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Dentistry — Integrated dental floss and handles

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

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Contents

Page

Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html.

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

This second edition cancels and replaces the first edition (ISO 28158:2010), which has been technically revised.

The main changes compared to the previous edition are as follows:

— inclusion of the alternative test method for the strength of the products using a tensile test equipment (e.g. push-pull force gauge, tensile testing equipment or equivalent);

— addition of the requirement that having no displacement which is more than 10 mm of the loading point in the direction of the loading at the force of 10 N;

— addition of the directions for procedure of tooth cleaning using the integrated dental floss and handles, if necessary, and a recommendation on safety information recommending the user to apply a gentle “sawing” or “zig-zag” motion of the floss during insertion into and removal of the floss from the area between teeth to reduce possible injury to the interdental gingiva potentially caused by the floss snapping forcefully into the soft gingival tissue.

Any feedback or questions on this document should be directed to the user’s national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Dentistry — Integrated dental floss and handles

1 Scope

This document specifies the requirements and test methods for integrated dental floss and handles used for home care, community care, professional care of oral health or a part of dental treatment.

This document 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 handles to which the floss is subsequently added.

This document excludes 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 documents are referred to in the text in such a way that some or all of their content constitutes requirements 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, *Dentistry — Vocabulary*

ISO 3696:1987, *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.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

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 and/or debris from the proximal surfaces of natural or artificial teeth and the gingival surfaces of pontics of fixed prostheses

[SOURCE: ISO 1942:2009, 2.69, modified]

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, burr or parts when examined according to 6.2 b), except when a part, if included, is designed and intended to be used as a tooth pick.

4.2 Strength

4.2.1 General

The integrated dental floss and handle shall be in accordance with the requirement prescribed in 4.2.2 or 4.2.3.

4.2.2 Strength determined by static test

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, a pull-out of the floss from the handle or displacement of more than 10 mm of the loading point in the direction of the loading when determined in accordance with the test method specified in Annex A.

4.2.3 Strength determined by tensile test

The integrated dental floss and handle shall withstand the load of 10 N applied by a tensile testing equipment without a breakage of the floss or handle, a pull-out of the floss from the handle or a displacement of more than 10 mm of the loading point in the direction of the loading when determined in accordance with the test method specified in Annex B.

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 ± 5) °C.

6.2 Visual inspection

a) Use visual inspection by normal acuity without magnification for determining conformity to 4.1.1.

b) Use visual inspection with ×10 magnification for determining conformity to 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.

The instructions for use should contain the following information, with an appropriate figure, if applicable:

a) Directions for the proper procedure of tooth cleaning using the integrated dental floss and handle, if necessary;

   EXAMPLE "Clean the interdental surface of the teeth with a gentle up and down motion of the dental floss."

b) A recommendation to the user to apply a gentle "sawing" or "zig-zag" motion of the floss during insertion into and removal of the floss from the area between teeth to reduce possible injury to the interdental gingiva potentially caused by the floss snapping forcefully into the soft gingival tissue.

An example of a gentle "sawing" or "zig-zag" motion of a dental floss and handle is provided in Figure 1.

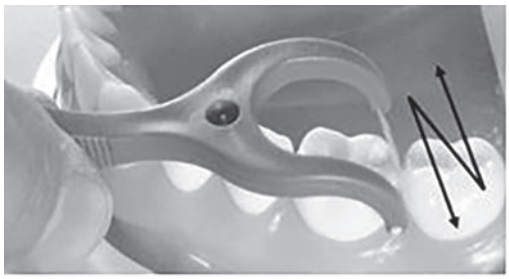


Figure 1 — Example of a gentle "sawing" or "zig-zag" motion of an integrated dental floss and handle

Annex A
(normative)

Determination of the strength of integrated dental floss and handles by static test

A.1 Principle

Assessment of the conformity to the strength of integrated dental floss and handles by static test is determined by this test method using static weight.

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 Ring with a slit, having a smooth surface, round shape with a cross-sectional diameter of (3,0 ± 0,5) mm, rigid enough for a tensile strength of not less than 100 N and a slit for hooking the floss and the test weight.

NOTE If the cross-sectional diameter of the ring with a slit is smaller than 2,5 mm or with a rough surface, or with both, it can cause a breakage of the dental floss due to the excess concentration of force at the junction of the ring and the floss.

