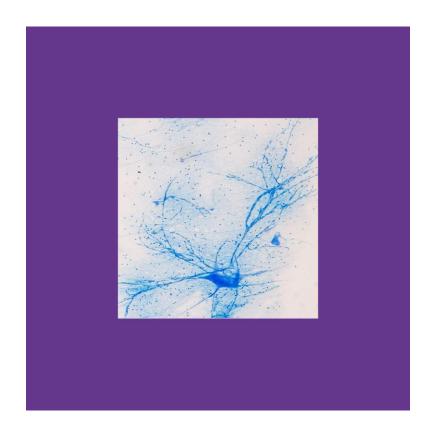


# **DICOM Conformance Statement**

Version 2.0





### **Reference Documents**

Title	Link
DICOMvert	https://www.tiger-technology.com/software/tiger-
User Manual	bridge/docs/
DICOM Standard	https://www.dicomstandard.org/current

### **Revision History**

Revision	Date	Comments
1.0	01 July 2024	First published version
2.0	16 April 2025	Regulatory Classification Disclaimer added



## 1 – Overview

DICOMvert is a thoughtfully designed solution which transforms a variety of image formats into a full-fledged DICOM file.

The main idea behind it is to allow for most images to adhere to the DICOM standard, which is rather practical for integrating with all modern imaging equipment, accessories, networking servers, workstations, printers, and picture archiving and communication systems (PACS) that may have been installed by multiple manufacturers.

## 2 – Introduction

#### 2.1 Audience

This document is intended for hospital technical health system integrators. It is assumed that the reader has a working understanding of DICOM.

### 2.2 Regulatory Classification Disclaimer

DICOMvert is not intended to be used for diagnostic or therapeutic purposes and must not be considered a medical device under Regulation (EU) 2017/745 (MDR) and Regulation (EU) 2017/746 (IVDR). It operates purely at the infrastructure level, automatically converting proprietary image formats (e.g., iSyntax) into DICOM for standardized storage, archival, and communication. The converted output is not meant for clinical interpretation.

As such, DICOMvert aligns with the classification of non-medical device software as described in the <u>MDCG 2019-11 Guidance on Qualification and Classification of Software under Regulation (EU) 2017/745 (MDR) and Regulation (EU) 2017/746 (IVDR)</u> (Figure 1 – Decision steps to assist qualification of MDSSW; Page 9).

#### 2.3 Definitions

Definitions, terms, and abbreviations used in this document are defined within the different parts of the DICOM standard.

Abbreviations and terms are as follows:

AE DICOM Application Entity

AET Application Entity Title

ASCE Association Control Service Element

IOD (DICOM) Information Object Definition



J2K Jpeg 2000

PACS Picture Archive and Communication System

PDU DICOM Protocol Data Unit

SCU DICOM Service Class User (DICOM client)

SCP DICOM Service Class Provider (DICOM server)

SOP DICOM Service-Object Pair

TLS Transport Layer Security

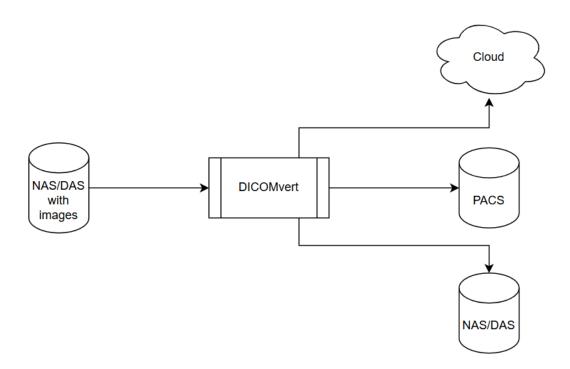
VR Value Representation

R Required Key Attribute

O Optional Key Attribute

U Unique Key Attribute

# 3 – Implementation diagram





# 4 – AE Specification and networking

DICOMvert has the ability to send converted images to different storage devices, such as PACS, cloud providers, NAS, and DAS.

### 4.1 AE Configuration

Upon successful conversion DICOMvert can issue a DIMSE Command that sends a DICOM Object (e.g. Image) from one application (Storage SCU) to another (Storage SCP). The C-STORE command is used in the "Storage Service".

The AE name for the SCU by default is THT-Client, although it can be easily altered based on user requirements.

Same applies for the end-point port, IP address and name.

### 4.2 Supported SOP classes for SCU(C-STORE)

This table can be easily extended to virtually any other class part of the DICOM standard.

