

BSI Standards Publication

Dentistry — **Endodontic absorbent points**



BS EN ISO 7551:2023 BRITISH STANDARD

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National foreword

This British Standard is the UK implementation of EN ISO 7551:2023. It is identical to ISO 7551:2023. It supersedes BS EN ISO 7551:1998, which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/106/1, Dental restorative and orthodontic materials.

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

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English Version

Dentistry - Endodontic absorbent points (ISO 7551:2023)

Médecine bucco-dentaire - Cônes absorbants utilisés en endodontie (ISO 7551:2023)

Zahnheilkunde - Absorbierende Spitzen (ISO 7551:2023)

This European Standard was approved by CEN on 3 March 2023.

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

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European foreword

This document (EN ISO 7551:2023) 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of an identical text or by endorsement, at the latest by November 2023, and conflicting national standards shall be withdrawn at the latest by November 2023.

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 7551:1998.

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, Türkiye and the United Kingdom.

Endorsement notice

The text of ISO 7551:2023 has been approved by CEN as EN ISO 7551:2023 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 document 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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This document was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 1, *Filling and restorative materials*, 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 second edition cancels and replaces the first edition (ISO 7551:1996), which has been technically revised.

The main changes are as follows:

- the format has been updated;
- absorbent points other than standard taper absorbent points have been added;
- <u>Table 2</u> has been added for the dimensions of greater taper absorbent points;
- the sizes of the absorbent points specified in this document have been aligned with the sizes for obturating points specified in ISO 6877 and for instruments from the ISO 6360 series;
- the nomenclature of "numbering system" has been changed to "nominal size designation" of the tip;
- Figure 2 has been removed.

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

The following information should be taken into account when using this document: specific qualitative and quantitative test methods for demonstrating freedom from unacceptable biological risks are not included in this document but it is recommended that, for the assessment of such biological risks, reference be made to ISO 7405 and ISO 10993-1.

Dentistry — **Endodontic absorbent points**

1 Scope

This document specifies the requirements and test methods for sterilized absorbent points used in endodontic procedures. Absorbent points are marketed sterilized or non-sterilized. The requirements apply to absorbent points which have been sterilized once in a manner approved by the manufacturer. This document specifies numerical systems and a colour-coding system for designating the sizes of absorbent points.

<u>Clause 7</u> specifies the labelling and packaging needed, including the instructions for use. A claim by the manufacturer that the contents of the unopened pack are sterile is the responsibility of the manufacturer (see <u>Table 2</u>). This document does not specify requirements or test methods for sterility.

NOTE 1 Reference to applicable national regulations can be made.

Reference is made to internationally accepted pharmacopoeia.

NOTE 2 National requirements can apply.

Standards on methods of validating sterilization processes are also available: ISO 11137-1, ISO 11137-2 and ISO 11137-3.

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 3630-1, Dentistry — Endodontic instruments — Part 1: General requirements

ISO 6360-1, Dentistry — Number coding system for rotary instruments — Part 1: General characteristics

ISO 8601-1, Date and time — Representations for information interchange — Part 1: Basic rules

ISO 15223-1, Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements

ISO 20417, Medical devices — Information to be supplied by the manufacturer

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 1942, ISO 3630-1 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/