

Sterilisation of Vat-Printed Photopolymers: Dimensional Evidence and Qualification Gaps

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Statement of Significance

Sterilisation compatibility is not a property of a raw resin and cannot be inferred from dimensional retention alone. It is an equivalence claim for a defined printed article, post-processing state, sterilisation process, cycle count, conditioning history and intended function. Recent evidence shows why the full state must be tested: one vat-printed material retained relevant properties through several moist-heat cycles but degraded after 50 cycles, while other studies found method- and formulation-dependent changes in geometry, mechanics or optical response.

Keywords: sterilisation; moist heat; ethylene oxide; hydrogen peroxide plasma; gamma irradiation; dimensional accuracy; vat photopolymerisation; medical device; qualification.

Abstract

This targeted engineering review evaluates primary evidence on sterilisation-induced changes in vat-photopolymerised parts. The retained studies cover steam sterilisation, ethylene oxide, hydrogen peroxide gas plasma and gamma irradiation, with outcomes spanning dimensional accuracy, mechanical response, surface state, optical transmission, tightness and repeat-cycle durability. The evidence is heterogeneous and formulation-specific. A single steam cycle at 121 °C may preserve geometry in one workflow yet alter another material or functional endpoint; higher-temperature steam and repeated cycling can increase risk. Low-temperature methods avoid the same thermal load but can still change mechanics, optics or residual chemistry. Radiation response depends on dose and polymer state. The paper therefore defines a minimum qualification architecture that couples process validation with pre/post material, geometric, chemical, functional and biological gates. ISO 17665:2024, ISO 11135:2014+A1:2018 and ISO 11137-1:2025 anchor process validation; ISO 10993-1:2025 frames biological evaluation of the finished article. RP-02 provides the shared 3Dresyns evidence-to-decision method.

1. Scope and evidence boundary

This is a targeted engineering review, not a systematic review or meta-analysis. It retains primary studies that identify a vat-photopolymerisation material, a sterilisation or disinfection condition and at least one post-treatment endpoint. Most available studies concern dental surgical guides, proprietary resins and one treatment cycle. Their numerical results are not universal material constants and cannot be transferred to an unnamed 3Dresyns grade, a different printer, post-cure state, specimen geometry or sterilisation load.

Sterility assurance and material compatibility are separate questions. A validated microbial-inactivation process does not prove dimensional, mechanical, chemical or biological acceptability; conversely, an unchanged dimension does not demonstrate sterility. The qualification unit is the finished, packaged article and its complete manufacturing and sterilisation history.

2. Method-specific evidence

2.1 Moist heat

Steam-sterilised surgical-guide studies report material- and workflow-dependent dimensional outcomes. Sharma et al. found that steam treatment could alter the accuracy of printed guide materials [1]. Lan et al. likewise showed that material, sterilisation or disinfection route and template feature interact [2]. Keßler et al. found that printer, resin and preoperative autoclaving affected implant-placement accuracy, although the tested placements remained within the study's safety distance [3]. Hüfner et al. measured autoclaving-induced dimensional change in printed guides, reinforcing the need for feature-resolved rather than purely global metrology [4].

The temperature and the endpoint matter. In one SLA Surgical Guide Resin V1 study, a 121 °C cycle did not produce statistically significant change in the two measured zones, whereas 134 °C produced significant reductions; an untreated control also changed in one zone, demonstrating the importance of time-matched controls and a common measurement method [8]. In another guide workflow, a 121 °C cycle did not produce clinically relevant distortion of implant-placement precision, but the authors did not establish material fragility or repeat-cycle durability [9].

Repeat-cycle evidence is stronger but remains formulation-specific. Hoffmann et al. tested a heat-resistant vat-printed resin at 121 °C for up to 50 cycles. Tensile strength, elongation at break and Charpy impact did not change significantly through 20 cycles but decreased after 50 cycles with microcracking; tightness was retained through 20 cycles and the tested benchmark geometry showed no process-relevant deviation through 10 cycles [5]. This result demonstrates both the value and the limit of multi-endpoint qualification: geometric retention over ten cycles did not predict mechanical retention at fifty.

2.2 Ethylene oxide and hydrogen peroxide gas plasma

Low-temperature processing reduces the moist-heat exposure but does not create a neutral control. Go et al. compared one DLP surgical-guide resin after autoclaving, ethylene oxide and hydrogen peroxide gas plasma [7]. All three sterilised groups retained dimensional fit within the study criterion, while mechanical and optical responses differed: ethylene oxide increased flexural strength and modulus relative to the control in that formulation and reduced translucency; autoclaving produced the lowest mean flexural strength. These directions must not be generalised. EO aeration/residual control and peroxide compatibility remain part of the process-specific qualification, even when dimensions are retained.

2.3 Gamma irradiation

Daoset et al. exposed a medical-grade vat-photopolymer to 25–100 kGy after controlled post-curing [6]. Gamma irradiation increased compressive response but reduced tensile performance; doses above 25 kGy increased deterioration and brittleness in the studied system. The result shows why dose, post-cure state and loading mode must be reported together. No retained study supports pooling gamma and electron-beam response or assigning a radiation-compatible label to a resin family without product-specific data.

3. Material-response mechanisms and interpretation

Moist heat combines temperature, water activity, pressure, heating/cooling rate and dwell time. Depending on network chemistry and conversion state, the observed response may include water sorption and plasticisation, additional cure, residual-stress relaxation, thermal softening, hydrolysis or crack initiation. Radiation can promote further crosslinking, oxidation or chain scission. Reactive gas processes can change surface chemistry or leave process residues. These are mechanistic possibilities, not findings for every commercial formulation; they identify measurements that must be used to distinguish competing explanations.