SOP Class Name	SOP Class UID
VLWholeSlideMicroscopyImageStorage	1.2.840.10008.5.1.4.1.1.77.1.6

#### 4.3 Supported Transfer Syntaxes

Presentation Contexts	UID
LittleEndianImplicitTransferSyntax	1.2.840.10008.1.2
LittleEndianExplicitTransferSyntax	1.2.840.10008.1.2.1
BigEndianExplicitTransferSyntax	1.2.840.10008.1.2.2
JPEGProcess1TransferSyntax	1.2.840.10008.1.2.4.50
JPEGProcess2_4TransferSyntax	1.2.840.10008.1.2.4.51
JPEGProcess3_5TransferSyntax	1.2.840.10008.1.2.4.52
JPEGProcess6_8TransferSyntax	1.2.840.10008.1.2.4.53
JPEGProcess7_9TransferSyntax	1.2.840.10008.1.2.4.54
JPEGProcess10_12TransferSyntax	1.2.840.10008.1.2.4.55
JPEGProcess11_13TransferSyntax	1.2.840.10008.1.2.4.56
JPEGProcess14TransferSyntax	1.2.840.10008.1.2.4.57
JPEGProcess15TransferSyntax	1.2.840.10008.1.2.4.58
JPEGProcess16_18TransferSyntax	1.2.840.10008.1.2.4.59
JPEGProcess17_19TransferSyntax	1.2.840.10008.1.2.4.60
JPEGProcess20_22TransferSyntax	1.2.840.10008.1.2.4.61
JPEGProcess21_23TransferSyntax	1.2.840.10008.1.2.4.62
JPEGProcess24_26TransferSyntax	1.2.840.10008.1.2.4.63
JPEGProcess25_27TransferSyntax	1.2.840.10008.1.2.4.64
JPEGProcess28TransferSyntax	1.2.840.10008.1.2.4.65
JPEGProcess29TransferSyntax	1.2.840.10008.1.2.4.66



JPEGProcess14SV1TransferSyntax	1.2.840.10008.1.2.4.70
JPEGLSLosslessTransferSyntax	1.2.840.10008.1.2.4.80
JPEGLSLossyTransferSyntax	1.2.840.10008.1.2.4.81
JPEG2000LosslessOnlyTransferSyntax	1.2.840.10008.1.2.4.90
JPEG2000TransferSyntax	1.2.840.10008.1.2.4.91

## 5 – DICOM document

DICOMvert sets the following tags for each instance.

Typically, the patient/study information would be coming from external sources, like HL7 messaging, or REST APIs, but in case something is missing it would be automatically generated and generalized in order for the solution to create a valid DICOM file.

Any other tag can be also added on demand so long it adheres to the DICOM standard.

Attribute Name	Tag	VR	Value	Presence of Value	Source
Specific Character Set	0008, 0005	CS	ISO_IR 100 unless required otherwise	Conditional	C.12.1.1.2
Image Type	0008, 0008	CS	DERIVED PRIMARY VOLUME NONE	Conditional	
SOP Class UID	0008, 0016	UI	1.2.840.10008.5.1.4.1.1.77.1.6 for WSI, unless other input image	Always	Based on the input image
SOP Instance UID	0008, 0018	UI	Auto generated	Always	Auto generated
Study Date	0008, 0020	DA	Set to the same value from the external source	Always	Auto generated if missing
Series Date	0008, 0021	DA	Set to the same value from the external source	Optional	Auto generated if missing
Content Date	0008, 0023	DA	Set to the same value from the external source	Conditional	Auto generated if missing
Acquisition Datetime	0008, 002A	DT	Set to the same value from the external source	Always	Auto generated if missing
Study Time	0008, 0030	TM	Set to the same value from the external source	Always	Auto generated if missing
Series Time	0008, 0031	TM	Set to the same value from the external source	Optional	Auto generated if missing



