



**DECLARATION OF CONFORMITY
(DICOM CONFORMANCE
STATEMENT
FOR IMPLASTATION V.5)
PRODIGIDENT**

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Prepared By

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DECLARATION OF CONFORMITY

Consistent with the FDA guidance document entitled "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices" (September 14, 2018)

Name and address of the applicant:

Prodigident, Inc.
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Device identification:

Name of Device: Implastation v.5
Common or Usual Name: Implant Planning and Surgical Guide Creation Software
Classification Name: System, Image Processing, Radiological (21 CFR 892.2050)
Regulatory Class: II
Product Code: LLZ

Statement of conformity:

(See information provided below)

A list of standard(s) for which the DOC applies:

#	Recognition Number	Declaration of Conformity or General Use	Standards Development Organization (SDO), Designation Number-Year, and Title
1	12-300	Declaration of Conformity	NEMA PS 3.1 - 3.20 (2016) Digital Imaging and Communications in Medicine (DICOM) Set

The date and place of issuance of the DOC:

November 05, 2018
Suite 1B, 1350 Lake Street,
Roselle, IL 60172

Signature:

Andrii Gromov,
Chief Executive Officer



1. CONFORMANCE STATEMENT OVERVIEW

The Implastation supports reading of DICOM objects obtained over the network, from Media Storage and File Format for Data Interchange PS 3.10 files loaded from the local file system or from PS 3.12 compliant media according to one of the General Purpose Media Application Profiles of PS 3.11.

All single and multiframe with grayscale may be displayed.

Only hierarchical query and retrieval is supported. There is limitation of only supporting CT scan data Table 1-1.

Table 1-1
SUPPORTED IMAGE SOP CLASSES

Name	UID
Computed Tomography (CT) Image Storage	1.2.840.10008.5.1.4.1.1.2
Enhanced Computed Tomography (CT) Image Storage	1.2.840.10008.5.1.4.1.1.2.1

The Implastation supports the Media Services listed in (Table 1-2).

Table 1-2
MEDIA SERVICES

Media Storage Application Profile	Write Files (FSC or FSU)	Read Files (FSR)
General Purpose CD-R	NO	YES
General Purpose DVD-RAM	NO	YES
General Purpose USB	NO	YES

The Implastation conforms to the DICOM 3.0 2009 standard and supports the DICOM transfer syntaxes and Lossless methods listed in Table 1-3.

Table 1-2
SUPPORTED DICOM TRANSFER SYNTAXES AND LOSSLESS METHODS

Name	UID
Implicit VR Little Endian	1.2.840.10008.1.2
Explicit VR Little Endian	1.2.840.10008.1.2.1
JPEG Lossless First Order	1.2.840.10008.1.2.4.70

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3. INTRODUCTION

3.1 REVISION HISTORY

Document Revision	Date of Issue	Author	Description
1.0	November 05, 2018	Andrii Gromov	First release

3.2 AUDIENCE

This conformance statement is intended for existing or potential users of Implastation. It is assumed that the reader has a working understanding of DICOM and the reader of this document is familiar with the DICOM Standard and with the terminology and concepts which are used in that Standard.

The document is structured along the template definition as specified in "Part 2: Conformance" of the DICOM standard [1].

3.3 REMARKS

DICOM, by itself, does not guarantee interoperability. However, the Conformance Statement facilitates a first-level validation for interoperability between different applications supporting the same DICOM functionality.

The user should be aware of the following important issues:

- The comparison of different Conformance Statements is the first step towards assessing interconnectivity between Implastation and other DICOM equipment.
- This Conformance Statement is not intended to replace validation with other DICOM equipment to ensure proper exchange of information intended.

3.4 DEFINITIONS, TERMS AND ABBREVIATIONS

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
CD	Compact Disk
CD-R	Compact Disk Recordable
DVD	Digital Versatile Disc
FSC	File-Set Creator
FSU	File-Set Updater
FSR	File-Set Reader
HD	Hard Disk
IGS	Image Guided Surgery
IOD (DICOM)	Information Object Definition
ISO	International Standard Organization
MOD	Magneto Optical Disk
PDU DICOM	Protocol Data Unit
Q/R	Query and Retrieve
RCS	Reference Coordinate System
SCU DICOM	Service Class User (DICOM client)
SCP DICOM	Service Class Provider (DICOM server)
SOP DICOM	Service-Object Pair

