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STN	**Stomatológia Stomatologické súpravy a kreslo pre pacienta Časť 1: Všeobecné požiadavky a skúšobné metódy (ISO 7494-1: 2018)**	**STN EN ISO 7494-1 85 5350**

Dentistry - Stationary dental units and dental patient chairs - Part 1: General requirements (ISO 7494-1:2018)

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. 12/18

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Oznámením tejto normy sa ruší
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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 7494-1

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Supersedes EN ISO 6875:2011, EN ISO 7494-1:2011

English Version

Dentistry - Stationary dental units and dental patient chairs - Part 1: General requirements (ISO 7494-1:2018)

Médecine bucco-dentaire - Units dentaires fixes et fauteuils dentaires patient - Partie 1: Exigences générales (ISO 7494-1:2018)

Zahnheilkunde - Fest installierte Behandlungseinheiten und Patientenstühle - Teil 1: Allgemeine Anforderungen und Prüfverfahren (ISO 7494-1:2018)

This European Standard was approved by CEN on 27 May 2018.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
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Ref. No. EN ISO 7494-1:2018 E

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European foreword

This document (EN ISO 7494-1:2018) 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of an identical text or by endorsement, at the latest by January 2019, and conflicting national standards shall be withdrawn at the latest by January 2019.

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 6875:2011 and EN ISO 7494-1:2011.

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, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 7494-1:2018 has been approved by CEN as EN ISO 7494-1:2018 without any modification.

INTERNATIONAL STANDARD

ISO 7494-1

Third edition
2018-06

Dentistry — Stationary dental units and dental patient chairs —

Part 1: General requirements

Médecine bucco-dentaire — Units dentaires fixes et fauteuils dentaires patient —

Partie 1: Exigences générales

Reference number
ISO 7494-1:2018(E)

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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 on 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 the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 6, *Dental equipment*.

This third edition of ISO 7494-1 cancels and replaces ISO 7494-1:2011 and ISO 6875:2011, which has been technically revised.

A list of all parts in the ISO 7494 series can be found on the ISO website.

INTERNATIONAL STANDARD **ISO 7494-1:2018(E)**

Dentistry — Stationary dental units and dental patient chairs —

Part 1: General requirements

1 Scope

This document specifies requirements and test methods for stationary dental units, dental patient chairs, and combinations of both regardless of whether they are or not electrically powered.

This document also specifies requirements for the instructions for use, for the technical description, for marking and for packaging.

Operator's stools, portable dental equipment and operating lights are not in the scope of this document.

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 4073, *Dentistry — Information system on the location of dental equipment in the working area of the oral health care provider*

ISO 7494-2, *Dentistry — Dental units — Part 2: Air, water, suction and wastewater systems*

ISO 8191-1, *Furniture — Assessment of the ignitability of upholstered furniture — Part 1: Ignition source: smouldering cigarette*

ISO 9168, *Dentistry — Hose connectors for air driven dental handpieces*

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

ISO 11143, *Dentistry — Amalgam separators*

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*

IEC 60601-1:2005+AMD1:2012, *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 62353, *Medical electrical equipment — Recurrent test and test after repair of medical electrical equipment*

IEC 80601-2-60:2012, *Medical electrical equipment — Part 2-60: Particular requirements for basic safety and essential performance of dental equipment*

