



SLOVENSKI STANDARD
SIST EN ISO 11498:2000
01-januar-2000

Dental handpieces - Dental low-voltage electrical motors (ISO 11498:1997)

Dental handpieces - Dental low-voltage electrical motors (ISO 11498:1997)

Zahnärztliche Handstücke - Zahnärztliche elektrische Kleinspannungsmotoren (ISO 11498:1997)

Pieces a main dentaires - Moteurs électriques dentaires a basse tension (ISO 11498:1997)

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Ta slovenski standard je istoveten z: EN ISO 11498:1999
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ICS:

11.060.20	Z[à[ç@ã}æ]	Dental equipment
29.160.30	Motorji	Motors

SIST EN ISO 11498:2000 **en**

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EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 11498

May 1999

ICS 11.060.20; 29.160.30

English version

Dental handpieces - Dental low-voltage electrical motors (ISO
11498:1997)

Pièces à main dentaires - Moteurs électriques dentaires à
basse tension (ISO 11498:1997)

Zahnärztliche Handstücke - Zahnärztliche elektrische
Kleinspannungsmotoren (ISO 11498:1997)

This European Standard was approved by CEN on 16 April 1999.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

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

Central Secretariat: rue de Stassart, 36 B-1050 Brussels

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Foreword

The text of the International Standard from Technical Committee ISO/TC 106 "Dentistry" of the International Organization for Standardization (ISO) has been taken over as an European Standard by 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 1999, and conflicting national standards shall be withdrawn at the latest by November 1999.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Endorsement notice

The text of the International Standard ISO 11498:1997 has been approved by CEN as a European Standard without any modification.

NOTE: Normative references to International Standards are listed in annex ZA (normative).

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Annex ZA (normative)
Normative references to international publications
with their relevant European publications

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN</u>	<u>Year</u>
ISO 1942-3	1989	Dental vocabulary - Part 3: Dental instruments	EN 21942-3	1993
ISO 3696	1987	Water for analytical laboratory use - Specification and test methods	EN ISO 3696	1995
ISO 3964	1982	Dentistry - Dental handpieces - Coupling dimensions	EN 23964	1989
ISO 7494	1996	Dental units	EN ISO 7494	1997
ISO 7785-2	1995	Dental handpieces - Part 2: Straight and geared angle handpieces	EN ISO 7785-2	1997
ISO 9687	1993	Dental equipment - Graphical symbols	EN ISO 9687	1995

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INTERNATIONAL
STANDARD

ISO
11498

First edition
1997-02-15

**Dental handpieces — Dental low-voltage
electrical motors**

Pièces à main dentaires — Moteurs électriques dentaires à basse tension

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Reference number
ISO 11498:1997(E)

ISO 11498:1997(E)

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.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

International Standard ISO 11498 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 4, *Dental instruments*.

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International Organization for Standardization
Case postale 56 • CH-1211 Genève 20 • Switzerland
Internet central@iso.ch
X.400 c=ch; a=400net; p=iso; o=isocs; s=central

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Dental handpieces – Dental low-voltage electrical motors

1 Scope

This International Standard specifies requirements and test methods for dental low-voltage electrical motors used in connection with dental handpieces for application on patients. It also contains specifications on manufacturer's instructions, packaging and marking. All tests described in this International Standard are type tests.

Dental low-voltage electrical motors are operated by dental units or as independent mobile devices. They are used for straight and geared angle handpieces.

This International Standard takes priority over IEC 601-1:1988 as specified in the individual clauses of this International Standard.

Only the specifications laid down in this International Standard are applicable.

This International Standard refers to IEC 601-1, the basic standard on safety of medical electrical equipment, wherever relevant, by stating the respective clause numbers of IEC 601-1:1988.

