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Self-adhesive hanging devices for infusion bottles and injection vials — Requirements and test methods

*Systèmes de suspension autoadhésifs pour flacons de perfusion —
Exigences et méthodes d'essai*

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Foreword

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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 15137 was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection equipment for medical and pharmaceutical use*.

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Introduction

Self-adhesive hanging devices have become a common method for hanging infusion containers. The application is easy because no further equipment is needed. The intended purpose of self-adhesive hanging devices is to provide a simple and safe hanging of infusion containers during the administration of liquid pharmaceutical products.

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Self-adhesive hanging devices for infusion bottles and injection vials — Requirements and test methods

1 Scope

This International Standard specifies requirements and test methods for self-adhesive hanging devices (SAHD) used in combination with infusion containers, e.g. infusion glass bottles (see ISO 8536-1).

The purpose of this International Standard is to establish a safe SAHD for prescribed infusion containers while administering their content so as to ensure a safe application for the patient and for the user.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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

3 Terms and definitions

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

3.1

self-adhesive hanging device

SAHD

self-adhesive label consisting of an adhesive portion and a hanging portion

4 Designation

SAHDs in accordance with the requirements of this International Standard are designated as follows:

Self-adhesive hanging device ISO 15137

This should be marked on the label.

5 Materials

Materials selected for the SAHD shall ensure that all requirements specified in Clause 6 are met.

Some materials could be damaged by some influences such as disinfection fluids or UV-light. This should be considered when choosing a suitable material.

6 Requirements

6.1 Surface condition of the infusion container

The surface of the infusion container shall be clean, dry, free of dust and grease or any kind of release agents, e.g. agents containing silicone or wax.

NOTE Any treatment of the surface of the infusion container can have a negative impact on the adhesion force between the SAHD and the infusion container.

6.2 Label attachment

At least 95 % of the adhering part of the SAHD shall be in direct contact with the surface of the infusion container.

Care should be taken to avoid wrinkles, bubbles and uneven surfaces on the infusion containers.

6.3 Load resistance

6.3.1 Permanent load

The SAHD shall not break and shall not detach from the infusion container when tested according to 7.4.1.

6.3.2 Short term load

The SAHD shall not break and shall not detach from the infusion container when tested according to 7.4.2.

6.3.3 Gravitational load

The SAHD shall not break and shall not detach from the infusion container when tested according to 7.4.3.

6.4 Elongation

The distance between the hook and the infusion container shall not increase by more than 50 % when tested in accordance with 7.5 (see Figure 4).

6.5 Resistance in water bath

When testing in accordance with 7.6, the requirements specified in 6.3.1, 6.3.2 and 6.4 shall be met.

6.6 Adherence to vertical position

The hanging portion of the SAHD shall be designed in such a way that the infusion container shall not deviate from a vertical position by more than 10° (see Figure 3).

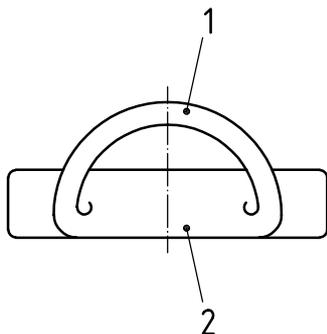
6.7 Long term performance

After having been attached to the infusion container and having been stored suitably (no UV-light, storage temperature between 10 °C and 30 °C), the SAHD shall comply with the requirements of this International Standard for 6 years or until the expiration date of the product.

7 Tests

7.1 General

7.1.1 Figure 1 illustrates a SAHD. With the adhesive portion, the SAHD is attached to a suitable container (see Figure 2). The hanging portion allows the infusion container to be hung on a hook (see Figures 3 and 5). In order to administer the content, the container is hung on a hook with its neck facing downwards (see Figure 3). Nevertheless, when testing, it is possible to change this orientation in order to simplify the test procedure (see Figures 3 and 4).



Key

- 1 hanging portion
- 2 adhesive portion

Figure 1 — Example of a SAHD

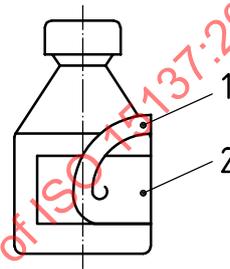
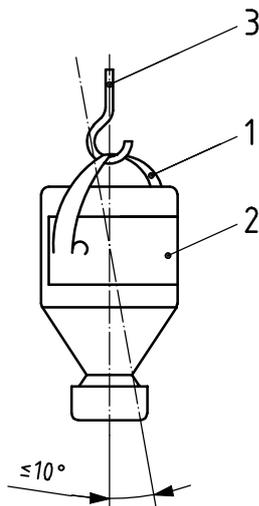


