clause 3, e.g.:

1997 Hanging device ISO 15010 - A 250

ICS 11.040.20

Descriptors: medical equipment, blood transfusion equipment, parenteral infusion equipment, bottles, disposable equipment, suspension devices, specifications, performance, tests, mechanical tests, marking, designation, packaging.

Price based on 3 pages