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Dentistry — Laser welding and filler materials

Médecine bucco-dentaire — Soudage par laser et matériaux d'apport

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Foreword

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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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Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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 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 http://www.electropedia.org/

— ISO Online browsing platform: available at https://www.iso.org/obp

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
<laser welding> metallic filling material used for *laser welding* (3.1)

4 Requirements

4.1 Chemical composition

4.1.1 Metallic materials to be joined

The metallic materials to be joined shall conform to ISO 22674:2016, 5.1 and 5.2.

4.1.2 Filler material

4.1.2.1 Chemical composition

For all elements that are present in excess of 1,0 % (mass fraction), the percentage by mass of each of the constituent elements shall be declared by the manufacturer and shall be reported to a precision of 0,1 % (mass fraction).

Any element that is present in a concentration in excess of 0,1 % (mass fraction), but not in excess of 1,0 % (mass fraction), shall be identified either by name or symbol.

4.1.2.2 Permitted deviation from the reported composition

For silver or noble-metal elements in filler materials, the percentage shall not deviate by more than 0,5 % (mass fraction) from the values stated in the instructions for use.

For base-metal elements in filler materials, all elements, present with more than 20 % (mass fraction) shall not deviate from the value stated in the instructions for use by more than 2 % (mass fraction). Those present in excess of 1 % (mass fraction) but not in excess of 20 % (mass fraction) shall not deviate from the value stated in the instructions for use by more than 1 % (mass fraction).

4.1.3 Hazardous elements in filler material

4.1.3.1 Recognized hazardous elements

For the purposes of this document the elements nickel, cadmium, beryllium and lead are designated to be hazardous elements.

4.1.3.2 Permitted limits for hazardous elements

The filler material shall contain no more than 0,02 % (mass fraction) of cadmium or beryllium or lead. If the filler material contains more than 0,1 % (mass fraction) of nickel, the percentage shall not exceed the amount indicated on the package or label or insert.

4.2 Biocompatibility

Specific qualitative and quantitative requirements for freedom from biological hazard 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.

4.3 Mechanical strength of laser welded joint (tensile strength)

If the 0,2 % proof strength of both of the metallic materials to be joined by laser welding is more than 350 MPa, the tensile strength of laser-welded specimens shall be at least 350 MPa.

If the 0,2 % proof strength of either one or both of the metallic materials to be joined by laser welding is below 350 MPa, the tensile strength shall exceed the lower 0,2 % proof strength of the two.

Testing shall be carried out in accordance with 7.3.