BIOCOMPATIBLE RESINS AND MEDICAL-GRADE POLYMERS

Materials Chosen for Performance, Safety and Fit

A Technical White Paper

Complete Fabrication Ltd

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This white paper contains a lot of detail. The quickest way to the right material is to talk to us: call 01223 836837 or email info@compfab.co.uk, and we will give you advice based on 40 years of making prototypes.

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Executive Summary

Choosing the right material for a medical device prototype or production component is one of the most important decisions in any development project. General industrial prototyping is mostly about dimensional accuracy and how the part looks. Medical work adds a different set of priorities: patient safety, regulatory compliance, sterility, and long-term biological compatibility.

This white paper is a technical reference for biocompatible resins and medical-grade polymers across the processes most used for medical prototypes: stereolithography (SLA), digital light processing (DLP) including Carbon Digital Light Synthesis (DLS), fused deposition modelling (FDM), and vacuum casting in polyurethane (PU) and epoxy. Each section covers material options, performance data, the relevant standards, sterilisation compatibility, cleanroom requirements and compliance obligations.

In our Whittlesford workshop we print SLA, Carbon DLS, DLP and FDM parts, vacuum cast in polyurethane, and CNC machine plastics including solid PEEK. Our biocompatible print materials include Carbon MPU 100 and Carbon SIL 30, and we offer equivalent resins for vacuum-cast batches. SLS and MJF parts are sourced through partners.

Material selection for medical work isn't interchangeable with standard prototyping grades. Biocompatibility has to be validated, not assumed. The tables are a general market reference: they include widely used materials that we do not stock, and values come from manufacturers' published data. Check every material against the current data sheet and the relevant regulatory submissions before using it in a clinical or regulatory context, and ask us which grades we can run for your project.

1. Regulatory Framework and Compliance

1.1 ISO 10993: Biological Evaluation of Medical Devices

ISO 10993 is the internationally recognised series of standards for the biological evaluation of medical devices. It is published by the International Organization for Standardization and recognised by regulators including the US FDA, EU notified bodies under the MDR, and the UK MHRA.

The series has more than 20 parts, each covering a specific aspect of biological evaluation. The parts most often used for polymer-based medical devices are:

Part	Title	Relevance to Fabricated Polymers
Part 1	Evaluation and testing within a risk management process	Defines the framework; mandatory starting point for all evaluations
Part 3	Tests for genotoxicity, carcinogenicity and reproductive toxicity	Required for implants and prolonged-contact devices
Part 4	Selection of tests for interactions with blood	Relevant for any blood-contacting prototype or device component
Part 5	Tests for in vitro cytotoxicity	The most common initial screen; required for virtually all contact materials
Part 6	Tests for local effects after implantation	Required for implant-grade materials

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Part 10	Tests for skin sensitisation	Required for skin-contact and mucosal-contact applications
Part 12	Sample preparation and reference materials	Defines extraction and leachable testing protocols
Part 17	Establishment of allowable limits for leachable substances	Critical for resin-based materials where residual monomers may be present
Part 18	Chemical characterisation of medical device materials	Required for novel materials or non-standard formulations

A full biological evaluation under ISO 10993-1 does not necessarily require all tests from all parts. The required tests are determined by the nature and duration of patient contact, based on three contact categories (surface device, externally communicating device, implant) and three duration bands (limited: <24 hours; prolonged: 24 hours to 30 days; permanent: >30 days).

1.2 FDA Regulatory Pathways

In the United States, medical devices are regulated by the Food and Drug Administration (FDA) under 21 CFR Parts 800–898. The relevant pathway depends on the device classification:

- Class I (low risk): general controls only. Most Class I devices are exempt from 510(k) premarket notification.
- Class II (moderate risk): usually needs a 510(k) premarket notification showing substantial equivalence to a predicate device.
- Class III (high risk): needs premarket approval (PMA), the most stringent pathway. This covers many implants and life-sustaining devices.

The FDA's guidance 'Technical Considerations for Additive Manufactured Medical Devices' (2017) sets out what it expects for 3D-printed devices: characterisation of the starting material, validation of the process and its parameters, control of post-processing, and testing of the finished device.

FDA does not pre-approve materials for medical use on their own. The complete device (material, process, post-processing, and intended use) has to be evaluated together. A material certified by its supplier as ISO 10993-compliant is not automatically cleared for use in your specific device.