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

A.2.5 Weight, capable of producing a static loading force of (10,0 ± 0,5) N including both the ring with a slit (A.2.3) and the string or chain (A.2.4).

A.2.6 Timer, accurate to 1 s.

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

A.2.8 Height gauge or equivalent, capable of measuring a height difference of (10 ± 0,5) mm.

A.3 Procedure

A.3.1 General

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

A.3.2 Test steps

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 (A.2.4) and the ring with a slit (A.2.3).

b) Immerse the specimen of the integrated dental floss and handle in water (A.2.7) at (37 ± 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 at the start of the test.

   2) The circumferential surface of the lower supporting washer(s) (Key 6) shall be positioned below the lower surface of the handle of the specimen at the centre of the user-gripping area. The surfaces of the pads (Key 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 ± 1) mm horizontally apart from the centre of the retaining points of the floss with the handle.

   3) The upper supporting washer(s) (Key 2) shall be positioned so as the circumferential surface(s) of the washer(s) is(are) positioned above the upper surface of the handle appropriately apart from the lower supporting washer(s) (Key 6) according to the shape and length of the handle.

d) Place the measurement point of the height gauge (A.2.8) at the centre of the imaginary straight line connecting the holding points of the dental floss inside of the handle.

e) Align the static weight [see A.3 a)] in the fully stretched position before loading. At $(60\,^{+0}_{-5})$ 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 $(10\,^{+1}_{-0})$ s.

f) Inspect the specimen to determine whether a pull-out of the floss from the handle, a breakage of the floss or displacement of the loading point of more than 10 mm in the direction of the loading has occurred.

g) After the removal of the weight, inspect the specimen to determine whether a breakage of 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, the handle does not break and the loading point does not displace more than 10 mm in the direction of the loading; or

b) **fail**, if the conditions given in A.4.1 a) are not met.

A.4.2 Conformity to the requirement

Conformity to the requirement of 4.2.2 can be claimed as follows.

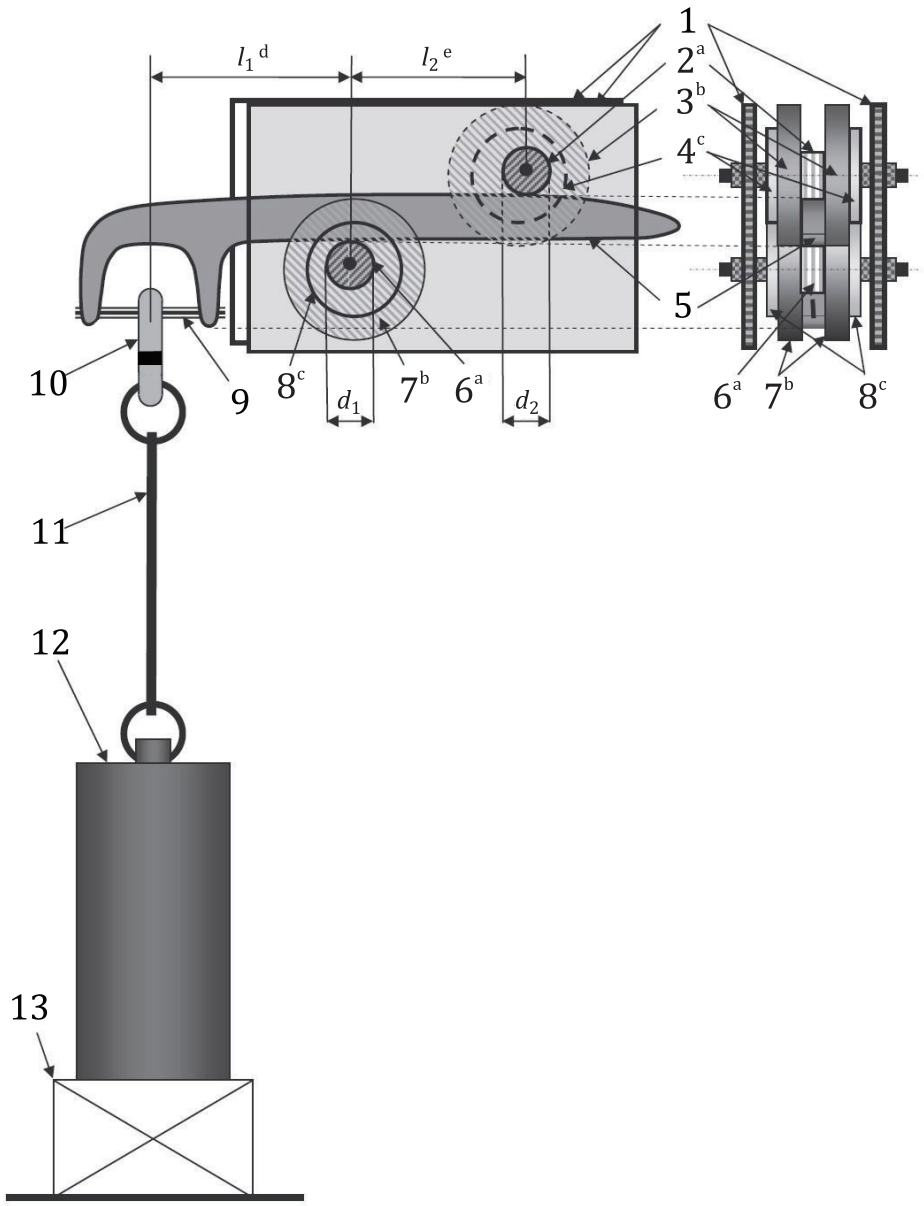
a) **Yes**: if 8 or more of the 10 specimens pass the test, the integrated dental floss and handle conforms to the requirement of 4.2.2.

