

Structured Selection Framework for VPP Materials and Processes

Candidate generation across application, material, process and validation requirements

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Highlights

- The SSF is a candidate-generation tool, not a product, device or process validation method.
- Eight levels separate application, route, legal/contact context, biological evidence, service envelope, mechanics, sustainability and process compatibility.
- MDR classification and ISO 10993 biological evaluation are distinct decision streams that converge within finished-device risk management.
- A commercial family designation can support candidate selection but cannot be made a universal regulatory route.
- The required output is a candidate product family and validation plan, never a compliant material declaration.

Abstract

The Structured Selection Framework is a candidate-generation tool for narrowing the 3Dresyns portfolio against application, service, mechanical, thermal, chemical, sustainability and printing-process requirements. Its output is a candidate material and process route, not a compliant product or validated device.

For medical and dental applications, three distinct questions must remain separate: the legal classification and intended purpose of the finished device; the biological-evaluation requirements determined within risk management; and the technical suitability of the selected material and manufacturing process. ISO 10993 does not assign MDR device classes, and an MDR class does not prescribe a fixed material or biological test battery.

The framework should therefore direct users to define final-device requirements and evidence gaps before selecting a candidate product. Mechanical, chemical, process and biological validation then determine whether the candidate is suitable for the intended application.

Keywords VPP · structured selection · candidate generation · ISO 10993 · Regulation (EU) 2017/745 · risk management · process compatibility · validation plan

Source use. The controlled selection framework and product documentation are mapped in [1–4]; photopolymer and additive-manufacturing context in [5–8]; risk, biological, legal and environmental boundaries in [9–16].

1. Purpose and decision boundary

VPP material selection is a multi-constraint problem. A candidate may satisfy a mechanical target yet fail the required chemical, thermal, dimensional or process envelope. Conversely, a documented biological data package does not demonstrate mechanical or manufacturing suitability. The SSF sequences these questions so that excluded options are removed transparently and evidence gaps remain visible [1–7].

The framework does not certify the selected material or complete a technical file. It records the intended article, constraints, current documented candidates and validation tasks. Final suitability depends on the manufactured article, processing conditions, service environment, risk management and applicable legal route.

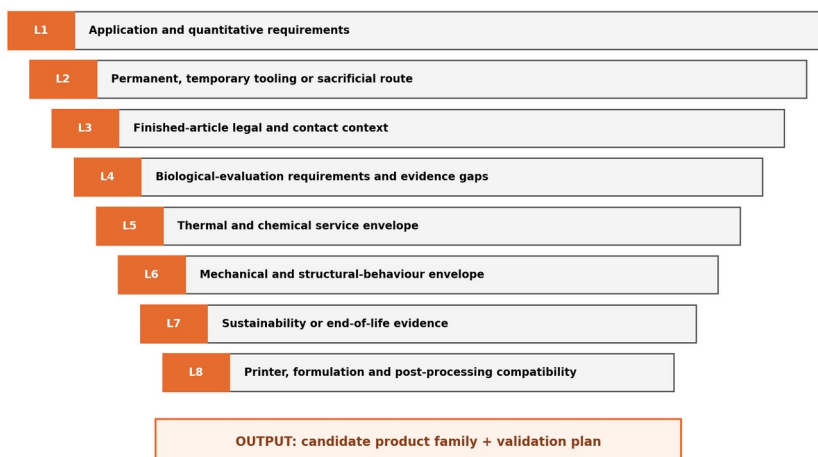


Figure 1. Corrected eight-level SSF. The output is a candidate product family and validation plan, not a compliant material or validated device.