1.3 EU Medical Device Regulation (EU MDR 2017/745)

The EU MDR replaced the previous Medical Device Directive (MDD 93/42/EEC) and became fully applicable in May 2021. It imposes significantly more rigorous requirements on clinical evidence, post-market surveillance, and material traceability than its predecessor.

Under the EU MDR, devices must meet the General Safety and Performance Requirements (GSPRs) in Annex I. For polymer materials, the most relevant are in Section 10, on chemical, physical and biological properties:

- Section 10.1: materials must be chosen with regard to toxicity and their compatibility with the biological tissues, cells and body fluids they contact.
- Section 10.4.1: devices may contain substances that are carcinogenic, mutagenic or toxic to reproduction (CMR, category 1A or 1B), or that have endocrine-disrupting properties, above 0.1% w/w only where this is justified.
- Section 10.2: devices must be designed to minimise the risk that contaminants and residues pose to patients and users.

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For UK-market devices post-Brexit, the MHRA applies equivalent requirements under the UK MDR 2002 (as amended). Devices must carry the UKCA mark (or CE mark under the current transitional arrangements) and comply with standards recognised by the MHRA.

Complete Fabrication Ltd is ISO 9001 certified (certificate 7774). We supply Certificates of Conformity for materials and manufacture when you flag the requirement at quote, and for each batch we record the materials and resin batch numbers, pattern and mould numbers, who made the parts and the inspection results.

2. Stereolithography (SLA): Biocompatible Resins

2.1 Process Overview

Stereolithography (SLA) uses a UV laser to cure photopolymer resin layer by layer. It gives among the best dimensional accuracy and surface finish of the polymer 3D printing processes, with layers as fine as 25 microns (we print at 0.05 mm as standard). That makes it the usual choice for anatomical models, surgical guides and high-fidelity form-study prototypes where surface quality matters.

The main limitation of SLA for medical work is residual monomer. Uncured or partly cured resin contains unreacted monomers and photoinitiators that can be cytotoxic and cause sensitisation. Medical-grade parts must be washed thoroughly, usually in isopropyl alcohol (IPA), and post-cured exactly to the resin maker's schedule.

2.2 Validated Biocompatible SLA Materials

Material	Supplier	ISO 10993 Status	Contact Category	Key Properties	Sterilisation
BioMed Clear Resin	Formlabs	ISO 10993 and ISO 7405 evaluated	Skin and mucosal contact (see data sheet for duration)	Transparent, rigid	EtO, gamma, e-beam, steam autoclave
BioMed Durable Resin	Formlabs	USP Class VI; ISO 10993 evaluated	Long-term skin contact	Transparent, impact resistant	See Formlabs data sheet
BioMed White Resin	Formlabs	ISO 10993 evaluated (see data sheet)	See Formlabs data sheet	Opaque white	See Formlabs data sheet
MED610 (VeroDentPlus)	Stratasys (PolyJet)	ISO 10993-3, -5, -10, -18; USP Class VI	Permanent skin; short-term mucosal	Rigid, transparent, 50–65 MPa tensile	Gamma; steam (see data sheet)
Dental LT Clear	Formlabs	FDA 510(k) (V2, K222061); EU MDR Class IIa	Long-term oral	Splints and occlusal guards	See Formlabs data sheet

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Post-curing must follow the resin maker's instructions exactly. Formlabs warns that improper post-curing can reduce both mechanical and biocompatibility performance, and its BioMed Clear data come from parts post-cured at 60 °C for 60 minutes in a Form Cure.

Do not substitute standard or engineering resins for medical-grade variants even in seemingly low-risk applications. Standard Grey, Clear, or Tough resins from any manufacturer have not been tested for biocompatibility and should never contact patients or sterile fields.

2.3 SLA Dimensional Accuracy for Medical Applications

We hold ±0.15 mm on most SLA work. If a surgical guide or patient-specific instrument needs tighter control, tell us the critical dimensions at quote so we can plan the build orientation and inspection.

3. Digital Light Processing (DLP): Biocompatible Resins

3.1 Process Overview

DLP is closely related to SLA but cures entire layers simultaneously using a projected UV image from a digital light projector or UV LED array, rather than a scanning laser. This makes DLP significantly faster than SLA for parts with large cross-sectional areas, while achieving comparable or superior surface resolution in the XY plane. Layer thicknesses of 25–100 microns are typical.