Content Time	0008, 0033	TM	Set to the same value from the external source	Conditional	Auto generated if
					missing
Accession	0008, 0050	SH	Set to the same value from the	Always	Auto
Number			external source		generated if
					missing
Modality	0008, 0060	CS	SM or other if the source image	Always	Based on
			is not WSI		the input
					image
Manufacturer	0008, 0070	LO	Set to the same value from the	Always	Auto
			external source		generated if
					missing
Referring	0008, 0090	PN	Set to the same value from the	Always	Auto
Physician <sup>'</sup> s	-		external source	_	generated if
Name					missing
Manufacturer's	0008, 1090	LO	Set to the same value from the	Always	Auto
Model Name	•		external source	,	generated if
					missing
Volumetric	0008, 9206	CS	VOLUME	Always	C.8.16.2.1.2
Properties	0000,7200		V G Z G I N I Z	, ways	0.0110.21112
Patient's Name	0010, 0010	PN	Set to the same value from the	Always	Auto
r defente 5 radine	0010,0010		external source	/ ways	generated if
			externational		missing
Patient ID	0010, 0020	LO	Set to the same value from the	Always	Auto
raciencio	0010,0020	LO	external source	Atways	generated if
			externat source		missing
Patient's Birth	0010, 0030	DA	Set to the same value from the	Always	Auto
Date	0010,0030	DA	external source	Atways	generated if
Date			externat source		missing
Patient's Sex	0010, 0040	CS	Set to the same value from the	Always	Auto
racient 3 Sex	0010,0040	CJ	external source	Atways	generated if
			externat source		missing
Device Serial	0018, 1000	LO	Set to the same value from the	Optional	Omitted if
Number	0018, 1000	LO	external source	Орионас	
Software	0010 1020	10	Set to the same value from the	Optional	missing Omitted if
	0018, 1020	LO	external source	Орионас	
Version(s)	0010 0073	FD		Ostissal	missing
Acquisition	0018, 9073	FD	Set to the same value from the	Optional	Omitted if
Duration	0000		external source	A.I.	missing
Study Instance	0020,	UI	Set to the same value from the	Always	Auto
UID	000D		external source		generated if
					missing
Series Instance	0020, 000E	UI	Set to the same value from the	Always	Auto
UID			external source		generated if
					missing
Study ID	0020, 0010	SH	Set to the same value from the	Always	Auto
			external source		generated if
			-		missing
Series Number	0020, 0011	IS	1 for WSI	Always	Auto
					generated
Instance	0020, 0013	IS	Sequential numbers for WSI	Always for	Auto
Number				WSI	generated
Patient	0020, 0020	CS	Empty unless required	Always	Auto
Orientation			otherwise		generated



Dimension Organization Sequence	0020, 9221	SQ	None – it is an organizational unit	Always for WSI	Auto generated for WSI
Dimension Organization UID	0020, 9164	UI	Auto generated based on the Instance UID	Always for WSI	Auto generated for WSI
Dimension Index Sequence	0020, 9222	SQ	None – it is an organizational unit	Always for WSI	Auto generated for WSI
Dimension Organization UID	0020, 9164	J	Auto generated based on the Instance UID	Always for WSI	Auto generated for WSI
Dimension Index Pointer	0020, 9165	AT	Pointer to tag 0048, 021E If the input image is WSI	Always for WSI	Auto generated for WSI
Functional Group Pointer	0020, 9167	AT	Pointer to tag 0048, 021A If the input image is WSI	Always for WSI	Auto generated for WSI
Samples per Pixel	0028, 0002	US	1 for gray scale images and 3 for RGB	Always	Auto generated
Photometric Interpretation	0028, 0004	CS	Based on the required image compression/transfer syntax)	Always	Auto generated
Planar Configuration	0028, 0006	US	Based on the required image compression/transfer syntax)	Conditional	Auto generated
Number of Frames	0028, 0008	IS	Based on the input image resolution	Conditional	Auto generated
Rows	0028, 0010	US	512 by default, unless required otherwise	Always	Auto generated
Columns	0028, 0011	US	512 by default, unless required otherwise	Always	Auto generated
Bits Allocated	0028, 0100	US	Depends on the image compression	Always	Auto generated
Bits Stored	0028, 0101	US	Depends on the image compression	Always	Auto generated
High Bit	0028, 0102	US	Depends on the image compression	Always	Auto generated
Pixel Representation	0028, 0103	US	Depends on the image compression	Always	Auto generated
Burned In Annotation	0028, 0301	CS	Depends on the input image	Always	Auto generated
Lossy Image Compression	0028, 2110	CS	Depends on the image compression	Always	Auto generated
Lossy Image Compression Ratio	0028, 2112	DS	Depends on the image compression	Conditional	Auto generated
Lossy Image Compression Method	0028, 2114	CS	Depends on the image compression	Conditional	Auto generated
Container Identifier	0040, 0512	LO	Set to the same value from the external source	Always for WSI	Auto generated if missing



