

## SLOVENSKI STANDARD oSIST prEN ISO 18618:2015

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Zobozdravstvo - Skladno delovanje sistemov CAD/CAM

Dentistry - Interoperability of CAD/CAM-systems

Zahnheilkunde - Interoperabilität der CAD/CAM-Systeme

## iTeh Standards

Ta slovenski standard je istoveten z: prEN ISO 18618

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# DRAFT INTERNATIONAL STANDARD ISO/DIS 18618

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## **Dentistry** — Interoperability of CAD/CAM Systems

Titre manque

ICS: 11.060.01

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#### **ISO/CEN PARALLEL PROCESSING**

This draft has been developed within the International Organization for Standardization (ISO), and processed under the **ISO lead** mode of collaboration as defined in the Vienna Agreement.

This draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel five month enquiry.

Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month approval vote in ISO and formal vote in CEN.

To expedite distribution, this document is circulated as received from the committee secretariat. ISO Central Secretariat work of editing and text composition will be undertaken at publication stage.



Reference number ISO/DIS 18618:2015(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. <a href="https://www.iso.org/directives">www.iso.org/directives</a>

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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: <u>Foreword - Supplementary information</u>

The committee responsible for this document is ISO/TC 106.

<u>SIST EN ISO 18618:20</u>

ISO 18618 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 9, *Dental CAD/CAM systems*.

#### Introduction

Manufacturers of Dental CAD/CAM (Computer Aided Design/Computer Aided Manufacturing) systems differ in how they exchange manufacturing information and three dimensional data. This causes difficulty in data processing, design processes, and manufacturing processes for users of those systems. In order to overcome these interoperability issues, a standard has been prepared to facilitate open interoperability between CAD/CAM systems in dentistry.

This International Standard is based on the open source Universal Dental Exchange (UDX) standard created by the Open Exchange Dental Interoperability Group (OXDIG). The UDX specification is licensed under the Open Software License version 3.0. Users who wish to implement this standard must obtain an open source license agreement from the licensor. The licensor will grant a worldwide, royalty-free, non-exclusive, sublicensable license upon request.

The licensor may be contacted at:

OXDIG LLC

4141 MacArthur Boulevard

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### Dentistry — Interoperability of CAD/CAM Systems

#### **1** Scope

IDS (Interface for Dental CAD/CAM Systems) is based on the UDX File Format Version 2.0 as provided by the OXDIG group. OXDIG has provided a release for utilization of the IDS File Format to ISO. This standard specifies an extensible markup language (xml) format to facilitate the transfer of dental case data and CAD/CAM data between software systems.

#### **2** Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 639-2:1998, Codes for the representation of names of languages -- Part 2: Alpha-3 code

ISO 1942, *Dentistry — Vocabulary* 

ISO 3166-1:2013, *Codes for the representation of names of countries and their subdivisions — Part 1: Country codes* 

(IIUps://stalluarus.iteli.al)

ISO 3950:2009, Dentistry -- Designation system for teeth and areas of the oral cavity

ISO 4217:2008, Codes for the representation of currencies and funds

ISO 8601:2004, *Data elements and interchange formats -- Information interchange -- Representation of dates and times* 

ISO 10646:2011, Information technology — Univrsal Coded Character Set (UCS)

ISO/IEC 15948:2004, Information technology – Computer graphics and image processing – Portable Network Graphics (PNG): Functional specification

ISO 16443:2014, Dentistry -- Vocabulary for dental implants systems and related procedure

JTC 1 Referencing Explanatory Report – PKWARE ZIP Application Note

StereoLithography Interface Specification, 3D Systems, Inc., October 1989

W3C - Extensible Markup Language (XML) 1.0 (Fifth Edition), November 2008

#### **3 Terms and definitions**

Throughout the IDS schema there are terms that have special meaning or definition. Understanding the use of these terms is key to well-defined IDS documents that all parties can understand universally.

The IDS schema defines several peer level nodes immediately within the enveloping root <IDS> element that organize the IDS document into structures for specific transactions. They represent a Submission, a Query, an Update of a previous submission, a Notification of an event or status change and a series of Catalogs. A single IDS document can contain a combination of different transaction nodes or may consist of only a single transactional node.

