



## EUROPEAN AND INTERNATIONAL STANDARDS ON MEDICAL DEVICES FOR DENTISTRY

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### ABSTRACT

Standards are produced for many different products and services, and may be created for company, national, regional or global application. In Europe there are three different categories of standard: **International standard** – a standard adopted by an international standardization organization; **European standard** – a standard adopted by a European standardization body; **National standard** – a standard adopted by a national standardization body and made available to the public. Harmonized standards play a special role in the EU. A harmonised standard is a European standard elaborated on the basis of a request from the European Commission to a recognised European Standards Organisation to develop a European standard that provides solutions for compliance with a legal provision. Most standards for dental materials have been harmonized through a so-called cumulative standard (EN 1641:2009 - Dentistry - Medical devices for dentistry - Materials). This European Standard specifies general requirements for materials used in the practice of dentistry for the restoration of the form and function of the dentition and which are medical devices. A multiplicity of laws, standards, and recommendations regulate the marketing of medical devices. The medical doctor and the dentist should be informed about the European and international standards concerning medical devices and use only those for which appropriate information is available. The manufacturer/importer is responsible for its products and is potentially liable for damages.

**Key words:** European standards, international standards, medical devices, dentistry

A **standard** is a document that provides requirements, specifications, guidelines or characteristics that can be used consistently to ensure that materials, products, processes and services are fit for their purpose. One dictionary definition of standard is: “a document specifying nationally or internationally agreed properties of manufactured goods, principles for procedure, etc”. (*New Shorter Oxford English Dictionary*)

Standards are produced for many different products and services, and may be created for company, national, re-

gional or global application. They may be used on a voluntary basis, or made mandatory by company policy, national or international regulation, or by law.

In Europe there are three different categories of standard:

- **International standard** – a standard adopted by an international standardization organization;
- **European standard** – a standard adopted by a European standardization body;
- **National standard** – a standard adopted by a national standardization body and made available to the public.

Standards play an important role as tools for organizing daily life. Standardization, which is done by interested groups, is the planned unification of material and immaterial matters for the benefit of the general public.

Standards are jointly defined by manufacturers, traders, users, and scientists, based on set rules. One of the aims of standards is to determine minimum requirements for the quality of products, such as medical devices and dental materials. Standards are intended to provide protection (e.g., of the consumers and the environment) and save costs by means of standardized elements.

Standards are regularly revised to adjust them to the newest technological standards. It is the general philosophy of the International Organization for Standardization (ISO) that international standards bring technological, economic and societal benefits. They help to harmonize technical specifications of products and services making industry more efficient and breaking down barriers to international trade. Conformity to International Standards helps reassure consumers that products are safe, efficient and good for the environment. They also make trade between countries easier and fairer [1].

ISO has over 19 500 standards touching almost all aspects of daily life. When products and services conform to International Standards consumers can have confidence that they are safe, reliable and of good quality. For example, ISO's standards on road safety, toy safety and secure medical packaging are just a selection of those that help make the world a safer place. International Standards on air,

water and soil quality, on emissions of gases and radiation and environmental aspects of products contribute to efforts to preserve the environment and the health of citizens.

ISO standards draw on international expertise and experience and are therefore a vital resource for **governments** when developing public policy. National governments can use ISO standards to support public policy, for example, by referencing ISO standards in regulations. This has a number of benefits, including:

- **Expert opinion** - ISO standards are developed by experts. By integrating an ISO standard into national regulation, governments can benefit from the opinion of experts without having to call on their services directly.

- **Opening up world trade** - ISO standards are international and adopted by many governments. By integrating ISO standards into national regulation, governments help to ensure that requirements for imports and exports are the same the world over, therefore facilitating the movement of goods, services and technologies from country to country [2].

International Standards are strategic tools and guidelines to help companies tackle some of the most demanding challenges of modern business. They ensure that business operations are as efficient as possible, increase productivity and help companies access new markets. Benefits include:

- **Cost savings** - International Standards help optimise operations and therefore improve the bottom line

- **Enhanced customer satisfaction** - International Standards help improve quality, enhance customer satisfaction and increase sales

- **Access to new markets** - International Standards help prevent trade barriers and open up global markets

- **Increased market share** - International Standards help increase productivity and competitive advantage

- **Environmental benefits** - International Standards help reduce negative impacts on the environment. Businesses also benefit from taking part in the standard development process [3].

