

Dentistry - Multifunction handpieces (ISO 22569:2020)

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

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English Version

Dentistry - Multifunction handpieces (ISO 22569:2020)

Médecine bucco-dentaire - Pièces à mains
multifonctions (ISO 22569:2020)

Zahnheilkunde - Mehrfunktionshandstücke (ISO
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European foreword

This document (EN ISO 22569:2020) 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of an identical text or by endorsement, at the latest by January 2021, and conflicting national standards shall be withdrawn at the latest by January 2021.

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Endorsement notice

The text of ISO 22569:2020 has been approved by CEN as EN ISO 22569:2020 without any modification.

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Foreword

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This document was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 4, *Dental instruments*, 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).

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

For many years, dental multifunction handpieces have been used in the field of dentistry to carry out treatment in the oral cavity of the patient.

Multifunction handpieces are connected to dental units and provide the user with water, air and spray for treatment purposes. Some multifunction handpieces provide also illumination of the situs.

Technological progress enables continual development of improved and new handpieces with simplified handling and extended range of applications.

These handpieces are produced by the dental industry as high-quality medical devices under application of quality management methods.

This document describes the applicable technical properties of products in order to maintain this high level of quality.

Dentistry — Multifunction handpieces

1 Scope

This document specifies requirements, test methods, instructions for use and marking for multifunction handpieces (colloquially called “syringes”) intended to be used in the oral cavity of the patient.

This document does not apply to dental handpieces and motors, intraoral cameras, dental polymerisation lamps, powered scalers, powder jet handpieces, prophylaxis handpieces, suction cannulas and saliva ejectors.

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 7494-1, *Dentistry — Stationary dental units and dental patient chairs — Part 1: General requirements*

ISO 9687, *Dentistry — Graphical symbols for dental equipment*

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 15223-1, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

ISO 17664, *Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices*

ISO 21530, *Dentistry — Materials used for dental equipment surfaces — Determination of resistance to chemical disinfectants*

ISO 21531, *Dentistry — Graphical symbols for dental instruments*

IEC 60601-1, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

IEC 62366-1, *Medical devices — Part 1: Application of usability engineering to medical devices*

IEC 80601-2-60, *Medical electrical equipment — Part 2-60: Particular requirements for the basic safety and essential performance of dental equipment*

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/>