DLP is widely used in dental work, for models, splints, surgical guides and temporary restorations. We run a small number of specialist DLP resins; Carbon DLS (Section 3.3) is our main process of this type.

3.2 Validated Biocompatible DLP Materials

Material	Supplier	Regulatory Status	Primary Application	Notable Properties
NextDent C&B MFH	3D Systems	Check current data sheet	Dental crowns and bridges	Multi-shade, for long-term temporaries
NextDent Ortho Rigid	3D Systems	Check current data sheet	Orthodontic splints	Transparent, stiff, dimensionally stable
V-Print model	VOCO	Check current data sheet	Dental models	High accuracy, smooth surface, easy post-process

Pixel size is a key consideration with DLP. It sets the minimum XY feature size and the stepping visible on curved surfaces, so check it against your smallest critical feature.

DLP resins cure by the same photopolymerisation mechanism as SLA. All biocompatibility, post-curing, and washing requirements described in Section 2 apply equally to DLP. The process differs; the material chemistry and safety protocols do not.

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3.3 Carbon MPU 100: Medical-Grade White Polyurethane Resin

Carbon's MPU 100 (Medical Polyurethane 100) is a rigid, white medical-grade resin for Carbon's DLS process. Carbon describes it as combining mechanical strength, biocompatibility and sterilisability.

MPU 100 is a two-part polyurethane resin that runs only on Carbon's DLS platform. DLS uses continuous liquid interface production to make dense parts with fine features and smooth surfaces, closer to end-use quality than most prototype resins. We are a Carbon Certified Production Partner and run MPU 100 in-house.

Property	Value / Detail
Manufacturer	Carbon, Inc. (Sunnyvale, California)
Process	Carbon DLS (Digital Light Synthesis), photopolymer resin
Colour	White
Tensile Strength	35 MPa (5 ksi), ASTM D638
Heat Deflection Temperature	50 °C at 0.455 MPa; 40 °C at 1.82 MPa (ASTM D648)
Regulatory / Biocompatibility	ISO 10993-5 (cytotoxicity), -10 (sensitisation), -23 (irritation); ISO 10993-4 / ASTM F756 (haemolysis); USP <88> systemic toxicity and implantation. Tested by NAMSA
Sterilisation Compatibility	EtO, e-beam and gamma tested by Carbon; steam autoclave only for parts under no load (see note)
Chemical Resistance	Wipe and 24-hour soak tested with 5% bleach, 70% ethanol, 5% chlorhexidine gluconate and 0.13% benzalkonium chloride; the ethanol soak reduced stiffness most
Post-Sterilisation Biocompatibility	No cytotoxicity (ISO 10993-5) after EtO, e-beam, gamma or autoclave cycles
Key Applications	Single-use medical device components; surgical instrument handles and guides; diagnostic equipment parts; skin-contact components
Note	HDT is below autoclave temperatures. Carbon found parts keep their shape in an autoclave only if under zero load, including during cool-down, and strength fell by about 31% after five cycles.

Carbon's data sheet (Doc 108269-01 Rev F, June 2026) gives the full test results, which can support your own biological evaluation and reduce the testing you would otherwise commission from scratch.

Tested compatibility with EtO, e-beam and gamma sterilisation, a white colour and documented biocompatibility make MPU 100 a good fit for single-use instruments, diagnostic equipment components and skin-contact parts.

For most parts, specify EtO, e-beam or gamma sterilisation. EtO caused the least change in Carbon's tests; e-beam and gamma stiffened the material and caused some yellowing. Autoclaving is possible only for parts under no load, so tell us at project briefing if your device must be autoclaved.

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3.4 Carbon EPU Pro 50 and 90 Black: Biocompatible Elastomers

EPU Pro 50 Black and EPU Pro 90 Black are single-part elastomer resins from Carbon for its DLS platform. Carbon describes them as offering tunable stiffness and an extended pot life, for both low-volume product development and high-volume production. Where MPU 100 is rigid, EPU Pro gives a rubber-like part: EPU Pro 50 is soft (Shore A 53) and EPU Pro 90 is firmer (Shore A 88).

