BS EN ISO 5139:2023

BSI Standards Publication

Dentistry — Polymer-based composite machinable blanks

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The UK participation in its preparation was entrusted to Technical Committee CH/106/-/1, Dental CAD/CAM systems.

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

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Dentistry - Polymer-based composite machinable blanks (ISO 5139:2023)

Médecine bucco-dentaire - Ébauches usinables en composite à base de polymères (ISO 5139:2023)

Zahnheilkunde - Maschinell bearbeitbare Rohlinge aus Kompositen auf Polymerbasis (ISO 5139:2023)

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European foreword

This document (EN ISO 5139:2023) 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of an identical text or by endorsement, at the latest by November 2023, and conflicting national standards shall be withdrawn at the latest by November 2023.

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Endorsement notice

The text of ISO 5139:2023 has been approved by CEN as EN ISO 5139:2023 without any modification.

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Foreword

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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 9, *Dental CAD/CAM systems,* 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).

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Introduction

Specific qualitative and quantitative test methods for demonstrating freedom from unacceptable biological hazards are not included in this document, but it is recommended that, for the assessment of possible biological hazards, reference should be made to ISO 10993-1 and ISO 7405.

Requirements for the materials properties of polymer-based composite machinable blanks are not included in this document, but these requirements will be included in a future edition of ISO 10477.

The test method to determine the bonding properties between blank and holding jig is not included in this document, but it is recommended to adopt the test procedure given in Annex C when measuring the bonding properties between blank and holding jig.

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Dentistry — Polymer-based composite machinable blanks

1 Scope

This document specifies the characteristics of polymer-based composite machinable blanks with respect to the milling process and provides the test methods that address the clinical issues specific to those materials. In addition, this document specifies the items to be described on the packaging and materials, as well as descriptions to be included in the instructions for use.

The polymer-based composite machinable blanks covered in this document are blanks that are used for fabricating permanent dental restorative appliances (e.g. single crowns or inlays) by milling processes. They do not include large-sized blanks (e.g. discs) that allow for the fabrication of two or more units of crowns or bridges from one blank or materials for temporary use.

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 4049:2019, *Dentistry — Polymer-based restorative materials*

ISO 6344-3, *Coated abrasives — Determination and designation of grain size distribution — Part 3: Microgrit sizes P240 to P5000*

ISO 6872:2015, *Dentistry — Ceramic materials*

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

ISO 18675:2022, *Dentistry — Machinable ceramic blanks*

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 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
polymer-based composite machinable blank
piece of solid *polymer-based composite* (3.2) that is subjected to subtractive methods to remove material from the piece leaving the final desired part

3.2
polymer-based composite
polymer-based dental material including either organic filler or inorganic filler, or both fillers that have been treated by a coupling agent to ensure chemical bonding with the polymeric matrix

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