

| | | |
|------------|---|--|
| STN | Stomatológia Ručné zubné kefky Všeobecné podmienky a skúšobné metódy (ISO 20126: 2022) | STN EN ISO 20126 84 0007 |
|------------|---|--|

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

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 07/22

Obsahuje: EN ISO 20126:2022, ISO 20126:2022

Oznámením tejto normy sa ruší
STN EN ISO 20126 (84 0007) z augusta 2012

135168

EUROPEAN STANDARD

EN ISO 20126

NORME EUROPÉENNE

EUROPÄISCHE NORM

March 2022

ICS 97.170

Supersedes EN ISO 20126:2012, EN ISO
20126:2012/A1:2018

English Version

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

Médecine bucco-dentaire - Brosses à 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.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of 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 United Kingdom.



EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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

EN ISO 20126:2022 (E)

| Contents | Page |
|-------------------------------|-------------|
| European foreword..... | 3 |

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.

INTERNATIONAL STANDARD

ISO 20126

Third edition
2022-03

Dentistry — Manual toothbrushes — General requirements and test methods

*Médecine bucco-dentaire — Brosses à dents manuelles — Exigences
générales et méthodes d'essai*



Reference number
ISO 20126:2022(E)

© ISO 2022

ISO 20126:2022(E)**COPYRIGHT PROTECTED DOCUMENT**

© ISO 2022

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: 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 Requirements | 3 |
| 4.1 Pass-fail criteria..... | 3 |
| 4.1.1 Pass-fail criteria except for filament end-rounding..... | 3 |
| 4.1.2 Pass-fail criteria for filament end-rounding..... | 3 |
| 4.2 Physical inspection..... | 3 |
| 4.3 Tuft retention..... | 3 |
| 4.4 Handle impact strength..... | 3 |
| 4.5 Fatigue resistance..... | 4 |
| 4.6 Fatigue resistance after chemical challenge..... | 4 |
| 4.7 Filament end-rounding..... | 4 |
| 5 Test method | 4 |
| 5.1 Sampling..... | 4 |
| 5.2 General test conditions..... | 4 |
| 5.3 Physical inspection..... | 4 |
| 5.4 Tuft retention test..... | 4 |
| 5.4.1 Apparatus..... | 4 |
| 5.4.2 Procedure..... | 4 |
| 5.5 Handle impact test..... | 5 |
| 5.5.1 Apparatus..... | 5 |
| 5.5.2 Procedure..... | 6 |
| 5.6 Fatigue resistance test..... | 7 |
| 5.6.1 Apparatus..... | 7 |
| 5.6.2 Procedure..... | 8 |
| 5.7 Fatigue resistance test after chemical challenge..... | 8 |
| 5.7.1 Apparatus and chemicals..... | 8 |
| 5.7.2 Procedure..... | 8 |
| 5.8 Visual inspection for filament end-rounding..... | 9 |
| 5.8.1 General..... | 9 |
| 5.8.2 Apparatus..... | 9 |
| 5.8.3 Procedure..... | 9 |
| 6 Test report | 10 |
| 7 Marking and labelling | 10 |
| 8 Packaging | 10 |
| Bibliography | 11 |

ISO 20126:2022(E)

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).

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).

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.

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.

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*

koniec náhľadu – text ďalej pokračuje v platenej verzii STN