Carbon supplied printed test parts in both grades to NAMSA, a medical device testing laboratory, and reports that both met the requirements of three ISO 10993 tests: cytotoxicity, skin sensitisation and irritation (Carbon EPU Pro 50 and 90 Black technical data sheet, document 125561-01 Rev C, June 2026).

Property	Value / Detail
Manufacturer	Carbon, Inc. (Sunnyvale, California)
Process	Carbon DLS (Digital Light Synthesis), single-part elastomer resin
Colour	Black
Hardness	EPU Pro 50: Shore A 53; EPU Pro 90: Shore A 88 (ASTM D2240)
Ultimate Tensile Strength	EPU Pro 50: 14 MPa; EPU Pro 90: 22 MPa (ASTM D412 Die C, 0.8 mm)
Elongation at Break	EPU Pro 50: 820%; EPU Pro 90: 440%
Tear Strength	EPU Pro 50: 20 kN/m; EPU Pro 90: 45 kN/m (ASTM D624 Die C, 0.8 mm)
ISO 10993-5	In vitro cytotoxicity (MEM extract): met the requirements, both grades
ISO 10993-10	Skin sensitisation (closed patch study): met the requirements, both grades
ISO 10993-23	Irritation (intracutaneous study): met the requirements, both grades
Test Laboratory	NAMSA; further test details available from Carbon on request
Chemical Resistance	Under 5% mass gain after one week in 5% bleach, 10% ammonium chloride sanitiser, distilled water and sebum; over 30% in 95% ethanol (ASTM D543)
Key Applications	Soft-touch grips, seals, gaskets and skin-contact wearable components
Note	Carbon's data sheet does not list sterilisation compatibility or USP Class VI for EPU Pro. Confirm with Carbon before specifying it for a sterilised device.

Cytotoxicity, sensitisation and irritation are the three tests usually needed for a surface device in contact with intact skin. They do not make a finished device biocompatible on their own: as Section 1 explains, the complete device, including processing and post-processing, has to be evaluated. Carbon's results apply to parts printed, washed, cured and baked using its standard EPU Pro workflow.

The ethanol result matters for medical parts. If a device will be wiped with alcohol in use, test the effect on the finished part before committing to EPU Pro.

4. Fused Deposition Modelling (FDM): Medical-Grade Polymers

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4.1 Process Overview

FDM (sometimes called FFF, or Fused Filament Fabrication) extrudes thermoplastic filament through a heated nozzle to build parts layer by layer. Unlike photopolymer processes, FDM materials are thermoplastic polymers with well-established regulatory histories in medical device manufacture. Many have decades of clinical data behind them.

The biggest problem with FDM for medical work is the porous, layer-structured surface the process produces. Internal porosity and surface crevices trap bacteria and resist sterilisation by standard methods. Parts intended for sterile use must be post-processed (by chemical smoothing, infiltration with a biocompatible sealant, or machining) to reach the required surface quality.

4.2 Medical-Grade FDM Thermoplastics

Material	Process	ISO 10993	Tensile Strength	HDT	Key Medical Use
PEEK (medical grade)	FDM (specialist high-temperature printers)	Implant grades have a long clinical history	~100 MPa	~150 °C	Implant trials, surgical instruments
PC-ISO (Polycarbonate)	FDM (Stratasys)	ISO 10993 / USP Class VI (Stratasys)	57 MPa	133°C	Surgical instrument handles, enclosures
Ultem 1010 (PEI)	FDM (Stratasys)	ISO 10993 / USP Class VI; NSF 51	81 MPa	216°C	Autoclavable tools, food/medical contact
PA12 Medical (Nylon)	SLS (via our partners) or FDM	Biocompatible grade available	50 MPa	175°C	Prosthetics, braces, structural models
PETG (medical grade)	FDM	Some grades food-contact compliant	53 MPa	~70 °C	Non-contact housings, clear panels
TPU (medical grade)	FDM	Biocompatible grades available	30–45 MPa	n/a	Flexible device components, grips, gaskets

PEEK is the most clinically significant of these materials. Implantable grades such as Invibio PEEK-OPTIMA and Solvay Zeniva have a long clinical history in spinal cages, cranial implants and dental components. Printing PEEK needs very high nozzle and chamber temperatures and a dedicated high-temperature printer. For prototype PEEK parts we usually CNC machine from solid stock instead.