However, based on general experience, the generation of standards is a very time-consuming process and may take several years in some cases. An ISO standard is developed by a panel of experts, within a **technical committee**. Details about the further procedures are presented below (Fig.1) [2].

Fig. 1. Standard development process.



Therefore, newer technological developments might not be reflected by some standards. Overall, however, standards have proved to be valuable for quality assurance in all dental areas (and in other areas as well) for more than 80 years.

**Harmonized standards** play a special role in the EU. A harmonised standard is a European standard elaborated on the basis of a request from the European Commission to a recognised European Standards Organisation to develop a European standard that provides solutions for compliance with a legal provision. Such a request provides guidelines which requested standards must respect to meet the essential requirements or other provisions of relevant European Union harmonisation legislation. Their titles are published in the official journal of the EU [4].

The use of these standards remains voluntary. Manufacturers, other economic operators or conformity assessment bodies are free to choose any other technical solution that provides compliance with the mandatory legal requirements.

Within the context of some directives or regulations voluntary European standards supporting implementation of relevant legal requirements are not called “harmonised standards”. Such legislation and related European standards are also included in this information service, if relevant legislation foresees a need for a Commission standardisation request to European Standards Organisations and if publication of references in the Official Journal of the European Union is foreseen as a precondition for presumption of conformity or for other legal effect.

Standards that are not harmonized in terms of the MDD are characterized by a lesser obligation; this may play a role in cases of liability or legal conflicts. Harmonized standards are of high importance within the framework of European legislation on medical devices. The wording of the law explicitly calls them a possibility to specify the essential requirements that have to be met by a medical device regarding performance, safety, and quality.

Most standards for dental materials have been harmonized through a so-called cumulative standard (EN 1641:2009 - Dentistry - Medical devices for dentistry - Materials) [5]. This European Standard specifies general requirements for materials used in the practice of dentistry for the restoration of the form and function of the dentition and which are medical devices.

For the purposes of EN 1641 these materials are defined as restorative and orthodontic materials. Dental implants are specifically excluded and described in EN 1642. EN 1641 also specifies general requirements for materials used in the practice of orthodontics. This standard includes requirements for intended performance, design attributes, components, sterilization, packaging, marking, labelling, and information supplied by the manufacturer. **Since 2010 EN 1641:2009 has the status of Bulgarian standard.**

The following referenced documents are indispensable for the application 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.

EN 15223-1 to replace EN 980, as Europe’s Symbols for use in the labelling of medical devices

EN 1041, Information supplied by the manufacturer of medical devices

EN 21563, Alginate dental impression material (ISO 1563:1990)

EN ISO 1564, Dental aqueous impression materials based on agar (ISO 1564:1995) EN ISO 3107, Dentistry — Zinc oxide/eugenol and zinc oxide/non-eugenol cements (ISO 3107:2004)

EN ISO 4049, Dentistry - Polymer-based filling, restorative and luting materials (ISO 4049:2000)

EN ISO 4823, Dentistry - Elastomeric impression materials (ISO 4823:2000)

EN ISO 6872, Dentistry - Ceramic materials (ISO 6872:2008)

EN ISO 6873, Dental gypsum products (ISO 6873:1998)

EN ISO 6874, Dentistry - Polymer-based pit and fissure sealants (ISO 6874:2005) EN ISO 6876, Dental root canal sealing materials (ISO 6876:2001)

EN ISO 6877, Dentistry - Root-canal obturating points (ISO 6877:2006)

EN ISO 7405, Dentistry - Evaluation of biocompatibility of medical devices used in dentistry (ISO 7405:2008)

EN ISO 7491, Dental materials - Determination of colour stability (ISO 7491:2000) EN ISO 7551, Dental absorbent points (ISO 7551:1996)

EN ISO 9333, Dentistry - Brazing materials (ISO 9333:2006)

EN ISO 9693, Metal-ceramic dental restorative systems (ISO 9693:1999)

EN ISO 9917-1, Dentistry - Water-based cements - Part 1: Powder/liquid acid-base cements (ISO 9917-1:2007)