In addition to the transactional nodes mentioned above, the IDS schema also defines several nodes that provide traceability and source identification features as well as provide information on how to reply to a document transaction.

#### 3.1

#### broker

An entity that acts as a middleman or intermediary. Such organizations may take multiple orders from multiple sources and consolidate them into a single order for a Provider or they may take single orders from an Originator and split them amongst multiple providers or they may just pass orders thru between originators and providers.

Note 1 to entry: This term creates context within the document by identifying the Roles of entities creating data. This term is often used as suffixes to element or attributes names in order to indicate the perspective of the definition.

Note 2 to entry: Throughout the document when a name is prefixed or suffixed with these terms it denotes that the value of that element (or attribute) is based on the perspective of that role.

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#### cad data catalog

A collection of nodes describing CAD data associated with one or more of the orders and/or restorations. It can include digital scan and/or design files, etc.

#### 3.3

#### case

A set of one or more Orders for dental appliances, products or services, all of which are being submitted for a single Patient. For example, a Case might contain one Order for a mold, and another order for a bridge.

#### 3.4

#### catalogs section

Data that is referenced in other elements or areas. The catalogs are subdivided by the data they are grouping making it easier to manage and reference. Currently they include

#### 3.5

#### delivery request

Contains information for the out-going, finished Order, which will be sent to the Originator (or an Originator's agent) as a separate delivery. A delivery may be physical, electronic, or both.

#### 3.6

#### dentist

The dentist who requested the Order.

#### 3.7

#### dentistCatalog

A collection of <Dentist> nodes that provides attribute and elements to define the Dentists being referenced with the IDS document. The definition can include billing information, license information, etc.

#### 3.8

#### extra Info

Many of the elements will contain child nodes with the suffix "ExtraInfo" (i.e. <DentistExtraInfo>, <OrderExtraInfo>, etc. These sections are intended to be areas that can be used to extend the defined schema with proprietary or undefined XML. For example, an implementation may use one (or more) of these sections to embed XML that is only of use to the implementor for an internal workflow. Another use could be two business partners using these sections to experiment with XML they intend to propose for future versions or to pass proprietary XML they they have previously defined between themselves. The IDS schema and XSD will ignore the contents of these sections so they will not be validated as part of the IDS standard. It is highly recommended that if these sections are used, that any XML be enclosed within some proprietary element tag so that if the IDS passes thru multiple handlers there are no conflicts. Example:

#### SIST EN ISO 18618:2018

https<DentistExtraInfo>/catalog/standards/sist/ed2f1bc1-c95c-4ef5-a892-a2d2e11cbc89/sist-en-iso-18618-2018

<MyCompanyData>

data specific and of use only to "MyCompany" ...

</MyCompanyData>

</DentistExtraInfo>

#### 3.9

#### file catalog

A collection of <IDSFile> nodes that describe files associated with the <Case>, <Order> or CAD data (Scans, Design files, etc.).

#### 3.10

#### id map catalog

A collection of <IdMapItem> nodes which provide a means of defining alternate identifiers for key elements within the IDS.

#### 3.11

#### notification node

A means for publishing or returning a defined status, event or message related to an Order. Within the Notification node is an untyped element that can be defined according to the needs of the parties exchanging information.

#### 3.12

#### order

A request for a complete, self-contained dental appliance, service or product that is being requested by an Originator. Each Order in a Case might be created or manufactured by a different Provider. Each Order contains its own delivery (or reply) instruction nodes.

#### 3.13

#### order catalog

A collection of <Order> nodes that provide attributes and elements necessary to define or describe an Order. An <Order> will often contain one or more <Restoration> nodes but may omit those nodes when not needed.

#### 3.14

#### originator

An entity (organization or person) that is responsible for creating the current document, order, submission, etc. As such, they are the "originator" of the data being exchanged. Most often an Originator would be a dental practice. In some cases, an Originator may be a dental laboratory that is outsourcing work to another lab.

Note 1 to entry: This term creates context within the document by identifying the Roles of entities creating data. This term is often used as suffixes to element or attributes names in order to indicate the perspective of the definition.

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Note 2 to entry: Throughout the document when a name is prefixed or suffixed with these terms it denotes that the value of that element (or attribute) is based on the perspective of that role.

#### 3.15

#### parcel

A physical package that is mailed.