Standard FDM machines using commodity PLA, ABS, or generic PETG are not suitable for medical-grade applications. Material purity cannot be verified, ISO 10993 data does not exist, and the machines are not validated for medical production. Always source medical-grade filament with full documentation from the filament manufacturer.

4.3 Surface Porosity and Bacterial Ingress in FDM

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FDM parts have a rough, layered surface with small gaps between layers. These give bacteria more places to attach, and make parts harder to clean and sterilise reliably than smooth moulded parts.

Mitigation strategies include:

- Vapour smoothing (for example acetone on ABS): seals the surface but leaves chemical residues that need validating.
- Infiltration with medical-grade epoxy or cyanoacrylate: seals surface porosity but adds dimensional build and requires biocompatibility testing of the infiltrant.
- CNC post-machining of critical surfaces: effective but time-consuming; reserved for functional sealing faces.

5. Vacuum Casting in Polyurethane and Epoxy

5.1 Process Overview

Vacuum casting makes end-use quality polymer parts by drawing two-part liquid resin (PU or epoxy) into silicone moulds under vacuum. The master pattern is usually made by SLA or machining, and each silicone mould typically gives around 20 castings, sometimes fewer with resins that are hard on the silicone. The process bridges prototyping and low-volume production, with material properties close to injection-moulded plastics.

For medical work, vacuum casting is useful because it can produce parts in well-characterised polymers, some with published biocompatibility data, with surface finishes and mechanical properties close to the intended production material. It is widely used for device housings, handles and grips, and wearable device enclosures.

5.2 Medical-Grade Polyurethane (PU) Systems

Polyurethanes are the most common vacuum casting materials, from soft elastomers to rigid ABS-like grades. Most are engineering grades with no biocompatibility testing, so for any part that will touch a patient, choose a grade whose maker publishes ISO 10993 or USP Class VI results, such as the Hapco Steralloy range in Section 5.3, and confirm the current data sheet before casting.

USP Class VI (United States Pharmacopeia Plastics Class VI) is a complementary standard to ISO 10993, originating from pharmaceutical packaging. It tests for systemic injection toxicity, intracutaneous reactivity, and implantation response. Many medical device OEMs require USP Class VI certification for any material contacting drug delivery pathways or sterile fluids.

5.3 Hapco Steralloy™: Medical-Grade PU and Epoxy Systems

Hapco, Inc. (Hanover, Massachusetts) makes the Steralloy range of 100% solids polyurethane and epoxy systems for food and drug-related applications, including medical device manufacture.

As covered in Section 1, the FDA does not approve casting resins on their own; approval applies to the finished device. Hapco describes its Steralloy FDG elastomers as 'FDA approvable', meaning they are formulated to support the biocompatibility testing and documentation a device submission needs.

The range has two main series: elastomeric grades (the FDG E-Series, from about Shore 20A to 72D) and rigid epoxy grades (the R-Series).

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Steralloy Grade	Series / Type	ISO 10993 / Regulatory	Shore Hardness	Tensile Strength	Medical Application
Steralloy E-2871-4	E-Series (flexible)	Described by Hapco as biocompatible	See Hapco data sheet	See Hapco data sheet	Flexible device components, seals, grips
Steralloy R-2380	R-Series (rigid epoxy)	Food and drug grade	See Hapco data sheet	See Hapco data sheet	Rigid housings and enclosures
Steralloy R-2456	R-Series (rigid epoxy)	Passes ISO 10993-5	See Hapco data sheet	See Hapco data sheet	Structural parts, diagnostic enclosures

The elastomeric grades suit seals, grips and wearable components where hardness has to match the clinical use. The rigid R-Series epoxies suit structural parts and enclosures where stiffness, dimensional stability and chemical resistance matter.

Request Hapco's current data sheet and biocompatibility test report for the exact grade before using it in a regulated device, and ask us which casting resins we can supply for your project.

5.4 Medical-Grade Epoxy Systems

Few epoxy casting systems carry biocompatibility data. Medical-grade epoxies with published test results are mainly adhesives and potting compounds, which are useful for bonding, sealing and encapsulating parts in a prototype assembly.

