

The 3Dresyns MF VPP Framework: Monomer-Free Formulation as One Element of Material and Process Risk Control

Formulation attributes, post-processing controls and device-specific biological evaluation for professional VPP manufacturing

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Highlights

- The MF designation describes formulations manufactured without intentionally added reactive monomers, according to applicable controlled product documentation.
- Monomer-free formulation can remove one potential source of low-molecular-weight reactive species, but does not by itself establish biological safety or regulatory conformity.
- The final chemical profile depends on resin batch, additives, printing, cleaning, drying, post-curing, storage and sterilization where applicable.
- Biological evaluation of a finished medical device is planned within risk management under ISO 10993-1:2025.
- ISO 10993-10:2021 addresses skin sensitization and ISO 10993-23:2021 addresses irritation; endpoints are selected by the device-specific plan.
- MDR classification and conformity assessment remain the responsibility of the legal manufacturer.

Abstract

Vat-photopolymerization materials intended for professional biomedical and dental development must be evaluated as part of a complete material-process-device system. Formulation composition is relevant because low-molecular-weight reactive species, process additives, degradation products, cleaning residues and incomplete conversion may contribute to the chemical profile of the printed part. However, no single formulation attribute establishes biological safety for every geometry, manufacturing process or intended use.

The 3Dresyns MF framework uses formulations manufactured without intentionally added reactive monomers, as specified in the controlled documentation for the applicable grade. This architecture is intended to reduce one formulation-related source of low-molecular-weight reactive species. The realised profile nevertheless depends on printing, cleaning, drying, post-curing and any subsequent conditioning or sterilization.

Biological evaluation must be performed on the relevant final device or a justified representative article within risk management. ISO 10993-1:2025 provides the general framework. Chemical characterization, toxicological assessment and biological testing are selected according to the device, contact, materials, manufacturing process and existing evidence. ISO 10993 does not assign the device classes defined by Regulation (EU) 2017/745.

The MF framework is therefore a formulation and process-control strategy that may support a broader device-development programme. It is not a medical-device certification, a universal biocompatibility claim or a substitute for the legal manufacturer's validation and conformity assessment.

Keywords VPP · monomer-free formulation · chemical characterization · biological evaluation · ISO 10993 · risk management · process control

Source use. Controlled product and formulation documentation is mapped in [1]; photopolymer evidence in [2–3]; risk and biological-evaluation standards in [4–10]; dental, quality-system and legal scope in [11–14].

1. Monomer-free formulation as a controlled attribute

For this portfolio, monomer-free means that the supplied formulation is manufactured without intentionally added reactive monomers, subject to definitions and analytical boundaries in current product documentation. It must not be interpreted as free of all low-molecular-weight substances, extractables, leachables, reaction by-products or degradation products.

Oligomeric and polymeric constituents, photoactive components, stabilizers, colorants and processing additives may contribute to the cured-part chemical profile. Their relevance depends on concentration, conversion, geometry, surface-area-to-volume ratio, cleaning, post-curing and intended contact. The attribute can reduce one potential risk axis while the complete chemical and biological assessment remains device-specific [1–4].



Monomer-free is one controlled formulation attribute; it is not the final biological conclusion.

Figure 1. The final-article chemical profile depends on formulation and the complete manufacturing process; MF is one controlled input.

2. Product and formulation controls

Attribute / input	Permissible statement	Required control	Boundary
MF designation	Manufactured without intentionally added reactive monomers	Current product definition and formulation records	Not free of all low-molecular-weight substances
Specified-substance absence	Free of the named substance when documented	Current formulation records and SDS	Does not establish a non-hazardous formulation
Process additive	Documented compatible option for the exact route	Identity, dosage, TDS and formulation reassessment	Can change cure and chemical profile
Post-processing	Controlled workflow for the named grade	Cleaning, drying and post-cure validation	No universal recipe or conversion threshold
Biological evidence	Evidence for the tested final or representative article	Method, preparation, report and relevance	Does not certify every geometry or intended use

2.1 Specified-substance statements

Where a product is documented as TPO-free or free from another specified substance, the claim must be supported by current formulation records and SDS. It does not establish that the complete formulation is non-hazardous or biologically suitable. Current legal status and the exact product/use context must be checked at publication and use.

2.2 Additives and substitutions

Fine Tuners should be described as photoaccelerants where that is their documented role. Any Fine Tuner, Light Blocker, pigment, cleaner or supplier change can alter cure, residues and the final chemical profile. A Bio designation or documented compatibility is a starting condition, not proof that earlier evidence is preserved.

KEY INSIGHT

Component compatibility supports process design. It does not create a regulatory release chain or transfer biological conclusions automatically to a modified formulation.

3. Risk-based evaluation of the finished device

ISO 10993-1:2025 defines requirements and general principles for evaluating biological safety within risk management. The evaluation considers the finished device, intended purpose, contact, materials, manufacturing processes, chemical characterization, toxicological information and relevant endpoints.

