MDS-G30

Guidance on Patient-matched Medical Devices Using 3D Printers

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Foreword

Saudi Food and Drug Authority (SFDA) is an independent organization with purpose of regulating and monitoring of foods, drugs and medical devices. AHWP is a voluntary group of representatives from medical device regulatory authorities and the regulated industry in Asia. SFDA is adopting the document “Handbook for Approval of Patient-matched Medical Devices Using 3D Printers” (AHWP/WG1/F001:2017) published by AHWP on 21 November 2017, to provide recommendations related to patient-matched medical devices using 3D printers.

Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

FINAL DOCUMENT

Title: Handbook for Approval of Patient-matched Medical Devices Using 3D Printers

Authoring Group: Working Group 1

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Mr. Essam Mohammed Al Mohandis
Chair, Work Group 1

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Contents

1. Preface

The document herein was produced by the Asian Harmonization Working Party (AHWP), a voluntary group of representatives from medical device regulatory authorities and the regulated industry. The document is intended to specify requirements that are related to approval process and procedures for patient-matched medical devices using 3D printers. AHWP acknowledges that many regulatory authorities and organizations including TGA and IMDRF are currently developing the documents related to definitions and regulations of custom devices and 3D printing. AHWP is publishing this document to provide recommendations related to patient-matched medical devices using 3D printers, and is intended to be revised to harmonize terms and definitions with other regulatory authorities and IMDRF in the future.

2. Introduction

As for 3D printing technology development, many medical device manufacturers are using 3D printing technology to produce medical devices. In general, 3D printer uses Additive Manufacturing (AM) technology to build successive layers of raw material to produce the medical device. There are various devices manufactured using 3D technologies, but the scope of this handbook is to address regulatory requirements on patient-matched devices using 3D printers. This handbook is created mainly for regulators and applicants to help them understand the approval process and procedures for patient-matched medical devices using 3D printers. Due to various types and characteristics of 3D printed devices, it is impossible to cover all regulatory requirements for different types of patient-matched medical device using 3D printers. Instead, this document will explain the basic regulatory requirements that regulators need to review in order to increase the levels of understanding in evaluation when approving patient-matched medical devices using 3D printers. Regulators should follow the general regulatory requirements when evaluating the specific devices if there are no specific regulatory requirements stated in this document.

Since 3D printing technology uses distinctive manufacturing methods compared to the traditional manufacturing process such as subtractive or formative manufacturing, this document also gives a brief overview of 3D printing methods and characteristics. These patient-matched medical devices using 3D printers may need more flexible procedures for approval in order to rapidly respond to the needs of 3D printed medical devices for patient access.

In this document, it uses a term “patient-matched medical device”. A “patient-matched medical device” refers to a device that is built specifically for the patient based on patient’s

anatomical features. It is a size-modifiable device with pre-defined minimum and maximum specifications. Therefore, a "patient-matched medical device" is distinctive from a customized device, because it has to meet a defined set of anatomical requirements. Since this document is specific for the devices using 3D printers, so it will only discuss about the patient-matched medical devices using 3D printers.

Additional information can be found in relevant ISO and ASTM series, especially for biological safety and product performance standards. For the additional regulatory information regarding 3D printing, you should confirm with each countries' regulations.

More documents for specific device types and its relevant technologies and materials are expected to be further developed.

This document is by definition voluntary to be adapted, and is an overall recommendation for approval of patient-matched medical devices using 3D printers.

3. Definitions

In this document, **3D Printing** is defined as the "process of **manufacturing three-dimensional objects** by **laminating materials, using 3D model data."** 3D printing is referred to as "Additive Manufacturing (AM)" by ISO/ASTM 52900:2015 (E). It has a contrary meaning to subtractive manufacturing method, which cuts or grids materials.

Definition of Acronyms

AM	Additive Manufacturing
CAD	Computer Aided Design
CT	Computerized Tomography
FDM	Fused Deposition Modeling
MRI	Magnetic Resonance Image
SLA	Sterolithography
SLS	Selective Laser Sintering
STL	Stereolithography
SW	Software
3D	3 Dimentional

4. Purpose

This document is prepared in order to improve the convenience and the transparency of approval procedures by providing the detailed guidelines on application and technical document preparations for patient-matched medical devices using 3D printers.

5. Scope of Approval

This document addresses the scope of approval regarding patient-matched medical devices using 3D printers.

There are some devices that are not considered as medical devices although they are manufactured using 3D Printers. Some of examples are provided as follows.