b) **No**: if 6 or fewer of the 10 specimens pass the test, the integrated dental floss and handle does not conform to the requirement of 4.2.2.

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 passed the test [see A.4.1 a)]**			**Conformity to the requirement of 4.2.2**
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	Conformity to the requirement of 4.2.2
	7	9 to 10	16 to 17	Yes
		0 to 8	7 to 15	No



Key

1	base plate	10	ring with a slit
2	upper supporting washers	11	string or chain
3	upper clamping pads	12	weight
4	upper clamping plates	13	support for the weight until the loading starts
5	handle segment of the product	l_1	horizontal distance
6	lower supporting washers	l_2	horizontal distance
7	lower clamping pads	d_1	diameter of lower supporting washer (5 mm to 10 mm)
8	lower clamping plates	d_2	diameter of upper supporting washer (5 mm to 30 mm)
9	dental floss segment		

a Slightly thinner than the thickness of the floss handle at the place to be clamped.

b Clamp vertical sides of the floss handle. In the case of the upper clamping pads, it shall be used only if applicable according to the shape and size of the product.

c Place at outer-sides of clamping pads. In the case of the upper clamping plates, it shall be used only if applicable according to the shape and size of the product.

d According to the instructions for use, or to the size and shape of the product, otherwise (30 ± 1) mm

e According to the shape and size of the product.

Figure A.1 — Schematic alignment for the strength test using static weight

Annex B
(normative)

Determination of the strength of integrated dental floss and handles by tensile test

B.1 Principle

The assessment of the conformity to the strength of integrated dental floss and handles by tensile test is determined by this test method using tensile testing equipment.

B.2 Apparatus and material

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

B.2.2 Vice or chuck, capable of holding the clamping device (B.2.1) for push-pull force gauge or tensile testing equipment, respectively.

B.2.3 Ring with a slit, having a smooth surface, round shape with a cross-sectional diameter of (3,0 ± 0,5) mm, rigid enough for a tensile strength of not less than 100 N and a slit for hooking the floss and the test force.

NOTE If the cross-sectional diameter of the ring with a slit is smaller than 2,5 mm or with a rough surface, or with both, it can cause a breakage of the dental floss due to the excess concentration of force at the junction of the ring and the floss.

B.2.4 Hook and rod for push-pull force gauge or those equivalent capable of being held by the clamp of tensile testing equipment (B.2.5), rigid and having a tensile strength of not less than 100 N.

B.2.5 Tensile test machine or push-pull force gauge with pulling equipment, capable of moving at (300 ± 50) mm/min of cross-head speed or a rate of loading of (50 ± 16) N/min and recording a loading force of not less than 100 N and the strain corresponding to the applied load.

B.2.6 Timer, accurate to 1 s.

