

Dentistry - Elastomeric auxiliaries for use in
orthodontics (ISO 21606:2022)

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 21606:2022 sisaldab Euroopa standardi EN ISO 21606:2022 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 21606:2022 consists of the English text of the European standard EN ISO 21606:2022.
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English Version

Dentistry - Elastomeric auxiliaries for use in orthodontics
(ISO 21606:2022)

Médecine bucco-dentaire - Auxiliaires élastomériques
utilisés en orthodontie (ISO 21606:2022)

Zahnheilkunde - Elastomeres Zubehör für die
Kieferorthopädie (ISO 21606:2022)

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COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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European foreword

This document (EN ISO 21606:2022) 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of an identical text or by endorsement, at the latest by February 2023, and conflicting national standards shall be withdrawn at the latest by February 2023.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 21606:2007

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Endorsement notice

The text of ISO 21606:2022 has been approved by CEN as EN ISO 21606:2022 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).

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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 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 21606:2007), which has been technically revised.

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

- subclause [5.1](#) has been clarified to type test with specification of specimen test quantity;
- subclause [5.5.2](#) has been clarified with the addition of the word “quickly” to the transfer of specimens from support plate to tensile tester adapters.

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

This document has been developed as a result of the difficulty often encountered by clinicians in making meaningful comparisons between elastomeric auxiliaries using the information currently available from manufacturers and suppliers.

NOTE Auxiliaries include orthodontic elastics, orthodontic elastomeric chains, orthodontic thread, orthodontic elastomeric ligatures and orthodontic elastomeric separators.

Specific qualitative and quantitative requirements for freedom from biological hazards are not included in this document, but it is recommended that in assessing possible biological hazards reference should be made to ISO 10993-1 and ISO 7405.

Dentistry — Elastomeric auxiliaries for use in orthodontics

1 Scope

This document specifies the requirements and their test methods applicable to all elastomeric auxiliaries used for orthodontics both inside and outside the mouth, in conjunction with fixed and removable appliances.

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 3696:1987, *Water for analytical laboratory use — Specification and test methods*

ISO 1942, *Dentistry — Vocabulary*

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

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

elastomeric auxiliary

device with elastomeric properties used for transmission of forces including orthodontic *elastics* (3.2), orthodontic *elastomeric chains* (3.4), orthodontic threads, orthodontic *elastomeric ligatures* (3.5) and orthodontic *elastomeric separators* (3.6)

3.2

elastic

intra-oral and extra-oral elastomeric ring used to apply forces to orthodontic devices

3.3

elastomeric thread

elastomeric strand (that can be hollow) of constant cross-section used to apply forces to orthodontic devices

3.4

elastomeric chain

interconnected elastomeric rings or a multi-perforated elastomeric band used to apply forces to orthodontic devices

3.5

elastomeric ligature

elastomeric ring used to retain wires to orthodontic attachments