MDR device classification and ISO 10993 contact characterization are separate. A device is not Class I, IIa or IIb because of an ISO 10993 contact category, and contact exceeding 30 days does not automatically determine an MDR class. Classification is established by the legal manufacturer using the applicable rules.

Testing is not reduced to a fixed panel. The plan may include chemical characterization under ISO 10993-18, toxicological risk assessment under ISO 10993-17 and justified biological endpoints. ISO 10993-5 addresses in vitro cytotoxicity, ISO 10993-10:2021 skin sensitization and ISO 10993-23:2021 irritation [5–10].



ISO 10993-1:2025 frames the process; it does not assign MDR classes or a fixed test panel.

Figure 2. Device-specific biological-evaluation logic under ISO 10993-1:2025. Endpoint selection follows risk and evidence gaps.

4. Integrated manufacturing controls

- Select the grade using current TDS, SDS and the intended manufacturing process.
- Calibrate the resin–printer combination using documented optical and exposure conditions.
- Use only process additives and cleaning materials assessed for the intended workflow.
- Clean and dry the printed article using validated parameters appropriate to its geometry.
- Post-cure using equipment and conditions matched to the selected grade.
- Verify relevant physical, mechanical and chemical characteristics on the final or representative article.
- Perform device-specific biological evaluation and regulatory assessment under the legal manufacturer's quality system.

Degree of conversion may be a useful process indicator, but no universal value constitutes biological or regulatory release. Acceptance criteria must be established and justified for the particular material, process and device.

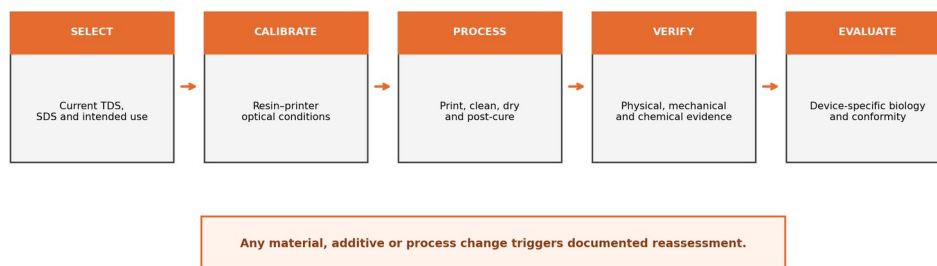


Figure 3. Integrated manufacturing controls. Changes trigger reassessment rather than automatic evidence transfer.

5. Dental and quality-system standards

ISO 4049 applies to polymer-based restorative materials within its scope. ISO 20795-1 applies to denture-base polymers within its scope. They are not general certifications for photopolymer resins. ISO 13485 defines quality-management-system requirements and does not certify a resin, establish biological safety or authorize an indication [11–13].

6. Minimum evidence record

- Exact product, formulation designation, variant, batch where applicable, and controlled-document revisions.
- All additives, cleaners and process aids with identities, concentrations and change status.
- Printer, wavelength/spectrum, irradiance, exposure, geometry and orientation.
- Cleaning, drying, post-curing, conditioning, storage and sterilization where applicable.
- Chemical-characterization, toxicological and biological reports with specimen preparation and relevance justification.
- Finished-device intended purpose, contact, classification, risk-management decisions and acceptance criteria.

7. Limitations

- The framework does not establish conformity for a finished medical or dental device.
- Monomer-free and TPO-free are formulation attributes, not absolute safety claims.
- Data from a resin coupon do not automatically represent a complex final device.
- Changes to colorants, Fine Tuners, cleaning fluids, printing, post-curing or sterilization can require reassessment.
- ISO 4049 and ISO 20795-1 apply only when material and indication fall within scope.
- Implantable, long-term-contact and other higher-risk applications require a device-specific strategy.

8. Conclusions

The 3Dresyns MF framework is a formulation and manufacturing-control strategy intended to reduce one source of low-molecular-weight reactive species while maintaining control of the complete VPP workflow. Final suitability depends on the printed article, processing conditions, intended use and device-specific evaluation. Monomer-free formulation can support risk management, but it does not replace chemical characterization, biological evaluation, manufacturing validation or regulatory conformity assessment by the legal manufacturer.

Revision note

Version 5.3 replaces the historical regulatory-release framework with a device-specific risk-control model; removes ISO 10993 and MDR class conflation, fixed test panels, universal conversion thresholds, automatic component-evidence transfer and absolute TPO/monomer safety claims; and updates ISO 10993-1, -10, -17, -18 and -23 framing.

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Disclosure. Dr. Juan Segurolo is founder and Scientific Director of 3Dresyns by Resyner Technologies S.L. Current controlled product documentation governs formulation attributes and use.

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