#### 3.16

#### patient

The Patient for whom an Order is being manufactured. (Note that Patient info is not a mandatory part of the IDS standard.)

#### 3.17

#### patient catalog

A collection of <Patient> nodes that provide attributes and elements to define patients that are referenced in the <Order> or <Case> elements. Because patients may be referenced in multiple <Order> nodes and/or multiple <Case> nodes the patient information is grouped into a catalog.

#### 3.18

#### product catalog node

A means for a Provider or Broker to publish the products that will be available for ordering. The node provides attribute and elements to define a product, include multiple descriptions in different languages and specify ordering options and variations.

#### 3.19

#### provider

An entity (company, lab, etc.) that is responsible for providing the services or products that are being requested in an Order. Most often, this would be a dental laboratory or manufacturer.

Note 1 to entry: This term creates context within the document by identifying the Roles of entities creating data. This term is often used as suffixes to element or attributes names in order to indicate the perspective of the definition.

Note 2 to entry: Throughout the document when a name is prefixed or suffixed with these terms it denotes that the value of that element (or attribute) is based on the perspective of that role.

#### 3.20

#### query node

A method to request data from another system or entity. It provides elements to define the data elements to be searched or matched on as well as elements to define the data requested in response.

#### 3.21

#### submission

A batch or group of one or more <Cases> described in the IDS document. In traditional (non digital) dentistry a Submission would be equivalent to receiving a physical package (parcel) containing one or more cases. In the digital IDS realm, the submission may represent any combination of one or more physical and/or digital cases that are being "submitted" to a Provider for production.

#### 3.22

#### submissionn Node

Analogous to a physical package or shipment that may contain one or more orders. Just like a physical package, the Submission node may contain one or more digital IDS orders. Because multiple orders may be related or linked to the same patient for a single treatment plan the IDS subverts the Order definition under a Case node that can tie together a collection of Orders.

#### 3.23

#### uid

An identifier defined to be GLOBALLY UNIQUE (also known as a GUID). UId's are a means of identifying key elements within the document. An <IdMap> section within the <Catalogs> section of the document provides a means of equating the UId with alternate identifiers that carry external meaning, such as a Lab Management system ids for a Dentist, case or patient. Note that UId values can have multiple alternate id's in the <IdMap> section but each UId must be defined only ONCE and used on a single key element. For example, if the UId "107face6-fc51-4366-805d-2ee23014d835" is assigned to the Dentist "Smith", that UId value may not be used on any other element as a key identifier and may only be used as a reference in other elements needing to associate with that specific Dentist.

#### 3.24

**update n**ns to send an abbreviated set of data elements to update or modify a previously submitted <Order>. It contains elements that allow the update to match expected values in addition to providing the new values.

#### **4 Data Security and Storage Methods**

The Internet has proven to be an effective means of communication, yet its vulnerability to interception raises issues of privacy, authentication and integrity of the communicated message. Therefore, data security is of utmost importance to users of dental information systems.

Because of the personal and private nature of health records, the dental practitioner needs to understand the security issues associated with "data at rest" and "data in transit." This paper is intended to explain security concepts and the risks associated with the maintenance of data in storage and transit, and over an internet connection. The ADA Standards Committee on Dental Informatics has published a series of technical reports that provide dental practitioners with guidelines in addressing issues of security of data in storage and transmission over the Internet.1-6

A ZIP file format is recommended for transport of the IDS xml file and related files, however, implementation of a file container is left up to the implementer.

#### **5** Naming

**iTeh Standards** 

The user can implement any file container for the IDS file. (S. 100, 21)

The file must end with a .ids file format. The file can be prepended with any naming convention that the user desires.

#### SIST EN ISO 18618:2018

**6 Tooth Numbering System** ps://bc1-c95c-4ef5-a892-a2d2e11cbc89/sist-en-iso-18618-2018

Throughout the entire document, the tooth number system is based on the ISO Standard 3950 for tooth numbering.

#### 7 Additional Restriction on IDS Xml Documents

In addition to the Schema provide above, a valid IDS document must also meet the following requirements:

a) the total length of the document must not exceed 2 megabytes (MB).

b) the document must contain no unrecognized Provider IDS.

c) the document must contain no unrecognized Broker IDS.

#### **8 XSD Reference**

Please look at Annex B for a reference to the XSD Document.