

# Mitsubishi Engineering Plastics – Medical and FDA Polycarbonate

## Iupilon™ Polycarbonate:

Mitsubishi Engineering-Plastics Corporation has a broad medical polycarbonate offering.

Rigid Tube Connectors:



## USP Class VI:

The United States Pharmacopoeia (USP) set protocols to ensure biocompatibility of plastics. MEP's polycarbonate resins meet the Class VI which requires the most stringent testing of all six classes. Our reputation for quality and consistency of properties is never appreciated more than in applications requiring these strict standards.

## ISO 10933:

MEP grades are compliant with the requirements of ISO 10993-1 for using medical devices (e.g. dialyzer housing, oxygenator, joint connectors of blood lines, and three-way stopcock), single use.

Grade\*: S-3001R (5313, 5355)

Relating tests are followings.

ISO 10993-5: Tests for in vitro cytotoxicity

ISO 10993-10: Tests for irritation and skin sensitization

ISO 10993-11: Tests for systemic toxicity

ISO 10993-18: Chemical characterization of materials

\*Other grades & colors are also available.

## Colors for Gamma-Ray Sterilization:

Our EB-grades for gamma-ray sterilization come in a variety of colors. Choose the color you want depending on your post-sterilization color desired.



When standard PC grades are irradiated by gamma-rays, the mechanical properties remain largely the same but the color can turn color to yellow. EB-grades reduce the yellowing effect from the gamma-ray sterilization. In addition, the yellowing effect fades with time after the irradiation is complete.

Color plates can be provided for comparison purposes.

Dialyzer and Filter Applications:



## FDA:

MEP's polycarbonate grades have been FDA compliant for CRF 21 section 177.1580 of the U.S. Food and Drug Administration (FDA) for use in contact with food for many years. Its history of compliance that should give your or your customer confidence that you'll never have to worry if you've chosen the wrong material.



# Mitsubishi Engineering Plastics – Medical and FDA Polycarbonate

## Material Selection Guide:

### Steam and EtO Serializable Polycarbonate

| Application: Clear   | Brand    | Grade   | MFR* | Mold Release | Sterilization            | Colors                              |
|--|----------|---------|------|--------------|--------------------------|-------------------------------------|
| Dialyzer housing, oxygenator, joint connectors, three-way stopcock, also single use trays etc. | lupilon™ | H-3001R | 30   | R            | EtO & Steam Sterilizable | 5313: Ice Blue<br>5355: Water Clear |
|  |          | S-3001R | 15   | R            |                          |                                     |
|  |          | S-2001R | 10   | R            |                          |                                     |
|  |          | S-1001R | 7    | R            |                          |                                     |
| Extrusion  |          | E-2001R | 5    | R            |                          |                                     |

### High Chemical Resistance Polycarbonate

| Application: Opaque                               | Brand    | Grade   | MFR* | FR Type        | Flammability | Colors |
|---|----------|---------|------|----------------|--------------|--------|
| Opaque Medical Housings, High Chemical Resistance | lupilon™ | EFY2501 | -    | Non Br & Non P | V-0 @1.0mm   | -      |

### Gamma-Ray Serializable Polycarbonate, excellent color retention

| Application: Clear   | Brand    | Grade    | MFR | Mold Release | Sterilization                        | Colors       |
|--|----------|----------|-----|--------------|--------------------------------------|--------------|
| Gamma-Ray Sterilized repeated use products: Dialyzer housing, etc. | lupilon™ | EB-3001R | 15  | R            | EtO & Steam Sterilizable & Gamma-Ray | R502NS, etc. |
|  |          | EB-2001R | 10  | R            |                                      |              |
|  |          | EB-1001R | 7   | R            |                                      |              |

More grades including datasheets are available at MEP's website at <http://m-ep.co.jp>.

Jeff Lowe

Sales Manager

San Diego, CA

[jeff.lowe@m-chem.com](mailto:jeff.lowe@m-chem.com)

Madeline Boyer

Application Development Engineer

Commerce, MI

[Madeline.Boyer@m-chem.com](mailto:Madeline.Boyer@m-chem.com)

General Tech: [mailto:Mepa\\_Tech@m-chem.com](mailto:Mepa_Tech@m-chem.com)

