

# Biocompatible Clear MED610™

MED610™ is a rigid, transparent, biocompatible material. The material is suitable for long-term (more than 30 days) contact to intact skin, limited (up to 24 hours) contact to mucosal-membranes and breached or compromised surface, and limited (up to 24 hours) contact to tissue, bone and dentin. The material is also suitable as a component in external communicating gas pathway devices.

## MED610 has been evaluated and deemed acceptable for the following biological risks

| Test                                | Standard             |
|-------------------------------------|----------------------|
| Cytotoxicity                        | EN ISO 10993-5:2009  |
| Irritation                          | EN ISO 10993-10:2013 |
| Delayed-type hypersensitivity       | EN ISO 10993-10:2013 |
| Genotoxicity                        | EN ISO 10993-3:2014  |
| Chemical characterization           | EN ISO 10993-18:2009 |
| USP Plastic Class VI                | USP 34 <88>          |
| External communicating gas pathways | EN ISO 18562-1:2017  |

| Property                | Standard / Procedure                           | Value                                                                                                                                                                                                                                                                                       |
|-------------------------|------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Tensile Strength        | D-638-03                                       | 50 – 65 MPa<br>(7,252 – 9,427 psi)                                                                                                                                                                                                                                                          |
| Elongation at Break     | D-638-05                                       | 10 – 25%                                                                                                                                                                                                                                                                                    |
| Modulus of Elasticity   | D-638-04                                       | 2,000 – 3,000 MPa<br>(290.1 – 435.1 ksi)                                                                                                                                                                                                                                                    |
| Flexural Strength       | D-790-03                                       | 75 – 110 MPa<br>(10,878 – 15,954 psi)                                                                                                                                                                                                                                                       |
| Flexural Modulus        | D-790-04                                       | 2,200 – 3,200 MPa<br>(319.1 – 464.1 ksi)                                                                                                                                                                                                                                                    |
| HDT @ 0.45 MPa          | D-648-06                                       | 45 – 50 °C<br>(113 – 122 °F)                                                                                                                                                                                                                                                                |
| HDT @ 1.82 MPa          | D-648-07                                       | 45 – 50 J/m<br>(113 – 122 °F)                                                                                                                                                                                                                                                               |
| Izod Notched Impact     | D-256-06                                       | 20 – 30<br>(0.37 – 0.56 ft-lb/in)                                                                                                                                                                                                                                                           |
| Water Absorption        | D-570-98 24HR                                  | 1.1 – 1.5%                                                                                                                                                                                                                                                                                  |
| Tg                      | DMA E                                          | 52 – 54 °C<br>(126 – 130 °F)                                                                                                                                                                                                                                                                |
| Shore Hardness          | Scale D                                        | 83 – 86 D                                                                                                                                                                                                                                                                                   |
| Rockwell Hardness Scale | Scale M                                        | 73 – 76 M                                                                                                                                                                                                                                                                                   |
| Polymerized Density     | ASTM D792                                      | 1.17 – 1.18 (g/cm³)<br>(0.676 – 0.682 oz/in³)                                                                                                                                                                                                                                               |
| Biocompatibility        | EN ISO 10993-1:2017<br><br>EN ISO 18562-1:2017 | Skin contact – permanent (>30 days)<br>Mucous membrane – short term (up to 24 hrs)<br>Tissue and bone – short term (up to 24 hours)<br>Component in external communicating gas pathway devices                                                                                              |
| Sterilization Methods   | ---                                            | Gamma sterilization <sup>1</sup> using a dose of 25–50 kGy<br>Steam sterilization <sup>2</sup> for four (4) minutes at 132 °C (270 °F)<br>with fractionated pre-vacuum<br>EtO sterilization <sup>3</sup> using 740mg EtO /l/6h exposure /45C/40-90%RH/<br>degassing 48h-96h/ up to 2 cycles |
| Support Removal Type    | ---                                            | Waterjet or soluble                                                                                                                                                                                                                                                                         |



# Biocompatible Clear MED610™

| System Availability                            | Minimum Layer Thickness Capability | Support Structure                                                                                                    | Available Colors |
|------------------------------------------------|------------------------------------|----------------------------------------------------------------------------------------------------------------------|------------------|
| Objet260/350/500™ Connex3                      | 16 microns (0.0006 in.)            | SUP705 (Waterjet removable)<br>SUP706B (soluble)                                                                     | Transparent      |
| J735/J750                                      | 14 microns (0.00055 in.)           | SUP705™ (Waterjet removable)<br>SUP706B™ (soluble)                                                                   | Transparent      |
| J750 Digital Anatomy™<br>J850 Digital Anatomy™ | 14 microns (0.00055 in.)           | SUP705™ (Waterjet removable)<br>SUP706B™ (soluble)<br>GelMatrix™ (waterJet removable) <sup>4</sup>                   | Transparent      |
| J5 MediJet®                                    | 18 microns (0.0007 in.)            | SUP710™ (Waterjet removable)<br>WSS™150 (water soluble) <sup>4</sup>                                                 | Transparent      |
| J5 Digital Anatomy™                            | 18 microns (0.0007 in.)            | SUP710™ (Waterjet removable)<br>WSS™150 (water soluble) <sup>4</sup><br>GelMatrix™ (waterJet removable) <sup>4</sup> | Transparent      |

All data provided herein, which is related to consumables, was collected from specific specimens and test conditions and is provided for information only. Characteristics may vary if different specimens and test conditions are applied. Unless expressly provided in writing, no warranties are made and warranties of merchantability or fitness for a particular purpose are expressly disclaimed.

<sup>1</sup> Gamma radiation may result in color change in the part.

<sup>2</sup> Allow the parts to cool down to room temperature before removing them from the autoclave. Flash autoclave may result in part deformations and changes to the flexural strength.

<sup>3</sup> EtO sterilization may result in part deformations and changes to the flexural strength.

<sup>4</sup> MED610 was not tested for biocompatibility with this support material.

For additional information about biological and toxicological assessment and the approved sterilization processes, refer to the [Biocompatible page in Stratasys support center](#).

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