Post-treatment timing is part of the result. Geometry and properties measured while a part is warm or water-conditioned need not match the dry, equilibrated state. A defensible protocol therefore records mass and dimensions before treatment, immediately after treatment where safe, and after a defined conditioning interval. It also separates reversible water uptake from irreversible network or damage effects. Statistical significance must be paired with an engineering acceptance margin; absence of significance is not evidence of equivalence when sample size or measurement uncertainty is inadequate.

4. Minimum qualification and reporting set

Control	Method and minimum record	Required interpretation
Article state	Resin/lot, printer, orientation, layer, wash, dry, post-cure, age and packaging	The claim applies only to the frozen manufacturing state
Process	Method, equipment, load, packaging, temperature/pressure/humidity or dose, dwell, aeration and cycle count	Process validation and material compatibility are distinct gates
Comparator	Time-matched untreated control from the same production lot; identical conditioning and metrology	Separate treatment effects from ageing, drift and method bias
Geometry	Pre/post 3D metrology of production-equivalent critical features with fixed datum and registration	Report signed local deviation, uncertainty and functional tolerance
Mechanics/thermal	Application-relevant loading plus Tg/HDT or DMA/DSC where thermal exposure is relevant	Do not infer retained strength from hardness or dimensions
Mass/chemistry	Mass uptake/recovery; extractables or residuals and surface chemistry where relevant	Sterility and dimensional retention do not establish chemical safety
Surface/optics	Roughness, wettability, colour or transmission when these affect function	Report method, conditioning time and acceptance criterion
Function	Production-equivalent fit, leakage, flow, alignment, drill guidance or other intended function	Coupon survival cannot replace article-level performance
Repeat use	Predefined cycle levels, attrition record and equivalence margin with confidence interval	Qualify the maximum supported cycle count, not an open-ended 'reusable' claim
Biological gate	ISO 10993-1:2025 risk-management evaluation of the finished processed and sterilised article	No automatic medical claim from resin, coupon, printability or sterility alone

5. Standards and method limits

- ISO 17665:2024 defines development, validation and routine control for moist-heat sterilisation. It replaced ISO 17665-1:2006 and the former technical-specification parts; it does not supply a polymer compatibility result.
- ISO 11135:2014 with Amendment 1:2018 remains current for ethylene oxide as of 3 September 2026, although ISO lists a replacement under development. EO residuals and aeration require their own controlled evidence; a low process temperature is not sufficient acceptance.
- ISO 11137-1:2025 is the current radiation-process anchor. Absorbed dose and dose distribution must accompany the material state and endpoint; a nominal sterilisation dose cannot be treated as a formulation-independent property test.
- ISO 10993-1:2025 places biological evaluation within risk management for the finished medical device. Biological acceptance is not inherited automatically from a raw resin or from successful sterilisation.

6. 3Dresyns implementation boundary

The 3Dresyns web page on sterilisation describes manufacturer workflow considerations for steam, hydrogen peroxide gas plasma, ethylene oxide and irradiation. It is useful for screening hazards and selecting a candidate route, but it is not independent evidence and does not establish compatibility for an unnamed grade. Any implementation must identify the exact resin and controlled TDS/IFU revision, printer, cleaning and post-cure route, packaging, sterilisation process, cycle count and acceptance criteria. The device manufacturer remains responsible for process validation, biocompatibility and final performance. Source: <https://www.3dresyns.com/pages/sterilization-of-3d-printed-resins>

7. Limitations and research priorities

The evidence base is dominated by small, in-vitro dental studies and proprietary formulations. Specimen geometry, print platform, post-cure, steriliser cycle, metrology and acceptance thresholds differ, preventing quantitative pooling. Several studies assess a single cycle; multi-cycle evidence is scarce. Evidence for hydrogen peroxide plasma, EO residual behaviour and electron-beam exposure in vat-printed parts remains especially limited.

Priorities are paired multi-cycle studies on production-equivalent articles that measure critical geometry, water uptake and recovery, mechanics, thermal state, surface/optical response, extractables or sterilant residuals and intended function at the same cycle levels.

Protocols should predefine equivalence margins and include time-matched controls, measurement uncertainty, failed-specimen accounting and the maximum supported reuse count.

8. Conclusions

- Sterilisation compatibility is bounded to a defined article-process-cycle state, not a generic resin label.
- Moist heat at 121 °C can be acceptable for selected formulations and endpoints, but higher temperature, repeated cycling and different geometries can change the result.
- Low-temperature gas methods and radiation avoid some thermal risks but introduce method-specific mechanical, optical, chemical or dose-dependent questions.
- A release decision requires process validation plus geometric, material, chemical, functional and biological evidence appropriate to the intended use.
- No 3Dresyns grade receives a sterilisation, reuse or medical claim without finished-article validation and controlled product documentation.

Declarations

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Standards

- ISO 17665:2024. Sterilization of health care products—Moist heat—Requirements for the development, validation and routine control of a sterilization process for medical devices. <https://www.iso.org/standard/80271.html>
- ISO 11135:2014/Amd 1:2018. Sterilization of health-care products—Ethylene oxide—Requirements for development, validation and routine control. <https://www.iso.org/standard/56137.html>
- ISO 11137-1:2025. Sterilization of health care products—Radiation—Part 1: Requirements for development, validation and routine control. <https://www.iso.org/standard/81721.html>
- ISO 10993-1:2025. Biological evaluation of medical devices—Part 1: Requirements and general principles for biological safety evaluation within a risk management process. <https://www.iso.org/standard/10993-1>

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