2. Eight-level decision structure

Level	Question	Required input	Output / boundary
L1	What must the article do?	Quantitative performance, environment and tolerance	Application requirement
L2	Permanent, tooling or sacrificial?	Next process and removal route	Manufacturing route
L3	What is the finished-article legal/contact context?	Intended purpose, market, contact and duration	Classification and legal questions
L4	What biological evidence is needed?	Risk management, chemistry and existing evidence	Evidence gaps; no fixed battery
L5	What thermal and chemical envelope applies?	Temperature, fluids, concentration and time	Service-screened candidates
L6	What mechanical behaviour is required?	Loads, stiffness, failure modes and ageing	Mechanical test plan
L7	What sustainability/end-of-life claim is required?	Claim definition, method and supply-chain scope	Evidence-qualified claim route
L8	Can the formulation and process be controlled?	Printer, wavelength, viscosity, additives and post-process	Candidate family + validation plan

KEY INSIGHT

A zero or blank compatibility cell should be interpreted as not documented or not recommended under the stated conditions unless physical impossibility has been demonstrated.

3. Legal classification and biological evaluation

For a finished medical device, the legal manufacturer defines intended purpose, target market and applicable classification rules. Device classification under Regulation (EU) 2017/745 is not assigned by ISO 10993 and is not a property of a resin. A material family must therefore not be labelled Class I, IIa or IIb [9,10].

ISO 10993-1:2025 provides requirements and general principles for evaluating biological safety within a risk-management process. The biological-evaluation plan considers the finished device, nature and duration of contact, materials, manufacturing process, chemical characterization, toxicological evidence and justified endpoints. It does not prescribe one universal fixed test battery for every device [9].

Material documentation can be an input to the legal manufacturer's assessment, but it does not establish final-device conformity or completeness of a technical file. Commercial family selection is a technical candidate decision, not a regulatory decision.

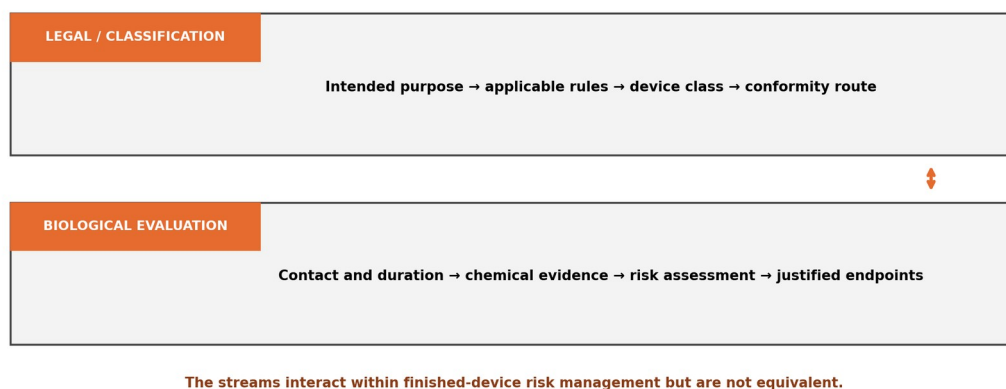


Figure 2. Legal classification and biological evaluation interact but are separate decision streams. ISO 10993 does not assign MDR classes.

4. Candidate-generation logic

4.1 Start from requirements

The selection begins with quantitative requirements and foreseeable failure modes, not a familiar product name or analogue label. Terms such as ABS-like, PEEK-like or silicone-like can orient an initial search but do not establish equivalent impact, heat, chemical, fatigue or regulatory performance.

4.2 Use current controlled data

Every product or process claim must be tied to the current TDS, SDS, IFU or controlled report for the exact variant. Family-level attributes must not be transferred automatically to additives, colours, viscosity versions or other variants. When a data point is absent, the framework records an evidence gap rather than an assumed pass or fail.

4.3 End with a validation plan

The candidate list is followed by a plan identifying methods, specimens, processing conditions, service environments and acceptance criteria. Validation can include mechanical, dimensional, thermal, chemical, optical, process-stability, biological or other evidence according to the intended article.

