

Photopolymer Materials for Biomedical Manufacturing Research and Professional Workflows

Supplier-side material information supporting, but not determining, finished-device evaluation

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Highlights

- The portfolio supports professional dental, otologic, scaffold-research and engineering-development workflows.
- Supplier data support but do not determine finished-device evaluation or conformity.
- Monomer-free can reduce one formulation constituent but does not establish biological safety.
- Research scaffolds are separated from products with documented device-manufacturing uses.
- Implant, sterilization, imaging and clinical mappings require exact product/device evidence.

Abstract

The portfolio contains professional photopolymer materials used in laboratory, research and engineering workflows.

Supplier data can support the legal manufacturer's technical documentation when relevant to exact formulation, processing and intended device. It does not establish a material-level MDR class or ISO certification.

Each finished device requires intended purpose, classification, manufacturing validation, chemical/biological evaluation, performance evidence and conformity assessment. Research materials remain clearly separated.

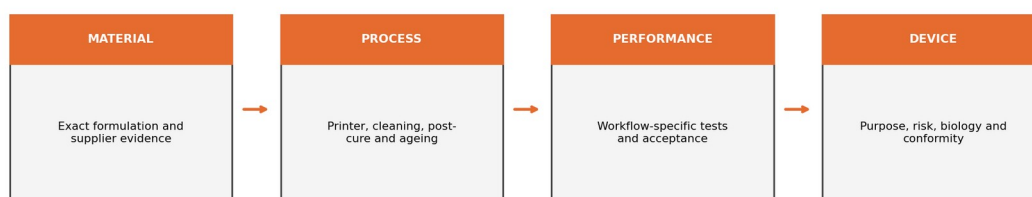
Keywords biomedical research · dental laboratory · otologic · scaffold · finished-device evaluation

Source use. Product evidence is in [1]; biological/QMS/legal scope in [2–4]; corrected product-family boundaries in [5–6].

1. Supplier-side evidence

Each entry identifies exact product, controlled TDS/report, tested specimen/process, endpoint and limitation. Generic ISO-evaluated table labels are replaced by exact information.

- Verify QMS certificate holder/scope if cited.
- Remove generic FDA framing.
- Separate formulation attributes from device evidence.



Release requires traceable evidence at every gate; a catalogue label cannot bypass the chain.

Figure 1. WP-39 evidence gates from controlled material description to final acceptance.

2. Workflow-specific mapping

Dental, otologic, scaffold research and engineering development are separate routes. Product-to-clinical mappings are retained only with documented intended use and evidence.

- No implant platform claim.
- No universal autoclave or imaging claim.
- Apply corrected PEEK-like boundaries.

3. Finished-device evaluation

The legal manufacturer selects biological endpoints through complete risk assessment and validates process, performance and conformity for the finished device.

4. Minimum controlled evidence before release

Control field	Required record	Release interpretation
Material	Exact formulation and supplier evidence	Catalogue description only until evidence is linked
Process	Printer, cleaning, post-cure and ageing	Control process variables and change triggers
Performance	Workflow-specific tests and acceptance	Report method, result, uncertainty and limits
Device	Purpose, risk, biology and conformity	Apply final acceptance and responsibility boundary



Description ≠ measured result ≠ certification or finished-device approval

Figure 2. WP-39 separates catalogue positioning, measured evidence and final application decisions.

KEY INSIGHT

Precise product or application language is retained only when the exact formulation, method, processed specimen and controlled evidence can be traced.

5. Limitations

- No platform-level implant claim is made.
- Monomer-free is not biological safety.
- Research scaffolds are not implant candidates.
- ISO 13485 is cited only as an exact certificate.
- Supplier data do not determine device conformity.

6. Conclusions

- The portfolio supports professional dental, otolastic, scaffold-research and engineering-development workflows.
- Supplier data support but do not determine finished-device evaluation or conformity.
- Implant, sterilization, imaging and clinical mappings require exact product/device evidence.
- This corrected candidate remains local and on HOLD until series-wide scientific, metadata and visual release checks are complete.

Revision note

Version 5.3 removes implant-platform, generic clinical/sterilization/FDA and material-level class claims and creates supplier-evidence, workflow and finished-device boundaries.

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Disclosure. Dr. Juan Segurola is founder and Scientific Director of 3Dresyns by Resyner Technologies S.L., the supplier of the materials discussed.

References

- [1] 3Dresyns. Current biomedical-workflow product TDS/IFU and controlled reports.
- [2] ISO 10993-1:2025. Biological evaluation of medical devices—Part 1.
- [3] ISO 13485:2016. Medical devices—Quality management systems.
- [4] Regulation (EU) 2017/745 on medical devices, current consolidated version.
- [5] 3Dresyns WP-10. PEEK-Like VPP Photopolymer, corrected candidate.
- [6] 3Dresyns WP-20. Research-Grade VPP Materials for Scaffold and Hydrogel Studies, corrected candidate.