Dentistry - Laser welding and filler materials (ISO 28319:2018)



#### EESTI STANDARDI EESSÕNA

#### NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 28319:2018 sisaldab Euroopa standardi EN ISO 28319:2018 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 28319:2018 consists of the English text of the European standard EN ISO 28319:2018.		
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.		
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 16.05.2018.	Date of Availability of the European standard is 16.05.2018.		
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#### ICS 11.060.10

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## EUROPEAN STANDARD

NORME EUROPÉENNE

### **EN ISO 28319**

## EUROPÄISCHE NORM

May 2018

ICS 11.060.10

Supersedes EN ISO 28319:2010

#### **English Version**

# Dentistry - Laser welding and filler materials (ISO 28319:2018)

Médecine bucco-dentaire - Soudage par laser et matériaux d'apport (ISO 28319:2018)

Zahnheilkunde - Laserschweißen (ISO 28319:2018)

This European Standard was approved by CEN on 15 March 2018.

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 CEN-CENELEC Management Centre 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 CEN-CENELEC Management Centre has the same status as the official versions.

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

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

### **European foreword**

This document (EN ISO 28319:2018) 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 November 2018, and conflicting national standards shall be withdrawn at the latest by November 2018.

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 28319:2010.

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 28319:2018 has been approved by CEN as EN ISO 28319:2018 without any modification.

Cor	itent	S		Page	
Fore	word			iv	
1	Scop	e		1	
2	( ) , <del>*</del>		ferences		
3					
4			S		
	4.1	Chemi	cal compositionMetallic materials to be joined		
			Filler material		
			Hazardous elements in filler material		
	4.2		ipatibility		
	4.3	Mecha	nical strength of laser welded joint (tensile strength)	2	
	4.4	Corros	ion resistance	3	
		4.4.1			
		4.4.2			
	4.5	Laser v	velding process	3	
5	Sam	pling		3	
6	Prep	aration	of specimens	3	
	6.1		1		
	6.2		ens for tensile testing		
			General		
		6.2.2			
	6.3	-	ens for corrosion testing		
		6.3.1 6.3.2			
_	3.7				
7			t and test methods		
	7.1 7.2	Chomi	inspectional composition		
	7.2	Tensile	testing		
	7.5	7 3 1	General	6	
		7.3.2		6	
		7.3.3			
	7.4	Corros	ion resistance by static immersion test		
		7.4.1	Reagents	7	
		7.4.2	Apparatus	7	
		7.4.3	Test solution		
		7.4.4	Test procedure		
		7.4.5 7.4.6	Analysis Migrogonia in an action		
		7.4.6 7.4.7	Microscopic inspection		
8	Instr	uction fo	or use		
9			labelling		
-	9.1	_	g		
	9.2		ng		
10	Test	est report			
Anno	ex A (in	formative	e) Laser welding process	10	
Ribli	iograpł	ıv		13	

#### 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 <a href="https://www.iso.org/directives">www.iso.org/directives</a>).

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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: <a href="https://www.iso.org/iso/foreword.html">www.iso.org/iso/foreword.html</a>.

This document was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 2, *Prosthodontic materials*.

This second edition cancels and replaces the first edition (ISO 28319:2010), which has been technically revised.

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

- a) reference to the corrosion standard ISO 10271:2011, for corrosion test methods and measurements has been added;
- b) a corrosion limit for the static corrosion test has been specified;
- c) Annex A has been revised in order to describe the laser welding process.

## **Dentistry** — Laser welding and filler materials

#### 1 Scope

This document specifies requirements and test methods for laser welding and the filler materials thereto used in the dental laboratory for welding of metallic restorations and appliances.

For filler materials used in laser welding, this document also specifies the information given in the instructions for use, marking and labelling.

#### 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 6344-1, Coated abrasives — Grain size analysis — Part 1: Grain size distribution test

ISO 10271:2011, Dentistry — Corrosion test methods for metallic materials

ISO 15223-1:2016, Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements

ISO 22674:2016, Dentistry — Metallic materials for fixed and removable restorations and appliances

#### 3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 1942, ISO 22674 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at <a href="http://www.electropedia.org/">http://www.electropedia.org/</a>
- ISO Online browsing platform: available at <a href="https://www.iso.org/obp">https://www.iso.org/obp</a>

#### 3.1

#### laser welding

method for joining similar or dissimilar metallic materials, using a laser beam as the heat source, with or without a metallic filler material (welding rod), which produces coalescence by melting abutting zones of metallic material components thereby creating a common fusion zone

#### 3.2

#### filler material

<a href="laser welding"><a href="laser welding"><a href="laser welding">(3.1)</a></a>