1) **Molds**, which are manufactured by 3D printers to shape medical devices in order to produce patient-matched devices accordingly for each individual patient's anatomical features, are **not classified as a medical device** since they are not directly in contact with a patient or implanted into a patient's body. Molds are managed depending on its usage either as **a form of materials** or **manufacturing equipment**.

i. **Liquid or powder materials, which are approved for manufacturing medical devices as a material form**, are allowed to be used in the medical facilities if they are used within its intended use. They can be used for shaping a medical device to be matched with patient's anatomical features by using molds manufactured by 3D printing technology. The manufacturing machine and its related materials shall be **maintained by the required levels of hygiene including cleaning and sterilization.**

ii. **Using a mold manufactured by 3D printer** in order to **produce a final finished medical device** is considered as **manufacturing equipment**; therefore, it should be managed according to the Quality Management System (QMS).

2) When **an anatomical model** is manufactured by 3D printers **for educational or patient-consulting purposes**, it is **not classified as a medical device**.

6. Application Instructions

When applying for approval of patient-matched medical devices using 3D printers, some of elements shall be prepared as suggested below. They may need to be modified depending on each product's characteristics.

1) Model Name

i. Model name shall be clearly stated in order to confirm the fact that 3D printer can manufacture the product accordingly as the sizes of each patient's anatomical features change.

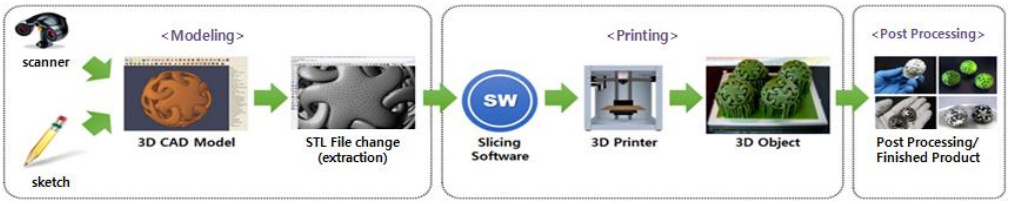
ii. Example of contents: All the sizes (A, B, C, T) which describe anatomical feature of the sample for the medical device manufactured by 3D printers shall be stated in the model name. Modification of medical device size is allowed. The exact model name should be written as ***Model Name*** **(A, B, C, T)** to state all the sizes on the name.

2) Operational Principle

i. The manufacturing process of 3D printing can be divided into 3 Phases: modelling, printing, post processing.

- Modelling: producing a digital 3D blueprint using CAD or an image from CT, MRI, 3D scanner, or other design SW
- Post processing: final phase involving removing of supporters and polishing, dyeing, and coating of the surface before commercialization
- STL File: commonly used international standard formats for 3D printers for 3D data conversion

Figure 1. 3 Phases of Manufacturing Process using 3D printers



ii. Manufacturing method can be divided depending on 3 different material types: **liquid**, **powder**, and **solid**

- Liquid, powder and solid can be processed by SLA, SLS, and FDM respectively, which are commonly used technologies in 3D printing, but a variety of other methods can be also utilized. For further information on types of 3D printer technologies and definition of terms, please refer to the relevant standards, ISO/ASTM 52900-15.

- Listed below are the commonly used manufacturing technologies and their characteristics.

Types	Technologies	Principles	Characteristics
Liquid	SLA	Hardening liquid resin with lasers	• High degree of precision • Fast building time
Powder	SLS	Sintering powder with lasers	• Can be applied to various materials including different types of metals • High solidity
Solid	FDM	Melting and laminating a filament type of raw materials	• Low manufacturing cost • High strength • Good water resistant

TabTable 1. Material Types and Technologies for 3D Printing

iii. Applicant should clearly state the applied 3D printing technology and the material type that has been used to manufacture the product.

iv. Example of contents: this product was manufacture with titanium powder materials by a 3D printer using a Selective Laser Sintering (SLS) technology.

3) Appearance

i. Applicant should provide a picture or an image to confirm the 3D appearance. The image should include all the component pieces that are connected to the product such as a flange. If necessary, applicant should provide each part's functions.

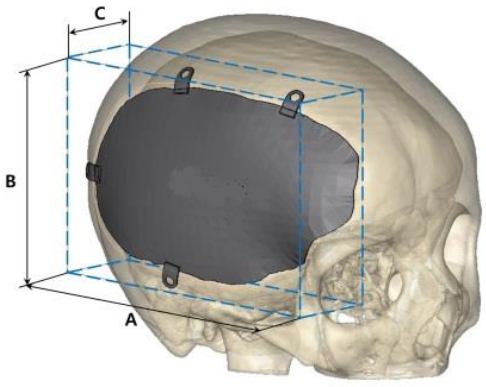


Figure 2. Example of 3D Image of Cranioplasty Plate

4) Size and Weight

i. Applicant should provide the pre-defined design ranges (minimum to maximum values) of each product's size and weight in order to confirm the fact that a 3D printing can manufacture the size-modifiable device for each patient's anatomical features within the defined design space.