Epoxy System	Supplier	Contact Type	Flexural Modulus	HDT	Notes
Epo-Tek 301-2 (biocompatible)	Epoxy Technology	USP Class VI; MED-301-2 version ISO 10993-5	See data sheet	See data sheet	Optical bonding and potting
Master Bond EP21LVMed	Master Bond	USP Class VI; ISO 10993-5	See data sheet	See data sheet	Medical device assembly

Bisphenol A (BPA) has been identified as an endocrine disruptor and is restricted under EU MDR Annex I Section 10.4 and REACH. Where possible, specify BPA-free alternatives for any patient-contact or implant-adjacent part.

5.5 Silicone Mould Compatibility

The silicone mould itself has to be checked for compatibility with medical-grade casting materials. Addition-cure (platinum-catalyst) silicones are strongly preferred over condensation-cure systems, as they produce no by-products during cure and are inherently more biocompatible. The mould silicone shouldn't be the same material that contacts the patient (it's a production tool), but any silicone residue that transfers to the cast part surface has to be considered in the biocompatibility evaluation.

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6. Sterilisation Compatibility

6.1 Overview of Sterilisation Methods

Sterilisation is the process of eliminating all viable microorganisms, including spores, from a device or surface. For medical device prototypes that will enter a sterile field, contact a surgical site, or be used in clinical trials, the appropriate sterilisation method must be selected based on material compatibility, device geometry, and the sterility assurance level (SAL) required. The internationally recognised target SAL for sterile medical devices is 10^{-6} (one chance in one million of a surviving organism).

Method	Temperature	SAL Achievable	Compatible Processes	Not Compatible With	Cycle Time
Steam autoclave (121°C)	121°C / 15 psi	10^{-6}	PEEK, Ultem, metal SLM, glass-filled PA	PLA, ABS, most standard SLA resins and PU	30–60 min + drying
Steam autoclave (134°C)	134°C / 30 psi	10^{-6}	PEEK, Ultem 1010, metal SLM only	All standard polymers	18 min + drying
Ethylene oxide (EtO)	<60°C	10^{-6}	All polymers, electronics, complex geometry	None (material-universal)	2–16 hrs + 24–48 hr aeration
Vaporised hydrogen peroxide (VHP)	<45°C	10^{-6}	All polymers, SLA/DLP resins, PU, epoxy	Cellulosic materials, some adhesives	1–4 hrs
Gamma irradiation	Ambient	10^{-6}	PA12, PEEK, PC, PU, metals	Some resins (yellowing), TPU (degradation)	Hours (dose-dependent)
E-beam irradiation	Ambient	10^{-6}	Dense, single-layer items; metals, PA	Complex geometry (poor penetration)	Minutes
UV surface irradiation	Ambient	Decontamination only	All surfaces	Internal channels, shadowed areas	Minutes
Dry heat (160–180°C)	160–180°C	10^{-6}	Metals, glass, PEEK	All standard polymers and resins	1–2 hrs

EtO and VHP are the most broadly compatible sterilisation methods for polymer-based medical device prototypes. EtO requires lengthy aeration (24–48 hours) to allow residual gas to dissipate to safe levels. VHP is faster and leaves no toxic residue, making it increasingly preferred in hospital and research settings.

6.2 Effect of Sterilisation on Material Properties

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Sterilisation processes can alter the mechanical properties, dimensional accuracy, colour, and surface chemistry of prototype materials. These effects must be characterised for any material used in a clinical or regulatory submission context.

Material	Autoclave Effect	EtO Effect	Gamma Effect	VHP Effect
PEEK (medical FDM)	No significant change	No significant change	Minor property change <25 kGy	No significant change
SLA BioMed Clear	Compatible (Formlabs-tested cycles)	Compatible (Formlabs-tested)	Compatible (29–31 kGy tested)	Not listed by Formlabs
Formlabs Surgical Guide	Designed for autoclave	See data sheet	See data sheet	See data sheet
Cast PU (typical)	Degradation at 121°C+	Acceptable; validate	Some discolouration	Preferred method
Epoxy (typical)	HDT-dependent; risk of distortion	Acceptable	Stable <50 kGy	Acceptable
PA12 (SLS)	Risk of warping	Acceptable	Stable, preferred	Acceptable
PC-ISO (FDM)	Acceptable (133°C HDT)	Acceptable	Some yellowing	Acceptable
Ultem 1010 (FDM)	Fully autoclavable	Acceptable	Stable	Acceptable
Carbon MPU 100	Possible only with no load on the part	Compatible (Carbon-tested)	Stiffens, some yellowing; no cytotoxicity	Not covered by Carbon's data

7. Cleanroom Requirements and Environmental Controls

7.1 ISO Cleanroom Classification

ISO 14644-1 defines cleanroom classes based on the maximum permitted concentration of airborne particles at specified sizes. Medical device fabrication and packaging operations are conducted in cleanroom environments to prevent contamination of sterile or clean device surfaces.