3.5 REFERENCES

1. DIGITAL IMAGING AND COMMUNICATIONS IN MEDICINE (DICOM) 3.0, VOL. PS 3.1-3.20, NEMA, 2016.

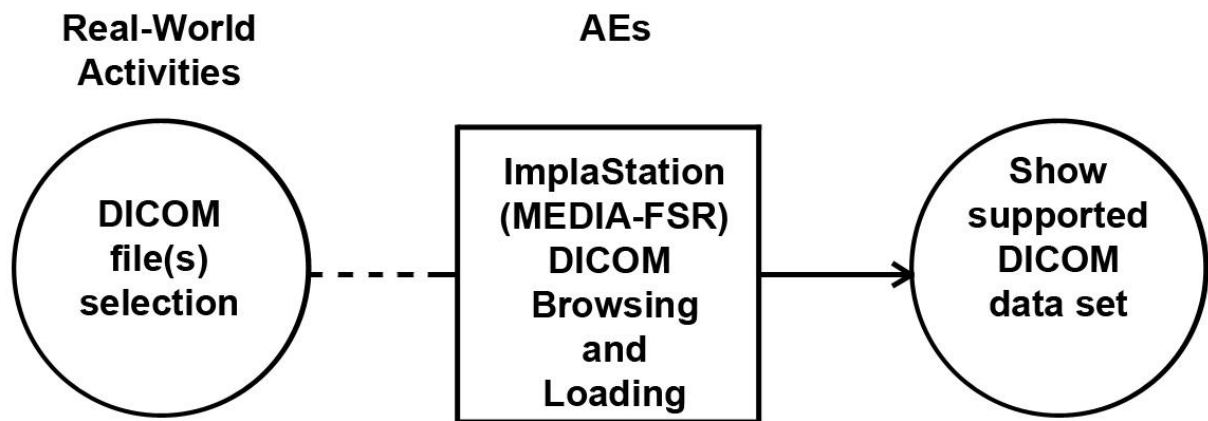
4. NETWORKING

Not applicable. The Implastation does not support importing or exporting of DICOM data over a network data flow.

5. MEDIA INTERCHANGE

5.1 IMPLEMENTATION MODEL

5.1.1 APPLICATION DATA FLOW DIAGRAM



**Figure 5.1.1-1.
IMPLEMENTATION MODEL**

The diagram (Figure 5.1.1-1) was created in accordance with a statement that the diagram depicts the functional relationships between the device and the DICOM services.

Rectangular boxes are used to represent the AEs, which are the DICOM software processes implemented on the device. The circles represent real-world activities and DICOM services related to the applications. The direction of the arrows between the AEs and the bubbles indicate the origination of the association.

The Implastation is a single software as a medical device that provides a user interface, media support as a File Set Reader and a tool set for Digital Implant Planning and Surgical Guide Creation.

Conceptually it may be modeled as the following single AE: MEDIA-FSR, which loads a user-selected PS 3.10* compliant file, which may be a DICOMDIR or an DICOM object, either from the local file system or from PS 3.12** compliant media according to one of the General Purpose Media Application Profiles of PS 3.11*** (CD-R or DVDRAM)

In addition user is required to browse and locate the DICOMDIR file. Furthermore, any DICOM image encoded in one of the standard uncompressed Transfer Syntaxes may be proposed first, even in the absence of a PS 3.10* compliant meta-information header, in which case a “best guess” at the Transfer Syntax will be shown.

* DICOM PS3.10 2017e - Media Storage and File Format for Media Interchange

** DICOM PS3.12 2017e - Media Storage and File Format for Media Interchange

***DICOM PS3.11 2017e - Media Storage and File Format for Media Interchange

5.1.2 FUNCTIONAL DEFINITIONS OF AE

5.1.2.1 IMPLASTATION AS A MEDIA-FSR

ImplaStation as a MEDIA-FSR is activated through the user interface to select directories, images and spectra for display, import into the local database.

5.1.3 SEQUENCING OF REAL-WORLD ACTIVITIES

All File Set Reader activities are sequentially initiated in the user interface, and another activity may not be initiated until the prior activity has completed. User select DICOM file(s) from the list of supported DICOM data set and software load a supported DICOM data set, which can be used for implant planning and surgical guide creation.

5.2 AE SPECIFICATIONS

5.2.1 IMPLASTATION SPECIFICATIONS

ImplaStation provides standard conformance to DICOM Interchange Option of the Media Storage Service Class. Implastation only supports the use of data from CT/CBCT scanners and limited to the use of the Media Storage Application Profiles listed in Table 5.2.1-1.

**Table 5.2.1-1
APPLICATION PROFILES, ACTIVITIES, AND ROLES FOR MEDIA-FSR**

Media Storage Application Profile	Real World Activity	Role
General Purpose CD-R	Brows and Load directory or file	FRS
General Purpose DVD-RAM	Brows and Load directory or file	FRS
General Purpose USB	Brows and Load directory or file	FRS

5.2.1.1 FILE META INFORMATION FOR THE APPLICATION ENTITY

Not applicable, since MEDIA-FSR is not an FSC or FSU.