EN ISO 9917-2, Dental water-based cements - Part 2: Light-activated cements (ISO 9917-2:1998) EN ISO 10139-1, Dentistry - Soft lining materials for removable dentures - Part 1: Materials for short-term use (ISO 10139-1:2005)

EN ISO 10139-2, Dentistry - Soft lining materials for removable dentures — Part 2: Materials for long-term use (ISO 10139-2:1999)

EN ISO 10271, Dental metallic materials - Corrosion test methods (ISO 10271:2001) EN ISO 10477, Dentistry — Polymer-based crown and bridge materials (ISO 10477:2004)

EN ISO 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing (ISO 10993-1:2003)

EN ISO 13716, Dentistry - Reversible-irreversible hydrocolloid impression material systems (ISO 13716:1999)

EN ISO 14155:2011, Clinical investigation of medical devices for human subjects

EN ISO 14971, Medical devices - Application of risk management to medical devices (ISO 14971:2007)

EN ISO 15841, Dentistry - Wires for use in orthodontics (ISO 15841:2006)

EN ISO 15854, Dentistry - Casting and baseplate waxes (ISO 15854:2005)

EN ISO 20795-1, Dentistry - Base polymers - Part 1: Denture base polymers (ISO 20795-1:2008)

EN ISO 21606, Dentistry - Elastomeric auxiliaries for use in orthodontics (ISO 21606:2007)

EN ISO 22112, Dentistry - Artificial teeth for dental prostheses (ISO 22112:2005) EN ISO 22674, Dentistry — Metallic materials for fixed and removable restorations and appliances (ISO 22674:2006)

EN ISO 24234, Dentistry - Mercury and alloys for dental amalgam (ISO 24234:2004) ISO 8601, Data elements and interchange formats - Information interchange - Representation of dates and times

The cumulative standard EN 1641 has been generated to simplify matters; it summarizes a variety of different individual standards, including ISO 7405 for dentistry [6]. This International Standard concerns the evaluation of the biocompatibility of medical devices used in dentistry. This International Standard contains special tests, for which ample experience exists in dentistry and which acknowledge the special needs of dentistry. Only test methods for which the members of the committee considered there was sufficient published data have been included. In recommending test methods, the need to minimize the use of animals was given a high priority. It is essential that the decision to undertake tests involving animals be reached only after a full and careful review of the evidence indicating that a similar outcome cannot be achieved by other types of test. In order to keep the number of animals required for tests to an absolute minimum, consistent with achieving the objective indicated, it can be appropriate to conduct more than one type of test on the same animal at the same time, e.g. pulp and dentin usage test and pulp capping test. However, in accordance with ISO 10993 (see below) these tests are performed both in an efficient and humane way [7]. On all occasions when animal testing is undertaken, such tests are conducted empathetically and according to standardized procedures as described for each test.

**This International Standard does not explicitly describe test methods for occupationally related risks.**

This standard applies specifically to dental materials (semihorizontal standard) and supplements the mentioned series of horizontal standards, **ISO 10993:2009 Biological Evaluation of Medical Devices**. These comprise a series of accepted test methods including testing for acute and chronic toxicity, sensitization, and teratogenicity. These documents were preceded by the tripartite agreement and is a part of the international harmonisation of the safe use evaluation of medical devices. The following referenced documents are indispensable for the application of this document.

- ISO 1942, *Dentistry — Vocabulary*
- ISO 6344-1, *Coated abrasives — Grain size analysis — Part 1: Grain size distribution test*
- ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*
- ISO 10993-2, *Biological evaluation of medical devices — Part 2: Animal welfare requirements*

· ISO 10993-3:2014, *Biological evaluation of medical devices — Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity*

· ISO 10993-5:2009, *Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity*

· ISO 10993-6:2009, *Biological evaluation of medical devices — Part 6: Tests for local effects after implantation*

· ISO 10993-10:2010, *Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization*

· ISO 10993-11:2006, *Biological evaluation of medical devices — Part 11: Tests for systemic toxicity*

· ISO 10993-12:2007, *Biological evaluation of medical devices — Part 12: Sample preparation and reference materials*

· ISO 10993-13:2010 Identification and quantification of degradation products from polymeric medical devices

· ISO 10993-14: 2001 Identification and quantification of degradation products from ceramics