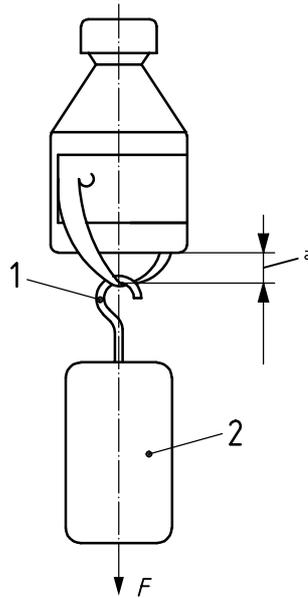
Figure 2 — Example of a SAHD attached to an infusion container



Key

- 1 hanging portion
- 2 adhesive portion
- 3 hook

Figure 3 — Example of an infusion container with attached SAHD



Key

- 1 test hook
- 2 test weight piece (from 3 kg to 6 kg)
- F test load
- ^a The distance from infusion container to test hook (shall not increase by more than 50 %).

Figure 4 — Example of an infusion container with attached SAHD during test procedure

7.1.2 All tests shall be performed at a temperature of (23 ± 3) °C and a relative humidity of (50 ± 10) %.

7.2 Label attachment

7.2.1 Make sure that the infusion containers used for the test correspond to 6.1.

7.2.2 Properly attach the SAHD under test to the infusion container. Check visually if the contact area between the adhesive portion of the SAHD and the infusion container corresponds to 6.2.

7.2.3 After applying the SAHD to the infusion container, allow the label adhesive to cure according to the manufacturer’s specification [see 10 a)] before starting the tests.

7.3 Test weight pieces

Test weight pieces used for the load tests are specified in Table 1.

Table 1 — Test weight pieces

Nominal volume ml	Test weight pieces kg		
	Permanent load 24 h	Short term load 30 s	Fall-test made with
< 250	3	6	filled infusion container
250 to 1 000	5	6	filled infusion container

7.4 Load tests

7.4.1 Permanent load test

Take an infusion container with an attached SAHD. Select the appropriate test weight piece from Table 1 and connect the test weight piece with a test hook given in Figure 5. Connect the hanging portion of the SAHD with the test weight piece using the test hook as indicated in Figure 4. Apply the test load for 24 h. The apparatus under test passes the test if the requirements specified in 6.3.1 are fulfilled for at least 24 h.

7.4.2 Short term load test

Take an infusion container with an attached SAHD. Select the appropriate test weight piece from Table 1 and connect the test weight piece with a test hook given in Figure 5. Connect the hanging portion of the SAHD with the test weight piece using the test hook as indicated in Figure 4. Apply the test load for 30 s. The apparatus under test passes the test if the requirements specified in 6.3.2 are fulfilled for at least 30 s.

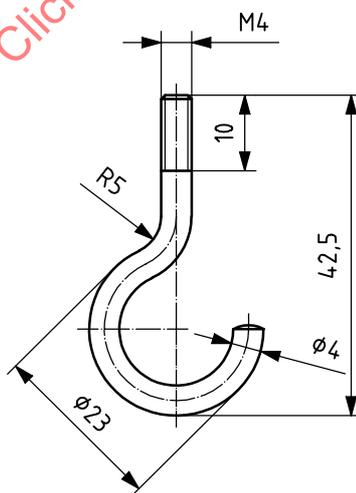
7.4.3 Gravitational test

Take a filled infusion container with an attached SAHD. Connect one end of a stable cord to the hanging portion of the SAHD and connect the other end of the cord to a fixed bracket in such a way that the container can hang and swing freely without interference. Lift the container to a height of 30 cm above its resting position and let it fall freely. The apparatus under test passes the test if the requirements specified in 6.3.3 are fulfilled.

7.5 Elongation test

The distance from the test hook to the infusion container is measured at the beginning and at the end of the permanent load test in accordance with 7.4.1. The apparatus under test passes the test if the requirements specified in 6.4 are fulfilled.

Dimensions in millimetres



General tolerances according to ISO 2768-m (see ISO 2768-1:1989).

Figure 5 — Test hook

7.6 Water resistance test

Place a filled infusion container with an attached SAHD into a water bath for 24 h at a water temperature of $(40 \pm 3) ^\circ\text{C}$. Ensure that the SAHD is totally immersed in the water for the duration of the test. Remove the infusion container from the water bath and wait for 5 min. Then perform the test according to 7.4.1. The apparatus under test passes the test if the requirements specified in 6.5 are fulfilled.