

Digital Traceability of Patient-Specific Photopolymer Devices: Design Input, Material Lot, Process History and Release

A release architecture linking authorised design, material state, executed process and acceptance evidence

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Abstract

Patient-specific photopolymer devices require traceability across a chain in which patient data, segmentation, design transforms, build preparation, material identity, machine state, post-processing and release evidence can all change the final device. This review defines a digital thread that preserves these dependencies without assuming that a single file name, UDI or batch record is sufficient. It separates patient identity from device identity, design intent from manufacturing representation, material lot from vat history, and nominal machine settings from the executed process record. A non-compensatory release architecture is proposed in which the correct patient, approved design, qualified material, controlled process history and acceptance evidence must all reconcile before release. The framework is aligned with medical-device quality-system, risk-management, additive-manufacturing and EU traceability principles while remaining implementation-neutral.

Keywords: patient-specific devices; additive manufacturing; photopolymers; traceability; design control; material lot; process history; release; UDI; quality system

1. Significance and scope

Patient-specific manufacturing collapses the distance between design and production. A change in imaging, segmentation, anatomical landmark selection, scaling, support generation or post-processing can alter one physical device without creating a conventional mass-production revision. Traceability must therefore reconstruct the complete chain from the approved clinical/design input to the released article [1,2]. ER-172 retains incoming photoresin identity and lot equivalence; ER-173 retains declaration and control of compounding/process variables; ER-71 retains in-situ monitoring, state estimation and digital twins; ER-51 retains custom orthoses/prosthetic workflow qualification; ER-175 retains cleaning validation; ER-181 retains post-cure process engineering; ER-206 retains dimensional metrology; ER-245 retains patient-specific design/manufacturing evidence; and ER-246 retains release-oriented qualification. ER-260 owns the joins among these states for patient-specific photopolymer-device traceability. It does not define clinical decision authority, data-protection law, cybersecurity architecture or a specific commercial manufacturing execution system.

1.1 Four identities that must not be conflated

A robust system distinguishes at least four identities: the patient or case, the intended device design, the manufacturing job or build instance, and the released physical unit. These identities can be linked but should not be collapsed into one mutable file name. Patient identity may need controlled pseudonymisation; the design identity must distinguish approved geometry from intermediate models; the build identity must capture the executed manufacturing instance; and the device identity must persist through inspection, packaging and release.

2. Design-input provenance

The traceability chain begins before CAD [1,2,7-9]. Record the source image or scan dataset, acquisition date, relevant reconstruction series, segmentation revision, operator or approved automated workflow, anatomical landmarks and any clinical prescription or written instruction that controls geometry. The design record should capture each intentional transform, including smoothing, offsets, mirroring, hole placement, lattice generation or mating geometry. The manufacturing mesh or sliced representation is a derivative, not the design master, unless the quality system explicitly defines it that way.

3. Material identity is more than a commercial name

Photopolymer traceability should identify the material specification [1,2], supplier or controlled source, lot or batch, receipt and expiry where applicable, storage history, opening date, additions to the vat, filtration or replenishment events, and any controlled blending rule. For resin systems, the executed material state can differ from a sealed-container lot because the vat accumulates thermal, optical and contamination history. When reuse is permitted, the quality system should define how vat history is linked to the build and when a material state is retired or requalified.

4. Process history: nominal recipe versus executed build

The release record should preserve the parameter set that was approved and the parameters actually executed [1,2]. Depending on platform capability, useful fields include machine identifier, software and firmware versions, build file hash, orientation, support strategy, layer thickness, exposure recipe identifier, environmental state, start/end times, interruptions, alarms, operator interventions and maintenance state. The absence of direct telemetry should be explicit; a nominal slicer profile is not proof that every parameter was executed as intended.

5. Post-processing is part of manufacturing history

For photopolymers, washing, drying, support removal, post-cure, thermal treatment, surface finishing and sterilisation can materially affect residuals, conversion, dimensions and mechanical properties [1,8]. Each controlled step therefore needs an identified procedure revision and, where critical, executed values such as time, temperature, wavelength, intensity range, solvent identity or cycle count. Rework must create a new state transition, not overwrite the original record.

