

STN	Stomatológia Držiaky s integrovanou dentálnou niťou (ISO 28158: 2018)	STN EN ISO 28158 85 6359
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Dentistry - Integrated dental floss and handles (ISO 28158:2018)

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. 02/19

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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)

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EN ISO 28158:2018 (E)

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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of an identical text or by endorsement, at the latest by April 2019, and conflicting national standards shall be withdrawn at the latest by April 2019.

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Endorsement notice

The text of ISO 28158:2018 has been approved by CEN as EN ISO 28158:2018 without any modification.

INTERNATIONAL STANDARD

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Second edition
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Dentistry — Integrated dental floss and handles

Médecine bucco-dentaire — Porte-fil et fil dentaire intégré



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ISO 28158:2018(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).

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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.

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*

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