INTERNATIONAL STANDARD

ISO 16409

Second edition 2016-10-15

Dentistry — Oral care products — Manual interdental brushes

Médecine bucco-dentaire — Produits de soins bucco-dentaires — Brosses interdentaires manuelles



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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.

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).

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Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information.

The committee responsible for this document is 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 with the following changes:

- addition of bigger brush size 8 in Table 1;
- specification of number of test samples (eight manual interdental brushes) in Clause 6;
- clarification of measuring procedure for the passage hole diameter for cylindrical and tapered brush heads.

It also incorporates the Amendment ISO 16409:2006/Amd 1:2010.

Introduction

Contain polication.

Recurrence of the containing of the containin 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 regions.

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Dentistry — Oral care 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 and consisting of a wired stem with inserted filaments. It also specifies the accompanying information such as manufacturer's instructions for use and labelling of the packaging.

Excluded are interdental brushes with a plastic core.

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 documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. 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* (3.5) emanating radially from a *stem* (3.4) intended for cleaning of interdental surfaces

3.2

interdental brush head

part of *manual interdental brush* (3.1), which passes in and out of spaces between the teeth to clean the exposed surfaces

Note 1 to entry: The brush head may be fixed or removable, but is fixed during use.

3.3

interdental brush handle

part of manual interdental brush (3.1), which holds the stem (3.4) of the manual interdental brush

3.4

stem

central support structure of the manual *interdental brush head* (3.2), usually composed of twisted wire, which secures the *filaments* (3.5)

Note 1 to entry: The stem is either secured

- in the handle,
- in a connector, or
- fulfils the function of a handle itself.