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**Dentistry — Integrated dental floss and handles**

*Médecine bucco-dentaire — Porte-fil et fil dentaire intégré*

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## Foreword

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ISO 28158 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 7, *Oral care products*.

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## Introduction

This International Standard has been prepared in order to present the requirements and test methods for integrated dental floss and handles used for home care, community care, professional care of oral health or as a part of dental treatment.

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# Dentistry — Integrated dental floss and handles

## 1 Scope

This International Standard is applicable to integrated dental floss and handles for manual use. It does not include dental floss and handles which contain a continuous supply of dental floss, or dental floss and handles to which the floss is subsequently added.

This International Standard does not specify specific qualitative and quantitative test methods for demonstrating freedom from unacceptable biological risks. For assessment of such biological risks, see ISO 10993-1 and ISO 7405.

## 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 1942:2009, *Dentistry — Vocabulary*

ISO 3696, *Water for analytical laboratory use — Specification and test methods*

## 3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 1942 and the following apply.

### 3.1

#### **dental floss**

multiple filaments gathered into thread, spun yarn, single filament or tape, commonly synthetic fibre, with or without coating material(s), designed for the removal of plaque or debris, or both, from the proximal surfaces of natural or artificial teeth and the gingival surfaces of pontics of fixed prostheses

NOTE Adapted from ISO 1942:2009, definition 2.69.

### 3.2

#### **integrated dental floss and handle**

oral hygiene device holding **dental floss** (3.1) as a fixed integral part

## 4 Requirements

### 4.1 Material and shape

#### 4.1.1 Material

The dental floss and handle shall be free from extraneous matter when examined according to 6.2 a). Materials intentionally added to dental floss or handle, such as wax, pigments or flavouring agents, shall be considered as part of the device.

#### 4.1.2 Shape

The integrated dental floss and handle shall not have any sharp surface or parts when examined according to 6.2 b), except when a part, if included, is designed and intended to be used as a toothpick.

### 4.2 Strength

The integrated dental floss and handle shall withstand the static load of 10 N for 10 s without a breakage of the floss or handle, and without a pull-out of the floss from the handle when determined in accordance with the test method specified in Annex A.

## 5 Sampling

Obtain a sufficient number of test specimens which are identical to the marketed product to complete all the prescribed tests and any necessary repeat tests.

## 6 Test conditions and visual inspection

### 6.1 Test conditions

Prepare and test all specimens at a temperature of  $(23 \pm 5)$  °C.

### 6.2 Visual inspection

- a) Use visual inspection by normal acuity without magnification for determining compliance with 4.1.1, Clause 7 and Clause 8.
- b) Use visual inspection with  $\times 10$  magnification for determining compliance with 4.1.2.

## 7 Packaging

The packaging shall be such that it will neither contaminate nor permit contamination of the integrated dental floss and handle.

## **8 Accompanying information**

### **8.1 Labelling of the package**

The package shall be labelled with the following information:

- a) trade name of the product;
- b) name and address of the manufacturer and/or responsible distributor;
- c) manufacturer's tracking code.

### **8.2 Instructions for use**

The integrated dental floss and handle shall be supplied with instructions for use.

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## Annex A (normative)

### Determination of the strength of integrated dental floss and handles

#### A.1 Principle

The assessment of the compliance of the strength of integrated dental floss and handles is determined by this test method.

#### A.2 Apparatus and material

**A.2.1 Clamping device** capable of sufficiently clamping the specimen, such as that shown in Figure A.1.

**A.2.2 Vice**, capable of holding the clamping device (A.2.1).

**A.2.3 Hook**, having a tensile strength of not less than 100 N, smooth surface and cross-sectional diameter  $(3,0 \pm 0,5)$  mm.

NOTE Hooks with a sectional diameter smaller than 2,5 mm or with a rough surface, or with both, can cause a breakage of the dental floss due to the excess concentration of force at the junction of the hook and the floss.

**A.2.4 String or chain, or both**, rigid, and having a tensile strength of not less than 100 N.

**A.2.5 Weight**, capable of producing a static loading force of  $(10,0 \pm 0,5)$  N including both the hook (A.2.3) and the string or chain, or both (A.2.4).

**A.2.6 Timer**, accurate to 1 s.

**A.2.7 Water**, Grade 3 of ISO 3696 or equivalent.

#### A.3 Procedure

Perform the following procedure to determine the strength of each specimen. Test 10 specimens. (See Figure A.1 for the schematic alignment for the strength test.)

- a) Fix the clamping device (A.2.1) to the vice (A.2.2). Assemble the static weight by connecting the weight (A.2.5), the string or chain, or both (A.2.4) and the hook (A.2.3).
- b) Immerse the specimen of the integrated dental floss and handle in water (A.2.7) at  $(37 \pm 2)$  °C for  $(90^{+10}_0)$  s.
- c) Immediately after the removal from water, remove excess water on the surface of the specimen while holding it by shaking the specimen twice with a sharp snap of the wrist, and clamp the specimen on the clamping device as follows.
  - 1) The longitudinal axis of the floss of the specimen shall be horizontal at least on the start of the test.
  - 2) The circumferential surface of the lower supporting washer(s) (Item 6) shall be attached to the lower surface of the handle of the specimen at the centre of the user-gripping area. The surfaces of the pads (Item 7) which face the handle shall press up against the respective surfaces of the handle, including the centre of the user-gripping area of the handle supporting the specimen. The

user-gripping area shall be specified according to the shape of the handle, or according to the manufacturer's instructions for use. Otherwise, the centre of an assumed user-gripping area of the handle shall be  $(30 \pm 1)$  mm horizontally apart from the centre of the retaining points of the floss with the handle.

- 3) The upper supporting washer(s) (Item 2) shall be positioned so as the circumferential surface(s) of the washer(s) to attach to the upper surface of the handle appropriately apart from the lower supporting washer(s) (Item 6) according to the shape and length of the handle.
- d) Align the static weight [see A.3 a)] in the fully stretched position before loading. At  $(60_{-5}^0)$  s after finishing the immersion, hang the hook at the centre of the length of the floss, then start loading by carefully removing the supporting device or operator's hand from under the weight, and without imparting an unintended or sudden increase in force, start the timer (A.2.6) and keep loading for  $(10_{-0}^{+1})$  s.
- e) After the removal of the weight, inspect the specimen to determine whether a breakage of the floss or handle or a pull-out of the floss from the handle has occurred.

## A.4 Treatment of results

### A.4.1 Pass-fail criteria

For each specimen tested, express the results as either:

- a) **pass**, if the floss neither pulls out of the handle nor breaks, and the floss and handle does not break; or
- b) **fail**, if the conditions given in a) are not met.

### A.4.2 Compliance with the requirement

Compliance with the requirement of 4.2 can be claimed as follows.

- a) **Yes**: if 8 or more of the 10 specimens pass the test, the integrated dental floss and handle complies with the requirement of 4.2.
- b) **No**: if fewer than 7 of the 10 specimens pass the test, the integrated dental floss and handle do not comply with the requirement of 4.2.
- c) **Repeat the whole test**: if 7 of the 10 specimens pass the test, repeat the test (A.3) with 10 new integrated dental floss and handles. Interpret the results in accordance with Table A.1.

Table A.1 — Treatment of results

Test	Number of specimens passing the test [see A.4.1 a)]			Compliance with the requirement of 4.2
First test	8 to 10			Yes
	7			Repeat the whole test (10 new specimens)
	0 to 6			No
First test + second (repeat) test	First	Second	Total	Compliance with the requirement of 4.2
	7	9 to 10	16 to 17	Yes
		0 to 8	7 to 15	No