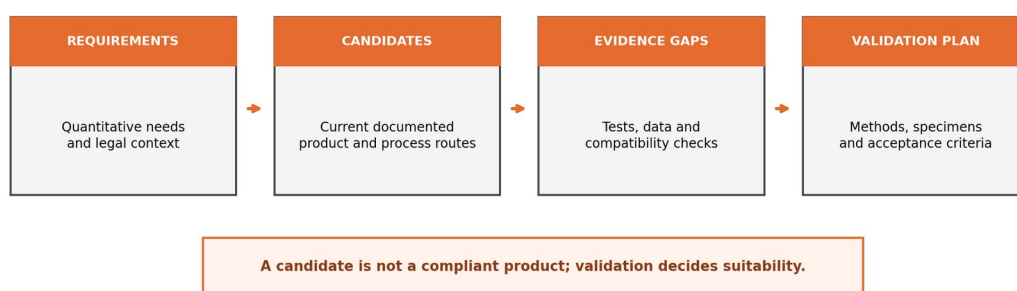


Figure 3. Selection output. A documented candidate and evidence-gap analysis are converted into an application-specific validation plan.

5. Corrected application example: intraoral splint

Define the intended purpose, duration and nature of contact, applicable device classification and mechanical requirements. Identify the biological-evaluation information required for the finished, printed and post-processed device within risk management. Select candidate materials only after these requirements are defined.

Validate water sorption, dimensional stability, mechanical performance, chemical residues, biological safety and the complete manufacturing process against the legal manufacturer's acceptance criteria. ISO 20795-1 applies to denture base polymers within its scope and must not be used as a universal threshold for every splint or intraoral device [11].

6. Other application archetypes

6.1 Engineering article

Define loads, temperature, chemical exposure, dimensional tolerance and failure mode. Screen candidates using current verified data, then test the named printed and post-processed article. An analogue label or Shore value alone is insufficient.

6.2 Sacrificial tooling

Define the next manufacturing step, temperature and pressure history, removal route and interaction with the cast or injected material. Select a candidate only after the documented thermal and removal envelope is matched. Product-specific data must be verified before retaining any quantitative example.

6.3 Sustainability-led selection

Define whether the required claim concerns biobased content, ready biodegradability, recyclability, solvent use, worker exposure or another endpoint. Each claim requires its own method, sample definition and boundary. Evidence for a supplied resin does not automatically describe the printed article after additives and post-processing.

7. Reporting requirements

- State the intended article, intended purpose, market and service environment.
- Record all eight levels, including rejected candidates and evidence gaps.
- Keep device classification, biological evaluation and material/process suitability in separate fields.
- Cite the exact controlled product document and revision for every retained claim.

- Label unknown compatibility as not documented or not recommended unless impossibility is demonstrated.
- Finish with the candidate family, formulation/process route, validation plan and decision owner.

8. Limitations

- The SSF does not validate, certify or authorize a material, process or finished article.
- Portfolio and regulatory information can change and must be rechecked at the time of selection and release.
- Long-term ageing, fatigue, humidity, sterilization and other service-specific risks require dedicated plans.
- Multi-material and graded parts require interface-specific evidence beyond the single-material framework.
- The legal manufacturer remains responsible for intended purpose, classification, risk management and conformity.

9. Conclusions

- The SSF is an eight-level candidate-generation framework that keeps requirements, evidence and uncertainty visible.
- Legal classification, biological evaluation and technical material/process suitability remain separate decision streams.
- The framework output is a candidate product family and validation plan, not a compliant material.
- Current product-specific documentation is required; family or variant attributes cannot be extrapolated automatically.
- Final suitability is established only through application-specific validation of the manufactured article and process.

Revision note

Version 5.3 separates finished-device classification from biological evaluation, updates ISO 10993-1 to the 2025 edition, removes material-level MDR classes and mandatory commercial-family routing, corrects the eight-level structure and changes the framework output to candidate product family plus validation plan.

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