

---

---

**Dentistry — Oral hygiene products —  
Manual interdental brushes**

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

**iTeh STANDARD PREVIEW**  
**(standards.iteh.ai)**

[ISO 16409:2006](https://standards.iteh.ai/catalog/standards/sist/8f15b717-3116-4932-8284-89e4a5587f27/iso-16409-2006)

[https://standards.iteh.ai/catalog/standards/sist/8f15b717-3116-4932-8284-  
89e4a5587f27/iso-16409-2006](https://standards.iteh.ai/catalog/standards/sist/8f15b717-3116-4932-8284-89e4a5587f27/iso-16409-2006)



**PDF disclaimer**

This PDF file may contain embedded typefaces. In accordance with Adobe's licensing policy, this file may be printed or viewed but shall not be edited unless the typefaces which are embedded are licensed to and installed on the computer performing the editing. In downloading this file, parties accept therein the responsibility of not infringing Adobe's licensing policy. The ISO Central Secretariat accepts no liability in this area.

Adobe is a trademark of Adobe Systems Incorporated.

Details of the software products used to create this PDF file can be found in the General Info relative to the file; the PDF-creation parameters were optimized for printing. Every care has been taken to ensure that the file is suitable for use by ISO member bodies. In the unlikely event that a problem relating to it is found, please inform the Central Secretariat at the address given below.

**iTeh STANDARD PREVIEW**  
**(standards.iteh.ai)**

ISO 16409:2006

<https://standards.iteh.ai/catalog/standards/sist/8f15b717-3116-4932-8284-89e4a5587f27/iso-16409-2006>

© ISO 2006

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office  
Case postale 56 • CH-1211 Geneva 20  
Tel. + 41 22 749 01 11  
Fax + 41 22 749 09 47  
E-mail [copyright@iso.org](mailto:copyright@iso.org)  
Web [www.iso.org](http://www.iso.org)

Published in Switzerland

## Contents

Page

Foreword.....	iv
Introduction .....	v
1 Scope .....	1
2 Normative references .....	1
3 Terms and definitions .....	1
4 Classification.....	2
5 Requirements .....	2
5.1 Defects or contamination.....	2
5.2 Brush size.....	2
5.3 Filament retention.....	3
5.4 Stem retention.....	3
5.5 Stem durability .....	3
6 Sampling.....	3
7 Test methods.....	3
7.1 General.....	3
7.2 Pass/fail criteria .....	3
7.3 Visual inspection .....	3
7.4 Passage hole diameter.....	4
7.5 Filament retention.....	5
7.6 Stem retention.....	6
7.7 Stem durability .....	7
8 Test report .....	11
9 Accompanying information .....	11
9.1 Manufacturer's instructions for use .....	11
9.2 Labelling on the package.....	11
10 Packaging .....	11

## 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.

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 16409 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 7, *Oral care products*.

## iTeh STANDARD PREVIEW (standards.iteh.ai)

ISO 16409:2006

<https://standards.iteh.ai/catalog/standards/sist/8f15b717-3116-4932-8284-89e4a5587f27/iso-16409-2006>

## 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.

## iTeh STANDARD PREVIEW (standards.iteh.ai)

[ISO 16409:2006](https://standards.iteh.ai/catalog/standards/sist/8f15b717-3116-4932-8284-89e4a5587f27/iso-16409-2006)

<https://standards.iteh.ai/catalog/standards/sist/8f15b717-3116-4932-8284-89e4a5587f27/iso-16409-2006>

**iTeh STANDARD PREVIEW**  
**(standards.iteh.ai)**

ISO 16409:2006

<https://standards.iteh.ai/catalog/standards/sist/8f15b717-3116-4932-8284-89e4a5587f27/iso-16409-2006>

# 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 the 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, nor is it applicable 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*, <https://standards.iteh.ai/catalog/standards/sist/8f15b717-3116-4932-8284-89e4a5587f27/iso-16409-2006>

## 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 can 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 secured in the handle or in a connector, or fulfils the function of a handle itself.

**3.5 filament**

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.

iteh STANDARD PREVIEW  
 (standards.iteh.ai)  
<https://standards.iteh.ai/catalog/standards/sist/8f15b717-3116-4932-8284-89e4a5587f27/iso-16409-2006>  
 ISO 16409:2006

**5 Requirements**

**5.1 Defects or contamination**

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

Testing shall be done in accordance with 7.3.

**5.2 Brush size**

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

**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



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 when tested 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.

Testing shall be done in accordance with 7.6.

### 5.5 Stem durability

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

Testing shall be done 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.

## 7 Test methods

ISO 16409:2006  
<https://standards.iteh.ai/catalog/standards/sist/8f15b717-3116-4932-8284-89e4a5587f27/iso-16409-2006>

### 7.1 General

All tests shall be conducted using dry interdental brushes at a temperature of  $(23 \pm 5) ^\circ\text{C}$  and  $(50 \pm 10) \%$  relative humidity.

### 7.2 Pass/fail criteria

For the filament retention, stem retention and stem durability tests, if no product fails, the product set passes. If one manual interdental brush does not meet the minimum requirement, test another eight interdental brushes. If no more manual interdental brushes fail, the product passes. If a total of two or more manual interdental brushes of the sixteen fail, the product fails.

For the determination of the passage hole diameter, see 7.4.

### 7.3 Visual inspection

Visual inspection shall be performed with normal visual acuity, without magnification.