B.2.7 Water, Grade 3 of ISO 3696:1987 or equivalent.

B.3 Procedure

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

a) Fix the clamping device (B.2.1) to the vice (for push-pull force gauge) or chuck (for tensile test machine) (B.2.2). Assemble tensile test machine or push-pull force gauge with pulling equipment (B.2.5), the hook and rod (B.2.4) and the ring with a slit (B.2.3).

b) Immerse the specimen of the integrated dental floss and handle in water (B.2.7) at (37 ± 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 perpendicular to the pulling direction of the tensile test machine or push-pull force gauge at least at the start of the test;

   2) The circumferential surface of the first supporting washer(s) (Key 6) shall be positioned below the lower surface of the handle of the specimen at the centre of the user-gripping area, and the surfaces of the pads (Key 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 ± 1) mm horizontally apart from the centre of the retaining points of the floss with the handle;

   3) The second supporting washer(s) (Key 2) shall be positioned so as the circumferential surface(s) of the washer(s) is(are) positioned above the upper surface of the handle appropriately apart from the first supporting washer(s) (Key 6) according to the shape and length of the handle.

d) Align the tensile testing machine, push-pull force gauge or equivalent equipment [see B.3 a)] in the fully stretched position before loading. Place the remotest and inner surface of the hook (B.2.4) at the centre of the imaginary straight line connecting the holding points of the dental floss inside of the handle. At $(60\,^{+0}_{-5})$ s after finishing the immersion, then start loading at (300 ± 50) mm/min of cross-head speed or a rate of loading of (50 ± 16) N/min and record the relation of strain and load until the dental floss is pulled-off from the handle, is broken or any fracture of the handle occurs.

e) Inspect the specimen to determine whether a pull-out of the floss from the handle or a breakage of the floss has occurred.

f) Inspect the chart of the relation of strain and load so as to determine the load applied to the specimen when the displacement of 10 mm of the loading point in the direction of the loading, a pull-out of the floss from the handle, breakage of the floss or breakage of the handle has occurred.

B.4 Treatment of results

B.4.1 Pass-fail criteria

B.4.1.1 Pass

The specimen passes the test when, after the load of 10,0 N is applied, none of the events described in a), b) and c) below occurred.

a) pull-out of the floss from the handle or breakage of the floss;

b) breakage of the handle;

c) displacement of more than 10 mm of the loading point in the direction of the loading.

B.4.1.2 Fail

The specimen fails the test if the conditions described in B.4.1.1 are not met.

B.4.2 Conformity to the requirement

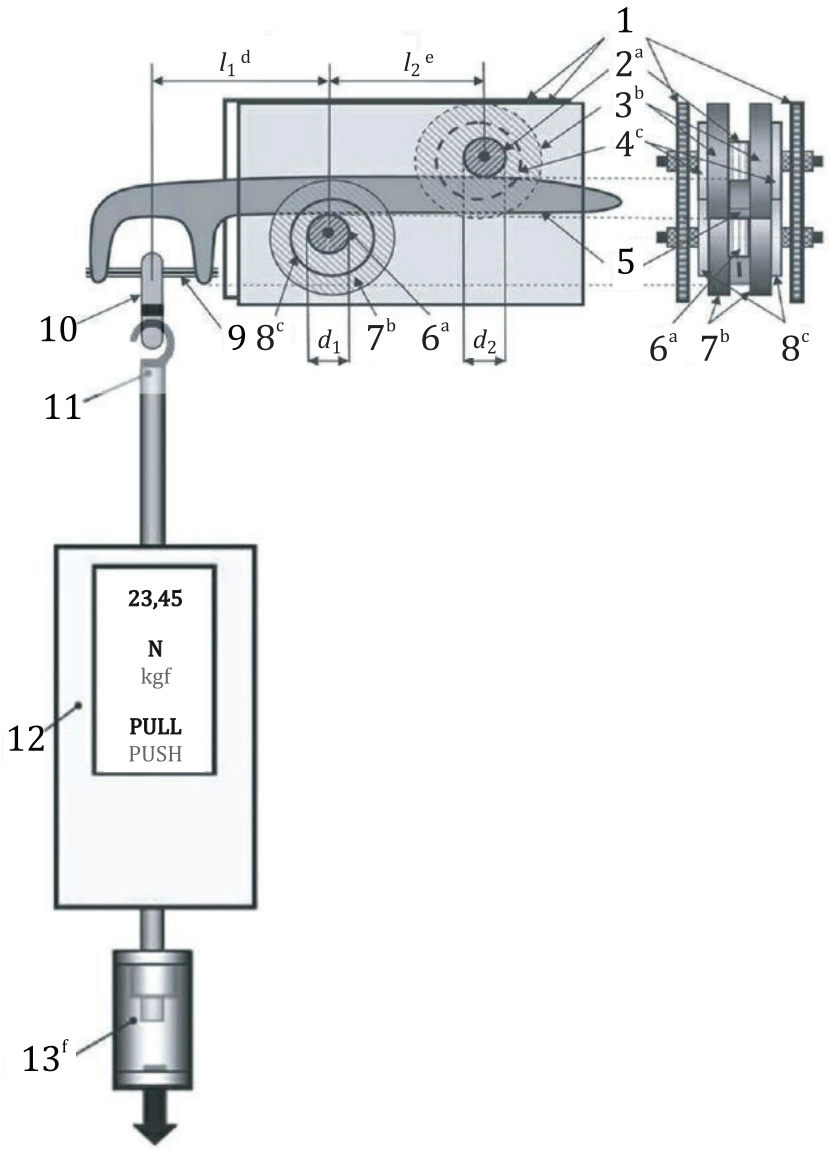
a) **Yes**: If 8 or more of the 10 specimens pass the test, the integrated dental floss and handle conforms to the requirement of 4.2.3.