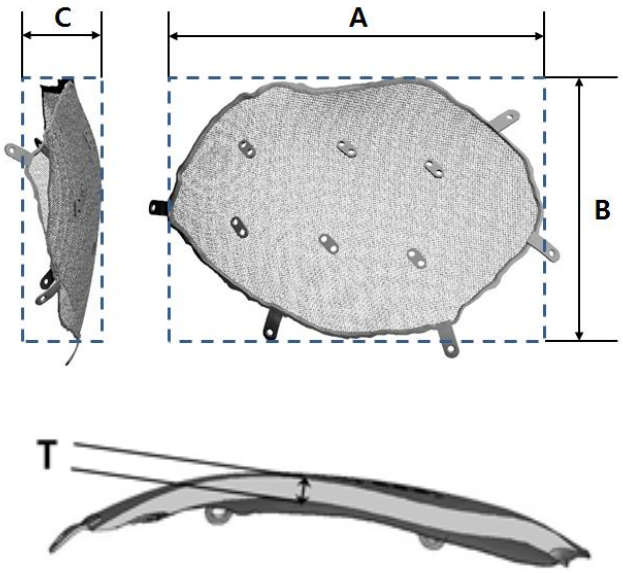


Figure 3. Notation Example of Cranioplasty Plate Size

Model Name and Size	A	B	C	D	Weight
Model Name (A, B, C, T)	○○~○○	○○~○○	○○~○○	○○~○○	○○~○○○g

Table 2. Example of Size Chart

5) Intended Use

i. Applicant should state the intended use of the device with additional information about the 3D printing if the device is manufactured using 3D printers.

ii. Example of content writing for artificial cheekbones: A patient-matched artificial cheekbone manufactured by a 3D printer is intended to be used for replacement of a cheekbone during the recovery period after a surgery.

6) Indications For Use

i. Instructions should state and confirm the requirements of the device. The requirements are the physician's prescription, the design image that are matched with the patient's anatomical features, and the size-modifiable data of the device.

ii. Example of content writing for Indications For Use: Before using this device, please confirm that the physician has prescribed the use of this device and the patient-matched design image is adequately applied when manufacturing the device.

7. Considerations for Technical Document Review

When reviewing patient-matched medical devices using 3D printers for approval, following technical documents should be considered for review.

1) Documents for Intended Use

i. Provide documents to confirm about the intended use of a patient-matched medical device using 3D printers

ii. Example of documents: manufacturer documents that clearly indicate the intended use and need of a patient-matched medical device using 3D printers for the patient's disease as an optimal alternative

2) Documents for Operational Principles

i. Provide documents for manufacturing method and operational principles of a patient-matched medical device using 3D printers

ii. Example of documents: manufacturer documents that clearly state the specific manufacturing method with operational principles of a patient-matched medical device using 3D printers

3) Documents for Biological Safety

i. Provide documents for biological safety of a patient-matched medical device using 3D printers same as those of general medical devices, especially if the device is implanted into or in contact with the human body or biological materials such as blood, body fluid, or drugs. These documents should prove that there is no change in the physical and chemical properties of raw materials after manufacturing the device.

ii. The standard and testing methods for biological safety should be complying with international standards such as ISO 10993.

4) Documents for Performance

i. Provide documents that show the results of the performance test conducted on the most designated model among the various types of the devices (hereafter referred to as "test coupon"). If the test coupon is used for the performance test, it has to be appropriately selected to represent all the same types of devices. Manufacturers should select the test coupon with the worst-case condition among the all of the same types of devices.

- Since the patient-matched medical device using 3D printers is manufactured in various sizes, it is difficult to prove the device's performance by just one sample test on a test coupon. Therefore, applicant should provide documents that describe the reason why the particular model is selected for a test coupon.
- Applicant should provide documents which prove that the test coupon is manufactured through the same manufacturing process (algorithm) of the final finished product.

ii. Provide documents that confirm the device's safety and effectiveness of mechanical performance

- Since the physical and chemical characteristics of raw materials can be changed during manufacturing process, manufacturer should prove the device's safety and effectiveness by providing test results of compression strength, tensile strength, fatigue strength, and flexural strength of the final finished product.

- Addition to the listed test results above, manufacturer may need to provide the test result of surface roughness for some devices due to the characteristics of 3D printing.

5) Documents for Physiochemical Properties

i. Provide documents for physiochemical properties of a patient-matched device using 3D printers same as those of general medical devices, especially if the device is implanted into or in contact with the human body or biological materials such as blood, body fluid, or drugs

ii. Due to the unique characteristics of 3D printing, manufacturer also need to provide the testing results of microstructure analysis, porosity, surface roughness, surface hardness, density, size effectiveness analysis, component analysis, biodegradable analysis (if necessary), and residue analysis to prove the safety of physicochemical properties of the final finished product.