ISO Class	Equivalent (old)	Max particles ≥0.5 µm /m³	Typical HVAC Changes/hr	Typical Application
ISO 5	Class 100	3,520	240–480	Aseptic fill/finish, implant assembly
ISO 6	Class 1,000	35,200	150–240	Sterile device assembly, implant packaging
ISO 7	Class 10,000	352,000	60–90	Medical device assembly, final packaging

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ISO 8	Class 100,000	3,520,000	10–25	Device sub-assembly, gowning areas
Unclassified	(controlled)	>3,520,000	Variable	Model making, non-sterile prototyping

Our workshop is not a classified cleanroom. Medical parts are cleaned with medical-grade isopropanol wipes, or to a cleaning regime you specify, and any sterilisation must be done by a validated method. If your application needs fabrication in a classified cleanroom, for example aseptic assembly of sterile implants, raise it at project briefing.

7.2 Post-Processing in Controlled Environments

Post-processing steps, including support removal, washing, post-curing, sanding and finishing, are potential contamination events. For medical-grade parts, good practice is to control them to suit the device's intended sterility status, for example:

- Support removal and washing: a dedicated area with filtered air, tools kept for medical work, and IPA wash tanks changed at defined intervals.
- UV post-curing (SLA/DLP): cure unit cleaned with IPA between medical batches, and lamp output checked against the maker's specification.
- Final inspection and packaging: ISO 8 or better for any part intended for clinical use, with double-bagging in medical-grade pouches.
- Personnel controls: gloves, hair cover and beard snood for anyone handling medical-grade parts after washing, and no eating, drinking or cosmetics in the area.

Even if a part is to be terminally sterilised, cleanroom controls during fabrication reduce bioburden and make sterilisation more reliable. A part with very high initial bioburden places greater demand on the sterilisation process and increases the risk of sterilisation failure.

7.3 Environmental Monitoring

Where a project needs cleanroom fabrication, environmental monitoring typically covers:

- Particle counts: measured at rest and in operation with a calibrated counter, against ISO 14644-1 limits.
- Viable air sampling: active air samples and settle plates at defined frequencies.
- Surface contact plates: regular sampling of work surfaces, equipment and gloved hands.
- Temperature and humidity: Continuous data logging with alarm limits; relevant to material stability (especially PU two-part systems with defined mix-ratio sensitivity).

8. Traceability, Documentation and Compliance

8.1 Material Traceability

Medical device regulation, whether under the FDA, ISO 13485 or the EU MDR, requires traceability of materials from raw material to finished product. For a medical prototype, that means every batch of resin, filament or casting compound is tracked by lot number, with records kept for the period the applicable regulation sets. Under ISO 13485, that is at least the lifetime of the device, and no less than two years from release.

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A full traceability record for a medical build typically includes the items below. As standard we record the materials and resin batch numbers, pattern and mould numbers, who made the parts and the inspection results; tell us at quote if you need the full set.

- Material name, grade, and supplier
- Lot/batch number
- Supplier Certificate of Conformity
- ISO 10993 test reports (current, from supplier)
- Date of receipt and date used
- Build machine identifier and calibration status
- Operator name and qualification
- Post-processing log (method, duration, agent, date)
- Sterilisation certificate (if the parts are sterilised)
- Dimensional inspection record
- Final disposition (released / quarantine / rejected)

8.2 ISO 13485 and Quality Management

ISO 13485:2016 is the quality management system standard for organisations that design and make medical devices. EU notified bodies and Canada (through MDSAP) expect it, and since February 2026 the US FDA's Quality Management System Regulation has incorporated it by reference.

Its key requirements for prototyping and production work include:

- Controlled document management: All procedures, work instructions, and forms must be controlled, versioned, and approved.
- Non-conformance management: Any deviation from a build specification must be documented, investigated, and dispositioned before the part is released.
- Validated processes: Build processes for medical parts must be validated, demonstrating that consistent, defined process parameters produce consistent, specification-conforming output.
- Supplier control: Material suppliers must be qualified and monitored. ISO 10993 certification from a supplier cannot be accepted without reviewing the supporting test reports.
- Internal audits: Regular internal audits of the quality system and production processes are required.