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2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 554:1976, *Standard atmospheres for conditioning and/or testing — Specifications.*

ISO 1942-3:1989, *Dental vocabulary — Part 3: Dental instruments.*

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

ISO 3964:1982, *Dental handpieces — Coupling dimensions.*

ISO 4211:1979, *Furniture — Assessment of surface resistance to cold liquids.*

ISO 7494:1996, *Dental units.*

ISO 7785-2:1995, *Dental handpieces — Part 2: Straight and geared angle handpieces.*

ISO 9687:1993, *Dental equipment — Graphical symbols.*

ISO 13402:1995, *Surgical and dental hand instruments — Determination of resistance against autoclaving, corrosion and thermal exposure.*

IEC 601-1:1988, *Medical electrical equipment — Part 1: General requirements for safety.*

IEC 601-1-2:1993, *Medical electrical equipment — Part 1: General requirements for safety — Part 2: Electromagnetic compatibility of medical electrical equipment and/or systems.*

IEC 651:1979, *Sound level meters.*

3 Definitions

For the purposes of this International Standard, the definitions given in ISO 1942-3 and in IEC 601-1:1988, clause 2, apply.

4 Classification

4.1 Range of free-running speed

Dental low-voltage electrical motors can be classified by their free-running speed range in accordance with table 1.

Table 1 — Classification of motor

Type	Speed range r/min
1	up to 20 000
2	4 000 to 40 000
3	4 000 to over 40 000

4.2 Type of protection against electric shock

Dental low voltage electrical motors are classified as Class II equipment, in which protection against electric shock does not rely on basic insulation only, but in which additional safety precautions such as double insulation or reinforced insulation are provided, there being no provision for protective earthing or reliance upon installation conditions.

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4.3 Degree of protection against electric shock

Dental low-voltage electrical motors shall be grouped as either Type B or Type BF equipment (Type B equipment with an F-type isolated (floating) applied part).

4.4 Operating conditions

4.4.1 Intermittent operation

Dental low-voltage electrical motors are a type of dental equipment which is operated intermittently.

4.4.2 Environment

Dental low-voltage electrical motors shall not be used in the presence of a flammable anaesthetic gas mixed with air or with oxygen or nitrous oxide.

5 Requirements

5.1 General

5.1.1 Construction

The dental low-voltage electrical motor shall be constructed to provide safe and reliable operation and, if repairable on site, should be capable of being easily disassembled and reassembled for maintenance and repair, using readily available tools or those supplied by the manufacturer.

5.1.1.1 Mechanical strength

If not otherwise described by the manufacturer, the dental low-voltage electrical motor shall not incur damage such that its safety is no longer warranted as a result of a free fall from a height of 1 m onto a plain smooth ceramic floor surface.

Testing shall be carried out in accordance with 7.3.1 and, if applicable, IEC 601-1:1988, clause 21.5.

5.1.1.2 Surfaces, corners and edges

There shall be no uncovered rough surfaces, sharp corners or edges which may cause injury or damage.

Verification shall be carried out visually (7.3.1).

5.1.2 Power connection

The dental low-voltage electrical motor shall be capable of being easily disconnected from and reconnected to the power supply.

The service shall be supplied from a dental unit complying with ISO 7494.

Testing shall be carried out in accordance with 7.3.2.

5.1.3 Operating controls

5.1.3.1 General

Operating controls shall be designed and located to minimize unintentional activation.

Graphical symbols for operating controls and functions shall be in accordance with ISO 9687.

Verification shall be carried out visually (7.3.1).

5.1.3.2 Speed

The dental low-voltage electrical motor, or dental low-voltage electrical motor connected to a dental unit, shall be provided with operating controls to change the speed as described by the manufacturer.

Verification shall be carried out visually (7.3.1)

5.1.3.3 Direction of rotation

The dental low-voltage electrical motor, or dental low-voltage electrical motor connected to a dental unit, shall be provided with operator controls to allow clockwise and anticlockwise rotation as described by the manufacturer.

The controls shall be located on the dental low-voltage electrical motor itself or on the dental unit.

Verification shall be carried out visually (7.3.1)

5.1.4 Disinfection and cleaning

All accessible exterior parts of the dental low-voltage electrical motor shall be capable of undergoing surface disinfection and cleaning without causing deterioration of the motor's surface or markings, using agents recommended by the manufacturer.

Testing shall be carried out in accordance with 7.2.7.

5.1.5 Sterilizability

If applicable, the accessible exterior surfaces of the dental low-voltage electrical motor shall be sterilizable. Testing shall be carried out according to the manufacturer's instructions. The surfaces shall withstand a minimum of 250

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