6. Patient-matched, custom-made and UDI boundaries

Regulatory labels matter because traceability obligations differ. Under the EU MDR, the UDI system facilitates traceability [4] for devices other than custom-made and investigational devices, while production identifiers can include lot, serial number, software identification and dates. MDCG 2021-3 distinguishes custom-made, adaptable and patient-matched concepts [5]. A digital thread should therefore record the

regulatory category used for the specific device rather than assuming that all patient-specific articles are custom-made or that every one receives the same UDI treatment.

7. Release reconciliation

Release is not merely the final inspection result [2,3]. It is a reconciliation across identities and evidence. The released unit should point to the approved design revision, correct case, material state, build instance, post-process records, deviations, inspection results and authorisation. Where dimensional or functional acceptance is required, the measurement file or report should be immutable or checksum-controlled and linked to the physical unit. A release decision should fail closed when any critical link is missing.

8. Non-compensatory digital-thread matrix

The following matrix treats traceability as a set of mandatory joins rather than a completeness score.

Gate	Required link	Failure meaning
G1 Case identity	Case/patient token → authorised design input	Wrong-case risk
G2 Design identity	Approved design revision → manufacturing derivative/hash	Geometry provenance broken
G3 Material identity	Specified resin → lot/vat state → build	Material history not reconstructable
G4 Process history	Machine/job → approved recipe → executed record/deviations	Build state not reconstructable
G5 Post-process history	Wash/cure/finish/sterilisation records → unit/build	Final material state not reconstructable
G6 Acceptance	Inspection/functional evidence → physical unit	No evidence that released unit passed
G7 Release authority	Signed/electronic authorisation → reconciled record set	Administrative release without technical closure

9. Minimum digital record

At minimum, preserve stable identifiers for case, design revision, manufacturing file, material lot or controlled vat state, machine, build job, post-processing route, inspection record and released unit. Add cryptographic hashes for design/manufacturing files where feasible, because identical names do not prove identical bytes. Record software versions when they can change geometry, slicing or exposure logic. Timestamps should be offset-aware in backend systems even if human-facing documents use local textual dates. Retention rules should follow the applicable quality system and regulation.

10. Verification and change control

Traceability is only useful if the links are tested. Periodic record-reconstruction exercises should select a released unit and rebuild its chain backwards to design input and forwards to production and acceptance evidence. Change control should define when a modified design, resin source, build parameter set, software version or post-cure procedure requires re-verification. The digital thread should make such changes visible rather than silently substituting the latest master data.

11. Data integrity, immutability and auditability

A digital thread is vulnerable if records can be overwritten without preserving prior states [2]. Critical design, manufacturing and release objects should therefore be versioned, attributable and protected against silent substitution. Cryptographic hashes are useful for binary artefacts such as DICOM exports, meshes, build files and inspection reports, but hashes do not replace semantic metadata: two different files can both be valid and still represent different approved purposes. Electronic-signature and access-control requirements depend on jurisdiction and system scope, yet the engineering principle is stable: the released unit must point to immutable or audit-trailed evidence that existed at the time of release.

12. Deviations, rework and exceptional workflows

Patient-specific production frequently encounters exceptions [6-9]: a scan is repeated, segmentation is manually corrected, a build is interrupted, support is reworked, or a device is reprinted. The traceability model should represent these events as branches with explicit disposition rather than editing history into a single apparently clean path. A rejected build remains linked to its case but cannot inherit the released-device identifier. Rework should identify the starting state, authorised procedure, executed action and post-rework acceptance evidence. When clinical urgency justifies an exceptional pathway, the deviation and risk decision must remain visible to the final release authority.

