

# DRAFT INTERNATIONAL STANDARD

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## Dentistry — Oral hygiene products — Manual interdental brushes

*Médecine bucco-dentaire — Produits d'hygiène bucco-dentaire — Brosses interdentaires manuelles*

[Revision of first edition (ISO 16409:2006) and of ISO 16409:2006/Amd 1:2010]

ICS: 97.170

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### ISO/CEN PARALLEL PROCESSING

This draft has been developed within the International Organization for Standardization (ISO), and processed under the **ISO lead** mode of collaboration as defined in the Vienna Agreement.

This draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel five month enquiry.

Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month approval vote in ISO and formal vote in CEN.

To expedite distribution, this document is circulated as received from the committee secretariat. ISO Central Secretariat work of editing and text composition will be undertaken at publication stage.

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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.

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ISO 16409 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 16409:2006), which has been technically revised. The following changes are proposed:

- a) Addition of bigger bush size 8 in Table 1.

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## Introduction

Manual interdental brushes are used for oral hygiene purposes intended to provide health benefits. Their main application purpose is mechanical plaque removal, primarily from the interdental region.

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# Dentistry — Oral hygiene products — Manual interdental brushes

## 1 Scope

This International Standard specifies requirements and test methods for performance criteria for manual interdental brushes with a round cross-section of the brush head. It also specifies the accompanying information such as manufacturer's instructions for use and labelling of the packaging.

This International Standard is not applicable to powered interdental brushes, manual toothbrushes, dental floss, tapes, and strings and to interdental cleaners that do not include filaments.

## 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, *Dentistry — Vocabulary*

## 3 Terms and definitions

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

### 3.1

#### **manual interdental brush**

hand powered device composed of filaments emanating radially from a stem intended for cleaning of interdental surfaces

### 3.2

#### **interdental brush head**

portion of manual interdental brush, which passes in and out of spaces between the teeth to clean the exposed surfaces

NOTE The brush head may be fixed or removable, but is fixed during use.

### 3.3

#### **interdental brush handle**

portion of manual interdental brush, which holds the stem of the manual interdental brush

### 3.4

#### **stem**

central support structure of the manual interdental brush head, usually composed of twisted wire, which secures the filaments

NOTE The stem is either secured

- a) in the handle;
- b) in a connector;
- c) or fulfils the function of a handle itself.

**3.5**

**filament**

a single strand, attached to the stem

**3.6**

**stem retention force**

force required to remove the stem from the interdental brush handle holding it

**3.7**

**passage hole diameter**

minimum diameter of a hole through which a manual interdental brush head can pass without stem deformation

**3.8**

**brush size**

index of brush sizes determined by the passage hole diameter

**4 Classification**

Manual interdental brushes shall be classified as follows:

- **Type 1:** replacement heads may be mounted into a handle;
- **Type 2:** the brush head is permanently affixed into the handle;
- **Type 3:** the stem fulfils the function of a handle.

**5 Requirements**

**5.1 Defects or contamination**

Manual interdental brushes including all supplied parts shall be free of apparent defects or contamination.

Test in accordance with 7.3.

**5.2 Brush size**

The brush size of manual interdental brushes shall be in accordance with Table 1.

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**Table 1 — Brush size of interdental brushes**

Dimensions in millimetres

Brush size	Passage hole diameter
1	≤ 0,8
2	0,9 to 1,0
3	1,1 to 1,2
4	1,3 to 1,5
5	1,6 to 1,8
6	1,9 to 2,3
7	2,4 to 2,8
8	≥ 2,8

Determine the brush size of a manual interdental brush by using the passage hole diameter in accordance with 7.4

### 5.3 Filament retention

The filaments of manual interdental brushes shall not be removed.

Test in accordance with 7.5.

### 5.4 Stem retention

The stem of manual interdental brushes of Type 1 and Type 2 shall withstand a removal force not less than 15 N.

Test in accordance with 7.6.

### 5.5 Stem durability

The stem of manual interdental brushes shall withstand the repeated bending for 20 cycles.

Test in accordance with 7.7.

## 6 Sampling

The manual interdental brushes used for testing shall be representative of manufactured manual interdental brushes and shall not be altered or adjusted in any way, except as needed to perform the tests.

A minimum of eight manual interdental brushes of each type shall be tested.