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BSI Standards Publication

Dentistry — Manual toothbrushes — General requirements and test methods

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National foreword

This British Standard is the UK implementation of EN ISO 20126:2022. It is identical to ISO 20126:2022. It supersedes BS EN ISO 20126:2012+A1:2018, which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/106/7, Oral hygiene products.

A list of organizations represented on this committee can be obtained on request to its committee manager.

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Dentistry - Manual toothbrushes - General requirements and test methods (ISO 20126:2022)

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dents manuelles - Exigences générales et
méthodes d'essai (ISO 20126:2022)

Zahnheilkunde - Handzahnbürsten - Allgemeine
Anforderungen und Prüfverfahren (ISO 20126:2022)

This European Standard was approved by CEN on 12 February 2022.

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COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

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European foreword

This document (EN ISO 20126:2022) has been prepared by Technical Committee ISO/TC 106 "Dentistry" in collaboration with Technical Committee CEN/TC 55 "Dentistry" the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by September 2022, and conflicting national standards shall be withdrawn at the latest by September 2022.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 20126:2012.

Any feedback and questions on this document should be directed to the users' national standards body/national committee. A complete listing of these bodies can be found on the CEN website.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 20126:2022 has been approved by CEN as EN ISO 20126:2022 without any modification.

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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 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*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 55, *Dentistry*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This third edition cancels and replaces the second edition (ISO 20126:2012), which has been technically revised. It also incorporates the Amendment ISO 20126:2012/Amd.1:2018.

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

- a requirement (4.7) and a test method (5.8) for filament end-rounding have been added;
- the scope has been contracted to exclude specific types of manual toothbrushes from the application of this document.

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.

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Introduction

This document is intended to determine the physical properties of manual toothbrushes which are used for the removal of dental plaque and oral debris in order to facilitate oral hygiene.

Specific qualitative and quantitative requirements for freedom from biological hazards are not included in this document. It is recommended that, in assessing possible biological hazards, reference be made to ISO 7405 and ISO 10993-1.

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Dentistry — Manual toothbrushes — General requirements and test methods

1 Scope

This document specifies requirements and test methods for the physical properties of manual toothbrushes in order to promote the safety of these products for their intended use.

This document does not specify any requirements and test methods for the physical properties of toothbrushes for which all the cleaning elements in the head are elastomer.

This document does not apply to manual single tuft toothbrushes, single use, interdental and powered oral hygiene devices. These types of oral hygiene products are evaluated for their safety in-use by appropriate test methods or clinical trials.

In addition, for the filaments end-rounding requirements, this document does not apply to particular filament types which are very thin (less than 0,1 mm outside diameter) or have no sharp edges (e.g. tapered, feathered, with split tips, or spherical cap) or non-synthetic filaments, where applying end-rounding process is inappropriate or impossible. These types of manual toothbrushes are evaluated for their safety in-use by appropriate test methods or clinical trials appropriately.

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*

ISO 22254, *Dentistry — Manual toothbrushes — Resistance of tufted portion to deflection*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 1942 and ISO 22254 and the following apply.

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

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

— IEC Electropedia: available at <https://www.electropedia.org/>

3.1

manual toothbrush

hand-powered device, the working end of which carries *filaments* (3.3) primarily for cleaning surfaces within the oral cavity

3.2

brush head

working end of a *manual toothbrush* (3.1) to which the *filaments* (3.3) are attached

[SOURCE: ISO 22254:2005, 3.2, modified — the word "manual" has been added.]