13. Reconstruction testing and system qualification

The quality system should periodically challenge the traceability architecture by selecting a released unit and reconstructing the complete chain using only retained records. The exercise should recover the authorised design input, all critical file versions, material state, build and post-process history, deviations, acceptance evidence and release decision. Missing links, ambiguous identifiers or mutable records are system failures even if the physical device previously passed inspection. Software validation should additionally test identifier uniqueness, access control, backup/restore, clock handling, file-hash verification and prevention of accidental cross-case association.

14. Knowledge boundary and limitations

FDA additive-manufacturing guidance, ISO 13485, ISO 14971, the EU MDR and MDCG guidance define relevant quality and traceability principles [1-5], but they do not prescribe one database schema for photopolymer devices. Published patient-specific manufacturing workflows demonstrate the need for controlled design inputs, material verification and device verification, but their exact processes are not universal. This review therefore specifies information relationships and release logic, not a validated software architecture or jurisdiction-specific legal opinion.

15. Conclusions

The critical object in patient-specific manufacturing is not a standalone STL, build file or UDI. It is the controlled chain connecting authorised design input, patient or case identity, material state, executed process history, post-processing, acceptance evidence and release authority. For

photopolymer devices, material and post-cure histories are especially important because the final polymer state is produced across multiple steps. A traceability system is adequate only when a released physical unit can be reconstructed through those steps without ambiguity and when broken critical links block release rather than being averaged away.

References

1. U.S. Food and Drug Administration. Technical Considerations for Additive Manufactured Medical Devices. Guidance for Industry and Food and Drug Administration Staff. December 2017. <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/technical-considerations-additive-manufactured-medical-devices>
2. International Organization for Standardization. ISO 13485:2016. Medical devices - Quality management systems - Requirements for regulatory purposes. <https://www.iso.org/standard/59752.html>
3. International Organization for Standardization. ISO 14971:2019. Medical devices - Application of risk management to medical devices. <https://www.iso.org/standard/72704.html>
4. European Parliament and Council. Regulation (EU) 2017/745 on medical devices, consolidated text current to 1 January 2026, including amendments 2020/561, 2023/607 and 2024/1860. EUR-Lex. <https://eur-lex.europa.eu/eli/reg/2017/745/2026-01-01/eng>
5. Medical Device Coordination Group. MDCG 2021-3. Questions and Answers on Custom-Made Devices and considerations on Adaptable medical devices and Patient-matched medical devices. March 2021. https://health.ec.europa.eu/system/files/2021-03/mdcg_2021-3_en_0.pdf
6. Philip Nguyen, Ivan Stanislaus, Clover McGahon, Krishna Pattabathula, Samuel Bryant, Nigel Pinto, Jason Jenkins, Christoph Meinert. Quality assurance in 3D-printing: A dimensional accuracy study of patient-specific 3D-printed vascular anatomical models. *Frontiers in Medical Technology*. 2023;5:1097850. <https://doi.org/10.3389/fmedt.2023.1097850>
7. Robert J Morrison, Khaled N Kashlan, Colleen L Flanagan, Jeanne K Wright, Glenn E Green, Scott J Hollister, Kevin J Weatherwax. Regulatory Considerations in the Design and Manufacturing of Implantable 3D-Printed Medical Devices. *Clinical and Translational Science*. 2015;8(5):594-600. <https://doi.org/10.1111/cts.12315>
8. Harsha Ramaraju, April M Landry, Subhadra Sashidharan, Abhishek Shetty, Sarah J Crotts, Kevin O Maher, Steven L Goudy, Scott J Hollister. Clinical grade manufacture of 3D printed patient specific biodegradable devices for pediatric airway support. *Biomaterials*. 2022;289:121702. <https://doi.org/10.1016/j.biomaterials.2022.121702>
9. Marco Keller, Alissa Guebeli, Florian Thieringer, Philipp Honigmann. In-hospital professional production of patient-specific 3D-printed devices for hand and wrist rehabilitation. *Hand Surgery and Rehabilitation*. 2021;40(2):126-133. <https://doi.org/10.1016/j.hansur.2020.10.016>

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