· ISO 10993-15: 2000 Identification and quantification of degradation products from metals and alloys

· ISO 10993-16:2010 Toxicokinetic study design for degradation products and leachables

· ISO 10993-17: 2009 Establishment of allowable limits for leachable substances

· ISO 10993-18: 2005 Chemical characterization of materials

· ISO/TS 10993-19: 2006 Physicochemical, morphological, and topographical characterization of materials

· ISO/TS 10993-20: 2006 Principles and methods for immunotoxicological testing of medical devices

**ISO 14971:2012 Medical Devices – Application of Risk Management to Medical Devices.** Risk analysis and risk assessment are the basis for the justification of a risk. This standard summarizes the guidelines for the general procedure of risk management (including risk analysis). In doing so, the intended application of each material as well as its composition, solubility, and damaging potential are evaluated. The result of a risk analysis is either a determination of tests that still have to be done (test profile) or, if all necessary data are available, the decision of whether a risk is acceptable and/or under which limitations (for example, a special indication) it would be acceptable. This evaluation requires reference to products that are already available on the market [8].

**ISO 14155:2011 - Clinical Investigation of Medical Devices for Human Subjects.** This standard conceives clinical investigations as each systemic evaluation on test subjects and is intended to evaluate the safety and performance of a certain medical device under normal conditions of application. It describes the competences, responsibilities, and principle process of a clinical evaluation. A clinical investigation is essentially based on the prerequisites of the Declaration of Helsinki for the protection of test subjects (the current version can be downloaded from <http://www.wma.net/en/30publications/10policies/b3/index.html>). All levied data

and information are confidential, and the investigation must be approved by an ethics committee. The test subjects have to be informed in an appropriate manner; their consent must be given in writing and include the right to end their participation in the clinical investigation at any time without justification. The investigation itself has to be described in a detailed test protocol. Dental materials of class IIa must undergo a "clinical assessment." Approval for marketing is not necessarily linked to a clinical evaluation according to ISO 14155 [9, 10].

A multiplicity of laws, standards, and recommenda-

tions regulate the marketing of medical devices. Most laws and directives, however, are of newer date. Therefore, experiences are more limited. Thus, insecurities may exist in single cases during their application, such as for classification and the requirement for clinical evaluations. The medical doctor and the dentist should be informed about the European and international standards concerning medical devices and use only those for which appropriate information is available. The manufacturer/importer is responsible for its products and is potentially liable for damages.

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## REFERENCES:

1. <https://www.iso.org/obp/ui/#iso:std:iso:7405:ed-2:v1:en>
2. [http://www.iso.org/iso/home/standards\\_development.htm](http://www.iso.org/iso/home/standards_development.htm)
3. Benefits of International Standards. <http://www.iso.org/iso/home/standards/benefitsofstandards.htm>
4. [http://ec.europa.eu/enterprise/policies/european-standards/harmonised-standards/%20index\\_en.htm](http://ec.europa.eu/enterprise/policies/european-standards/harmonised-standards/%20index_en.htm)
5. CSN EN 1641 - Dentistry - Medical devices for dentistry – Materials. European Committee for Standardization, Brussels 1996. <http://www.en-standard.eu/csn-en-1641-dentistry-medical-devices-for-dentistry-materials/>
6. ISO 7405:2008 Dentistry — Evaluation of biocompatibility of medical devices used in dentistry. <http://www.en-standard.eu/iso-7405-dentistry-evaluation-of-biocompatibility-of-medical-devices-used-in-dentistry/>
7. International Organization for Standardization: ISO 10993: Biological evaluation of medical devices. International Organization for Standardization, Geneva. <https://www.iso.org/obp/ui/#iso:std:iso:7405:ed-2:v1:en>
8. BS EN ISO 14971 : 2012 Medical devices. Application of risk management to medical devices. <http://shop.bsigroup.com/ProductDetail/?pid=000000000030268035>
9. ISO 14155:2011 Clinical investigation of medical devices for human subjects — Good clinical practice. [http://www.iso.org/iso/catalogue\\_detail?csnumber=45557](http://www.iso.org/iso/catalogue_detail?csnumber=45557)
10. <http://standardsforum.com/new-bs-en-iso-14971-2012-edition-released-on-medical-devices-application-of-risk-management-to-medical-devices/>

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