5.2.1.2 REAL WORLD ACTIVITIES

5.2.1.2.1 ACTIVITY – LOAD DIRECTORY OR FILE

The Implastation supports reading of DICOM objects obtained over the network, from Media Storage and File Format for Data Interchange PS 3.10* files loaded from the local file system or from PS 3.12* compliant media according to one of the General Purpose Media Application Profiles of PS 3.11*.

* DICOM PS3.10 2017e - Media Storage and File Format for Media Interchange

** DICOM PS3.12 2017e - Media Storage and File Format for Media Interchange
 ***DICOM PS3.11 2017e - Media Storage and File Format for Media Interchange

When selecting a supported DICOM data set, next DICOM codes are shown:

- (0010,0010) Patient's Name
- (0010,0030) Patient's Birth Date
- (0010,0040) Patient's Sex
- (0008,0020) Study Date
- (0008,0030) Study Time
- (0020,0010) Study ID
- (0008,0060) Modality (For example CT)
- (0020,0011) Series Number
- (0008,0070) Manufacturer
- (0018,1000) Device Serial Number
- (0018,0050) Slice Thickness
- (0028,0004) Photometric Interpretation (For example MONOCHROME1; MONOCHROME2)
- (0028,1050) Window Center
- (0028,1051) Window Width
- (0008,103E) Series Description
- (0018,1150) Exposure Time (ms)
- (0018,0060) KVP (kV)
- (0018,1151) X-Ray Tube Current (mA)

Only hierarchical query and retrieval is supported. There is limitation of only supporting CT scan data Table 5.2.1.3-1.

Table 5.2.1.3-1
SUPPORTED IMAGE SOP CLASSES

Name	UID
Computed Tomography (CT) Image Storage	1.2.840.10008.5.1.4.1.1.2
Enhanced Computed Tomography (CT) Image Storage	1.2.840.10008.5.1.4.1.1.2.1

The Implastation conforms to the DICOM 3.0 2009 standard and supports the DICOM transfer syntaxes and Lossless methods listed in Table 5.2.1.3-2.

Table 5.2.1.3-2
SUPPORTED DICOM TRANSFER SYNTAXES AND LOSSLESS METHODS

Name	UID
Implicit VR Little Endian	1.2.840.10008.1.2
Explicit VR Little Endian	1.2.840.10008.1.2.1
JPEG Lossless First Order	1.2.840.10008.1.2.4.70

5.2.1.2.1.1 APPLICATION PROFILE SPECIFIC CONFORMANCE

There are no extensions or specializations.

5.3 AUGMENTED AND PRIVATE PROFILES

5.3.1 AUGMENTED PROFILES

None.

5.3.2 PRIVATE PROFILES

None.

5.4 MEDIA CONFIGURATION

None.

6. SUPPORT OF CHARACTER SETS

6.1 OVERVIEW

The application supports the default character repertoire.

Support extends to correctly decoding and displaying the correct symbol for all names and strings found in the DICOMDIR, in storage instances from media and received over the network, and in the local database.

6.2 CHARACTER SET

Default repertoire ISO 2022 IR 6

6.3 CHARACTER SET CONFIGURATION

Whether or not characters are displayed correctly depends on the presence of font support in the underlying operating system. Typically, as described in the Release Notes, it may be necessary for the user to add one of the “all Unicode” fonts to their system configuration in order to correctly display characters that would not typically be used in the default locale.

7. SECURITY

7.1 SECURITY PROFILES

None supported.

7.2 ASSOCIATION LEVEL SECURITY

None supported. Any Calling AE Titles and/or IP addresses may open an Association.

7.3 APPLICATION LEVEL SECURITY

None supported.

8. ANNEXES

8.1 IOD CONTENTS

8.1.1 CREATED SOP INSTANCES

None.

8.1.2 USAGE OF ATTRIBUTES FROM RECEIVED IOD'S

See DICOM Conformance Statement Overview

8.1.3 ATTRIBUTE MAPPING

Not applicable.

8.1.4 COERCED/MODIFIED FIELDS

No coercion is performed.

8.2 DATA DICTIONARY OF PRIVATE ATTRIBUTES

No private attributes are defined.

8.3 CODED TERMINOLOGY AND TEMPLATES

Not applicable.

8.4 GRAYSCALE IMAGE CONSISTENCY

Not applicable.

8.5 STANDARD EXTENDED/SPECIALIZED/PRIVATE SOP CLASSES

None

8.6 PRIVATE TRANSFER SYNTAXES

None.