8.3 Design History File (DHF) and Device History Record (DHR)

Regulated device makers must keep a record of design and development (traditionally the Design History File) and a production record for each unit or batch (traditionally the Device History Record).

We supply Certificates of Conformity for manufacture and materials, together with our build and inspection records, to support your device files and technical documentation. Tell us at quote if you have a regulatory submission requirement, so we can agree what the documentation pack needs to include.

8.4 Declaration of Conformity and Supplier Qualification

Where you need a formal statement that materials and manufacture meet your specification, we supply Certificates of Conformity for both, provided you flag the requirement at quote.

If your supplier qualification process includes an audit, contact us to discuss it.

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9. Consolidated Material Selection Guide

Use this table as a quick reference when choosing a process and material for a medical application. It is a general guide, not a list of materials we stock: ask us which options we can make for your project. All recommendations assume validated medical-grade variants with current biocompatibility documentation.

Application	Recommended Process	Recommended Material	ISO 10993 Tier	Preferred Sterilisation
Surgical planning model (non-sterile)	SLA or DLP	BioMed Clear / BioMed White	Part 5 (minimum)	Not required
Surgical drill guide (sterile)	SLA	Formlabs Surgical Guide Resin	Per maker's data	Steam autoclave (maker's cycle)
Anatomical teaching model	FDM or SLA	PA12 / BioMed White	Part 5 (minimum)	VHP or EtO if contact
Device housing (short-term skin)	Carbon DLS or vacuum cast PU	Carbon MPU 100 / tested PU grade	Parts 5, 10	EtO
Flexible grip / wearable	Carbon DLS or FDM TPU	Carbon EPU Pro 50 or 90 / medical TPU	Parts 5, 10, 23	Check with maker
Structural implant trial	CNC machining or FDM	Implant-grade PEEK	Full ISO 10993 suite	Autoclave (134°C)
Transparent cover / window	SLA	BioMed Clear	ISO 10993 evaluated	EtO, gamma, e-beam or autoclave
High-temp autoclavable tool	FDM	Ultem 1010	Parts 5, 10, NSF 51	Autoclave (134°C)
Dental splint / retainer	SLA (Formlabs) or DLP	Dental LT Clear / NextDent Ortho Rigid	FDA 510(k) (Dental LT Clear V2)	Per maker's data
Medical device housing (medical-grade PU)	Vacuum casting	Hapco Steralloy E-Series	Per Hapco test report	Per maker's data
Rigid diagnostic enclosure	Vacuum casting (rigid epoxy)	Hapco Steralloy R-2456	ISO 10993-5 passed	Per maker's data
Single-use surgical instrument	Carbon DLS	Carbon MPU 100	ISO 10993-4, -5, -10, -23; USP <88>	EtO (preferred); e-beam; gamma

10. References and Further Reading

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- ISO 10993-1:2018, Biological evaluation of medical devices: Evaluation and testing within a risk management process.
- ISO 14644-1:2015, Cleanrooms and associated controlled environments: Classification of air cleanliness by particle concentration.
- ISO 13485:2016, Medical devices: Quality management systems, Requirements for regulatory purposes.
- FDA, Technical Considerations for Additive Manufactured Medical Devices (Guidance, December 2017).
- EU MDR 2017/745, Regulation on medical devices, Annex I (General Safety and Performance Requirements).
- Formlabs, BioMed Resin Series Technical Data Sheets and ISO 10993 Test Reports (current edition).
- Stratasys, MED610 and PC-ISO Material Safety and Biocompatibility Documentation.
- Epoxy Technology, Epo-Tek 301-2 Biocompatibility Test Summary and Technical Bulletin.
- Master Bond, EP21LVMed Technical Data Sheet.
- Hapco, Inc., Steralloy technical data sheets and biocompatibility documentation (current editions).
- Carbon, Inc., MPU 100 Technical Data Sheet, Doc 108269-01 Rev F (June 2026).
- Ventola, C.L., Medical Applications for 3D Printing: Current and Projected Uses, Pharmacy and Therapeutics, 39(10), 2014.

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