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Issuer oof the Container Identifier Sequence	0040, 0513	SQ	Set to the same value from the external source	Always for WSI	Auto generated if missing
Container Type Code Sequence	0040, 0518	SQ	Set to the same value from the external source	Always for WSI	Auto generated if missing
Acquisition Context Sequence	0040, 0555	SQ	Set to the same value from the external source	Always for WSI	Auto generated if missing
Specimen Description Sequence	0040, 0560	SQ	Set to the same value from the external source	Always for WSI	Auto generated if missing
Specimen Identifier	0040, 0551	LO	Set to the same value from the external source	Always for WSI	Auto generated if missing
Specimen UID	0040, 0554	UI	Set to the same value from the external source	Always for WSI	Auto generated if missing
Issuer of the Specimen Identifier Sequence	0040, 0562	SQ	Set to the same value from the external source	Always for WSI	Auto generated if missing
Specimen Preparation Sequence	0040, 0610	SQ	Set to the same value from the external source	Always for WSI	Auto generated if missing
Imaged Volume Width	0048, 0001	FL	Distance in the direction of rows in each frame	Conditional	Auto generated
Imaged Volume Height	0048, 0002	FL	Distance in the direction of columns in each frame	Conditional	Auto generated
Imaged Volume Depth	0048, 0003	FL	Distance in the Z direction of focal planes	Conditional	Auto generated
Total Pixel Matrix Columns	0048, 0006	UL	Based on the total input image resolution if WSI	Always	Auto generated
Total Pixel Matrix Rows	0048, 0007	UL	Based on the total input image resolution if WSI	Always	Auto generated
Total Pixel Matrix Origin Sequence	0048, 0008	SQ	Auto generated based on the Instance UID	Always for WSI	Auto generated for WSI
X offset in Slide Coordinate System	0040, 072A	DS	Depends on the input image	Always for WSI	Auto generated if missing
Y offset in Slide Coordinate System	0040, 073A	DS	Depends on the input image	Always for WSI	Auto generated if missing
Specimen Label in Image	0048, 0010	CS	NO for WSI images	Always for WSI	Auto generated
Focus Method	0048, 0011	CS	AUTO for WSI images	Always for WSI	Auto generated
Extended Depth of Field	0048, 0012	CS	NO for WSI images	Always for WSI	Auto generated



Image Orientation (Slide)	0048, 0102	DS	Depends on 0048 ,021A	Conditional	Auto generated
Optical Path Sequence	0048, 0105	SQ	None – it is an organizational unit	Always for WSI	Auto generated for WSI
Illumination Type Code Sequence	0022, 0016	SQ	None – it is an organizational unit	Always for WSI	Auto generated for WSI
Code Value	0008, 0100	SH	111744 by default, unless required otherwise	Conditional	Auto generated
Coding Scheme Designator	0008, 0102	SH	DCM by default, unless required otherwise	Conditional	Auto generated
Code Meaning	0008, 0104	LO	Brightfield illumination by default, unless required otherwise	Always	Auto generated
ICC Profile	0028, 2000	ОВ	SRGB buffer	Conditional	Auto generated
Optical Path Identifier	0048, 0106	SH	Auto generated	Always for WSI	Auto generated
Optical Path Description	0048, 0107	ST	Auto generated	Conditional	Auto generated
Illumination Color Code Sequence	0048, 0108	SQ	None – it is an organizational unit	Conditional	Auto generated for WSI
Code Value	0008, 0100	SH	R-102C0 by default, unless required otherwise	Conditional	Auto generated
Coding Scheme Designator	0008, 0102	SH	SRT by default, unless required otherwise	Conditional	Auto generated
Code Meaning	0008, 0104	LO	Full Spectrum	Always	Auto generated
Shared Functional Groups Sequence	5200, 9229	SQ	None – it is an organizational unit	Always	Auto generated for WSI
Pixel Measures Sequence	0028, 9110	SQ	None – it is an organizational unit	Always	Auto generated for WSI
Slice Thickness	0018, 0050	DS	Based on the input image	Conditional	Auto generated for WSI
Pixel Spacing	0028, 0030	DS	Based on the input image	Conditional	Auto generated for WSI
Optical Path Identification Sequence	0048, 0207	SQ	None – it is an organizational unit	Always	Auto generated for WSI
Optical Path Identifier	0048, 0106	SH	Auto generated	Always	Auto generated for WSI
Per-frame Functional	5200, 9230	SQ	None – it is an organizational unit	Conditional	Auto generated for WSI



1	1			•	1
Groups Sequence					
Frame Content Sequence	0020, 9111	SQ	None – it is an organizational unit	Always if 5200, 9230	Auto generated for WSI
Dimension Index Values	0020, 9157	UL	Based on the tile count and orientation for WSI	Conditional	Auto generated for WSI
Plane Position (Slide) Sequence	0048, 021A	SQ	None – it is an organizational unit	Always if 5200, 9230	Auto generated for WSI
X offset in Slide Coordinate System	0040, 072A	DS	Depends on the input image	Always for WSI	Auto generated if missing
Y offset in Slide Coordinate System	0040, 073A	DS	Depends on the input image	Always for WSI	Auto generated if missing
Z offset in Slide Coordinate System	0040, 074A	DS	Depends on the input image	Always for WSI	Auto generated if missing
Column Position In Total Image Pixel Matrix	0048, 021E	SL	Based on the tile count and orientation for WSI	Always for WSI	Auto generated for WSI
Row Position In Total Image Pixel Matrix	0048, 021F	SL	Based on the tile count and orientation for WSI	Always for WSI	Auto generated for WSI
Pixel Data	7FE0, 0010	ОВ	Data of the stored image within the given DICOM file	Conditional	Auto generated



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