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BSI Standards Publication

Dentistry - Integrated dental floss and handles

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National foreword

This British Standard is the UK implementation of EN ISO 28158:2018. It supersedes BS EN ISO 28158:2010, which is withdrawn.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 secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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Compliance with a British Standard cannot confer immunity from legal obligations.

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English Version

Dentistry - Integrated dental floss and handles (ISO 28158:2018)

Médecine bucco-dentaire - Porte-fil et fil
dentaire intégré (ISO 28158:2018)

Zahnheilkunde - Zahnseide im
Halter (ISO 28158:2018)

This European Standard was approved by CEN on 13 August 2018.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
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CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

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European foreword

This document (EN ISO 28158:2018) 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of an identical text or by endorsement, at the latest by April 2019, and conflicting national standards shall be withdrawn at the latest by April 2019.

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 28158:2010.

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, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 28158:2018 has been approved by CEN as EN ISO 28158:2018 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).

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.

This second edition cancels and replaces the first edition (ISO 28158:2010), which has been technically revised.

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

- inclusion of the alternative test method for the strength of the products using a tensile test equipment (e.g. push-pull force gauge, tensile testing equipment or equivalent);
- addition of the requirement that having no displacement which is more than 10 mm of the loading point in the direction of the loading at the force of 10 N;
- addition of the directions for procedure of tooth cleaning using the integrated dental floss and handles, if necessary, and a recommendation on safety information recommending the user to apply a gentle "sawing" or "zig-zag" motion of the floss during insertion into and removal of the floss from the area between teeth to reduce possible injury to the interdental gingiva potentially caused by the floss snapping forcefully into the soft gingival tissue.

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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Dentistry - Integrated dental floss and handles

1 Scope

This document specifies the requirements and test methods for integrated dental floss and handles used for home care, community care, professional care of oral health or a part of dental treatment.

This document is applicable to integrated dental floss and handles for manual use. It does not include dental floss and handles which contain a continuous supply of dental floss, or handles to which the floss is subsequently added.

This document excludes specific qualitative and quantitative test methods for demonstrating freedom from unacceptable biological risks. For assessment of such biological risks, see ISO 10993-1 and ISO 7405.

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*

3 Terms and definitions

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

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

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <http://www.electropedia.org/>

3.1

dental floss

multiple filaments gathered into thread, spun yarn, single filament or tape, commonly synthetic fibre, with or without coating material(s), designed for the removal of plaque and/or debris from the proximal surfaces of natural or artificial teeth and the gingival surfaces of pontics of fixed prostheses

[SOURCE: ISO 1942:2009, 2.69, modified]

3.2

integrated dental floss and handle

oral hygiene device holding *dental floss* (3.1) as a fixed integral part