

# FAQ

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## What are the medical-grade resins ?

The medical-grade resins constitute a range of SL materials that can produce sterilisable parts for use as medical devices. It is the responsibility of the medical device or pharmaceutical manufacturer (“Manufacturer”) to determine the suitability of all component parts and raw materials, including all Huntsman products, in its final product. The Manufacturer of a medical device must ensure its safety in use and compliance with all applicable laws and regulations, including national legislation (e.g. FDA and EU Member States) and EU legislation and guidelines.

The Manufacturer is responsible to ensure that the device is technically suitable for its intended purpose.

### Range of medical resins

At the moment, there are the following medical-grade SL materials available

Renshape® SL Y-C 9300:

selectively colourable SL material for SLA® 3500/ 5000/ 7000/ Viper si2™

Renshape® SL Y-C 9500:

Clear SL material, can be custom pigmented for Solid State Laser SLA® systems

Renshape® SL Y-C 9500-FT#1:

Flesh-tone pink SL material for hearing aid manufacture for Solid State Laser SLA® systems

Renshape® SL 7800:

ABS-like resin for Solid State Laser SLA® systems, high long-term durability

Renshape® SL 7810:

Produces white, ABS-like parts; for Solid State Laser SLA® systems, high long-term durability

Renshape® SL 7820:

Produces black, ABS-like parts; for Solid State Laser SLA® systems, high long-term durability

Renshape® SL 7840:

Produces white, PP-like parts; for Solid State Laser SLA® systems, high long-term durability

Renshape® SL 7870:

For transparent parts with high impact resistance; for Solid State Laser SLA® systems, high long-term durability

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### Toxicology

The USP (United States Pharmacopoeia) test guidelines or ISO (International Standard) test guidelines are designed to evaluate the biological responses relevant to the safety of medical devices and materials. Medical devices are categorized by nature and duration of body contact. The product must be tested and must meet the appropriate specifications for the application (e.g. US Pharmacopoeia, ISO, EU Medical Directive or National Formulary). The above-mentioned products are classified in category A: Limited exposure (devices whose single or multiple use or contact is likely to be up to 24h). Before any medical use, the parts need to be sterilised. The Medical parts must not be left inside the body once the surgery is completed.

### Sterilisation

There are four methods of sterilization of Medical parts:

- Ethylene oxide at 55°C.

This is the most popular method, and should be available at most hospitals.

- Gamma radiation.

This is more commonly used in factory environments, and may not be available in hospitals.

- Low temperature (and pressure) steam (at 75°C). Regular steam (at 100°C) will damage the model.

- Formaldehyde at 80°C.

### Post-processing

The medical parts are post-cured in a UV curing oven like any other SL parts.

Before use, the parts should be kept cool, dry and away from bright light.

The models should be used for their primary purpose without too much delay.

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