

# 3Dresyns Forward Directions for 2025–2030

*A status-labelled research and commercialization roadmap with evidence boundaries*

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## Highlights

- Every roadmap item is labelled commercially available, publicly described, in user evaluation, research use or future direction.
- Monomer-free options are separated from product-specific biological test information.
- A cytotoxicity result is one input to biological evaluation, not overall biocompatibility.
- Medical, pharmaceutical, bioabsorbable and GMP-related directions retain precise research/use boundaries.
- Forecasts and quoted company labels require evidence and an as-of date.

## Abstract

The 2025–2030 roadmap separates current commercial products from public descriptions, user evaluation, research-use materials and future directions.

Monomer-free formulation does not establish biological suitability. Product-specific in-vitro cytotoxicity may provide one input to a broader biological evaluation but does not establish clinical suitability.

Regenerative, fixation, pharmaceutical, bioabsorbable and GMP-related directions are framed as research or development unless exact intended-use, manufacturing and regulatory evidence supports another status.

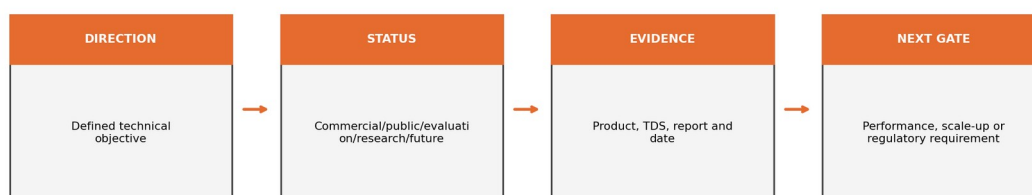
**Keywords** roadmap · future direction · research use · commercial maturity · 2025–2030

**Source use.** Roadmap status evidence is controlled in [1]; biological, ESD and legal frameworks in [2–6].

## 1. Status taxonomy

Every item receives one controlled status and an evidence date: commercially available, publicly described, user evaluation, research use or future direction.

- Link purchasable products and current TDS.
- Do not call research commercial circulation.
- Record date and source.



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

*Figure 1. WP-50 evidence gates from controlled material description to final acceptance.*

## 2. Evidence and maturity

The roadmap distinguishes formulation proof, laboratory evidence, application validation, manufacturing readiness and regulatory/device evidence.

- Treat quoted labels as claims.
- Identify missing gates.
- Avoid maturity inflation.

## 3. High-risk application boundary

Medical, pharma, regenerative, fixation and bioabsorbable directions require exact intended use, risk, performance, biological and regulatory evidence; research materials are not finished products.

## 4. Minimum controlled evidence before release

| Control field | Required record                                 | Release interpretation                              |
|---------------|-------------------------------------------------|-----------------------------------------------------|
| Direction     | Defined technical objective                     | Catalogue description only until evidence is linked |
| Status        | Commercial/public/evaluation/research/future    | Control process variables and change triggers       |
| Evidence      | Product, TDS, report and date                   | Report method, result, uncertainty and limits       |
| Next gate     | Performance, scale-up or regulatory requirement | Apply final acceptance and responsibility boundary  |



Description ≠ measured result ≠ certification or finished-device approval

Figure 2. WP-50 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

- Absolute safety and overall biocompatibility wording is removed.
- ISO 10993-5 evidence is not overall validation.
- Commercial maturity requires a current product/TDS/status.
- Research-use materials are not finished devices or medicines.
- Forecasts carry an evidence date and next gate.

## 6. Conclusions

- Every roadmap item is labelled commercially available, publicly described, in user evaluation, research use or future direction.
- Monomer-free options are separated from product-specific biological test information.
- Forecasts and quoted company labels require evidence and an as-of date.
- This corrected candidate remains local and on HOLD until series-wide scientific, metadata and visual release checks are complete.

## Revision note

Version 5.5 removes absolute safety and ISO-cytotoxicity-as-biocompatibility claims, introduces a five-level maturity taxonomy and adds evidence date and next-gate controls.

**Acknowledgements.** The author acknowledges the 3Dresyns technical team and users whose manufacturing experience informed this correction.

**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 product catalogue, controlled roadmap records and status evidence as of August 2026.
- [2] ISO 10993-1:2025. Biological evaluation of medical devices—Part 1.
- [3] ISO 10993-5:2009. Tests for in vitro cytotoxicity.
- [4] IEC 61340-5-1:2024. Electrostatics—General requirements for ESD control.
- [5] Regulation (EU) 2017/745 on medical devices.
- [6] Regulation (EU) 2017/746 on in vitro diagnostic medical devices.