

## Imaging guidelines for Custom-Made service

Industrie Biomediche Insubri SA provide Custom-Made Medical Devices according to the Medical Device Regulation 2017/745.

For the design of a custom-made medical device, the starting model can be supplied in different ways:

- CT/CBCT scan
- STL file
- Stereolithographic model

This document reports guidelines which can help the medical professionals to produce better models to guarantee the quality of the custom-made device.

### General guidelines

- Ensure that the patient has reached skeletal maturity
- Make sure that the model is as recent as possible, but in any case, it shall not be older than 4 months
- Artefacts in the models shall be prevented as far as possible
- Attach the requesting form with a brief clinical description of the medical regenerative intention

### Specific guidelines for CT/CBCT scans

- Movements of the patient while scanning must be strictly avoided
- Prevent artefacts in images as far as possible
- Scan all slices of the study in the same direction
- Provide scan data (CT/CBCT) in DICOM\* multislices format (i.e. 200 files .dcm)
- DICOM files can be sent via web transmission platform (recommended) or in CD, DVD or USB memory by using tracked shipment. Do not use web exchange platforms such as DropBox or GDrive
- Do not send DICOM files inserted in proprietary software

\*DICOM: Digital Imaging and Communications in Medicine (DICOM) is a standard for handling, storing, printing, and transmitting information in medical imaging. It includes a file format definition and a network communications protocol. The communication protocol is an application protocol that uses TCP/IP to communicate between systems. DICOM files can be exchanged between two entities that are capable of receiving image and patient data in DICOM format.

### Specific guidelines for STL files

- STL file of the graft can be provided by email

### Specific guidelines for stereolithographic models

- Stereolithographic model of the graft can be sent using tracked shipment