b) **No**: If 6 or fewer of the 10 specimens pass the test, the integrated dental floss and handle does not conform to the requirement of 4.2.3.

c) **Repeat the whole test**: If 7 of the 10 specimens pass the test, repeat the test (B.3) with 10 new integrated dental floss and handles. Interpret the results in accordance with Table B.1.

Table B.1 — Treatment of results

<table>
<tr><th>Test</th><th colspan="3">Number of specimens passing the test [see B.4.1 a)]</th><th>Conformity to the requirement of 4.2.3</th></tr>
<tr><td rowspan="3">First test</td><td colspan="3">8 to 10</td><td>Yes</td></tr>
<tr><td colspan="3">7</td><td>Repeat the whole test
(10 new specimens)</td></tr>
<tr><td colspan="3">0 to 6</td><td>No</td></tr>
<tr><td rowspan="3">First test
+
second (repeat) test</td><td>First</td><td>Second</td><td>Total</td><td>Conformity to the requirement of 4.2.3</td></tr>
<tr><td rowspan="2">7</td><td>9 to 10</td><td>16 to 17</td><td>Yes</td></tr>
<tr><td>0 to 8</td><td>7 to 15</td><td>No</td></tr>
</table>



Key

1	base plate	10	ring with a slit
2	upper supporting washers	11	hook and rod for push-pull force gauge or those equivalent
3	upper clamping pads	12	tensile test machine or push-pull gauge
4	upper clamping plates	13	connecting part of a pulling equipment
5	handle segment of the product	l_1	horizontal distance
6	lower supporting washers	l_2	horizontal distance
7	lower clamping pads	d_1	diameter of lower supporting washer (5 mm to 10 mm)
8	lower clamping plates	d_2	diameter of upper supporting washer (5 mm to 30 mm)
9	dental floss segment		

a Slightly thinner than the thickness of the floss handle at the place to be clamped.

b Clamp vertical sides of the floss handle. In the case of the upper clamping pads, it shall be used only if applicable according to the shape and size of the product.

c Place at outer-sides of clamping pads. In the case of the upper clamping plates, it shall be used only if applicable according to the shape and size of the product.

d According to the instructions for use, or to the size and shape of the product, otherwise (30 ± 1) mm.

e According to the shape and size of the product.

f Connected to pulling equipment (B.2.6), capable of (300 ± 50) mm/min of cross-speed or a rate of loading of (50 ± 16) N/min.

Figure B.1 — Schematic alignment for the strength test using tensile testing equipment

Bibliography

[1] ISO 7405, *Dentistry — Evaluation of biocompatibility of medical devices used in dentistry*

[2] ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

[3] ISO 20126, *Dentistry — Manual toothbrushes — General requirements and test methods*

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