

Printed Moulds and Interface Control for Indirect Additive Manufacturing

Cure inhibition, transfer, residue and final-part validation across mould, release treatment and injected material

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Highlights

- Mould, release treatment, cleaner and injected material form one interface system.
- A monomer-free mould attribute does not establish biological safety of the moulded part.
- No-transfer and platinum-cure claims require direct interface and migration evidence.
- Medical-grade describes the injected material supplier's documented scope, not the printed mould.
- The legal manufacturer evaluates the final device and complete process.

Abstract

Printed moulds enable indirect manufacturing only when the interface between mould, release treatment, cleaner and injected material is controlled.

Monomer-free or Bio designations do not establish a biocompatible interface or absence of transfer. Cure inhibition, residues, migration, surface chemistry and mould durability require direct testing.

The final moulded device retains the intended-use, biological and regulatory responsibilities of its legal manufacturer.

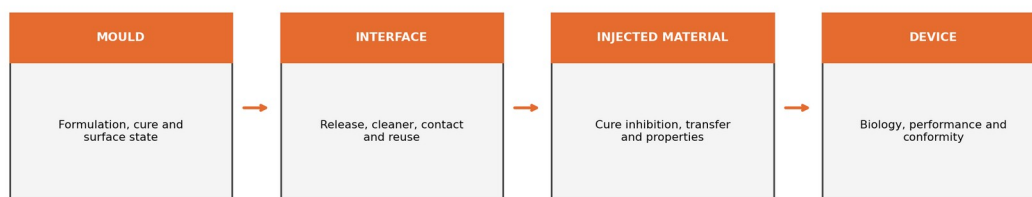
Keywords indirect additive manufacturing · mould · silicone cure · transfer · residue · interface

Source use. Product evidence is in [1]; chemical/biological methods in [2–3]; AM/material context and auxiliary control in [4–6].

1. Interface-system definition

The record identifies mould formulation/cure, release treatment, cleaner, injected material/cure, geometry and contact conditions.

- Control every formulation revision.
- Include worst-case area and contact time.
- Record mould reuse cycles.



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

Figure 1. WP-37 evidence gates from controlled material description to final acceptance.

2. Cure inhibition and transfer

Platinum-cure or other inhibition is tested with defined acceptance criteria. Transfer and residues require appropriate chemical analysis on the moulded surface or extracts.

- Do not assert no transfer without data.
- Verify removal/rinse procedure.
- Measure surface and mechanical effects.

3. Finished-device boundary

Medical-grade silicone wording applies only within the supplier's scope. It does not qualify the mould or validate the final device.

4. Minimum controlled evidence before release

Control field	Required record	Release interpretation
Mould	Formulation, cure and surface state	Catalogue description only until evidence is linked
Interface	Release, cleaner, contact and reuse	Control process variables and change triggers
Injected material	Cure inhibition, transfer and properties	Report method, result, uncertainty and limits
Device	Biology, performance and conformity	Apply final acceptance and responsibility boundary

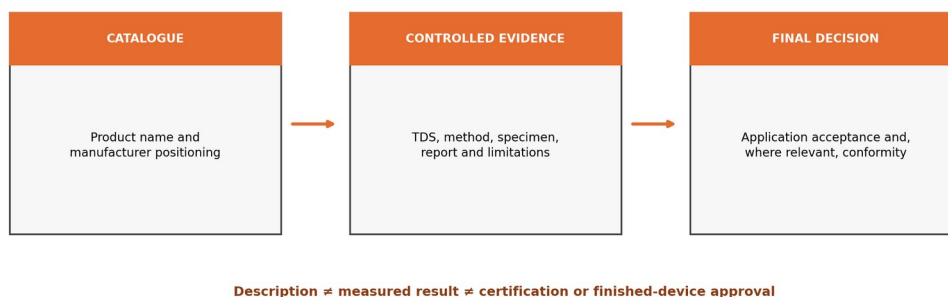


Figure 2. WP-37 separates catalogue positioning, measured evidence and final application decisions.

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

- Monomer-free does not mean biocompatible.
- No-transfer requires analytical evidence.
- Medical-grade is not inherited by the mould.
- Interface performance is process-specific.
- Final-device responsibilities remain separate.

6. Conclusions

- Mould, release treatment, cleaner and injected material form one interface system.
- A monomer-free mould attribute does not establish biological safety of the moulded part.
- The legal manufacturer evaluates the final device and complete process.
- 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 universal biocompatible-interface and no-transfer claims and introduces exact mould-release-cleaner-material interface validation.

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

References

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