

Photopolymers for Otoplastic and Dental Manufacturing Workflows

Material candidates across SLA/DLP/LCD and inkjet processes with finished-device validation requirements

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Highlights

- OTO and dental materials are candidates for distinct manufacturing uses, not one compliance category.
- Supplier data can support but do not complete finished-device biological evaluation.
- Material portfolios do not cover MDR Classes I, IIa or IIb.
- ISO 20795-1 is restricted to denture base polymers and not applied automatically to splints.
- Cleaning, disinfection or sterilization conditions are device-specific.

Abstract

The OTO and dental portfolios provide candidates across several mechanical envelopes and printing technologies. Selection uses exact intended manufacturing use, printer, geometry, mechanics, contact and controlled evidence.

Supplier tests can support the legal manufacturer's evaluation but do not constitute ISO 10993 certification or MDR class coverage. Hearing-aid shells, earmolds, models, guides, aligners and bonding trays have different intended purposes.

Each product is mapped only to documented manufacturing uses and a separate process, mechanical, chemical, biological and regulatory validation plan.

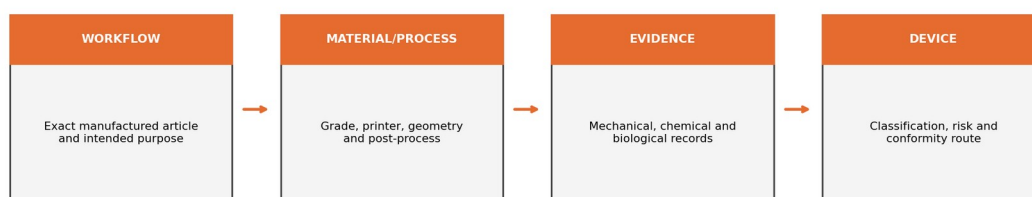
Keywords otoplastic · dental manufacturing · hearing aid shell · earmold · aligner · finished device

Source use. Product evidence is controlled in [1]; biological, QMS, dental and legal scope in [2–5]; dental workflow control in [6].

1. Workflow-specific mapping

Study models, guides, aligners, bonding trays, hearing-aid shells, earmolds and soft tips are treated as separate routes. A shared mechanical portfolio does not imply shared contact, standards or evidence.

- Record exact product and printer.
- Define intended purpose and patient contact.
- Set device-specific acceptance criteria.



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

Figure 1. WP-29 evidence gates from controlled material description to final acceptance.

2. Biological and conformity responsibilities

The legal manufacturer determines intended purpose and classification. Biological evaluation is performed for the finished device within risk management; supplier data are used only where relevant to exact formulation and processing.

- ISO 10993 is not certification.
- ISO 13485 concerns the QMS.
- Remove material-level MDR classes.

3. Dental/otoplastic standard scope

ISO 20795-1 concerns denture base polymers and is not automatically applicable to night guards or splints. Cleaning, disinfection and sterilization conditions must match the actual device and foreseeable use.

4. Minimum controlled evidence before release

Control field	Required record	Release interpretation
Workflow	Exact manufactured article and intended purpose	Catalogue description only until evidence is linked
Material/process	Grade, printer, geometry and post-process	Control process variables and change triggers
Evidence	Mechanical, chemical and biological records	Report method, result, uncertainty and limits
Device	Classification, risk and conformity route	Apply final acceptance and responsibility boundary

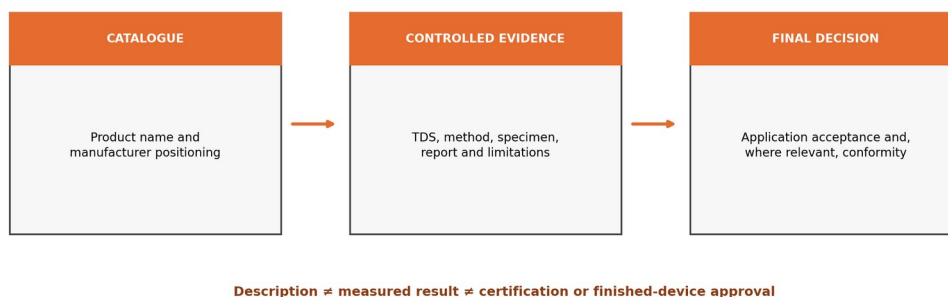


Figure 2. WP-29 separates catalogue positioning, measured evidence and final application decisions.

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

- A material does not deliver finished-device biocompatibility.
- OTO and dental uses do not share one compliance framework.
- Material portfolios do not cover MDR classes.
- Product standards apply only within scope.
- Unverified production-volume claims are removed.

6. Conclusions

- OTO and dental materials are candidates for distinct manufacturing uses, not one compliance category.
- Supplier data can support but do not complete finished-device biological evaluation.
- Cleaning, disinfection or sterilization conditions are device-specific.
- 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 material-level MDR classes, ISO 10993 certification and unified OTO/dental compliance; it splits workflows and corrects ISO 20795-1 and processing scope.

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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 OTO and dental grade-specific 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] ISO 20795-1:2013. Dentistry—Base polymers—Part 1: Denture base polymers.
- [5] Regulation (EU) 2017/745 on medical devices, current consolidated version.
- [6] 3Dresyns WP-09. Dental VPP Materials as Candidates in Device-Specific Manufacturing Workflows, corrected local candidate.