Issue 3: Preventing the 2026–2027 MDR Bottleneck: Certificate Cliffs, Renewal Waves, and SKU Triage

Executive context: extensions bought time, not safety

The MDR transition extensions to 2027–2028 were designed to avoid a regulatory cliff, not to guarantee a smooth landing. High-risk legacy devices can now remain on the market until 31 December 2027, with most remaining legacy devices following by 31 December 2028 — if manufacturers met strict conditions on QMS upgrades and NB agreements.

For large portfolios, this has a predictable side effect:
risk is now concentrated in a narrow window.

Certificates for multiple product families, NB capacity constraints, and rising evidence/QMS costs are all converging in 2026–2027. Companies that treat the extension as "extra breathing room" will experience a bottleneck. Those that treat it as a planning window can deliberately shape their portfolios.

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1. What an MDR "certificate cliff" looks like

A certificate cliff happens when a disproportionate number of high-value certificates expire in the same 12–18-month window, competing for the same internal and NB resources.

In a typical multinational portfolio, you see:

- Legacy MDD certificates with harmonized end dates due to historical recertification cycles.
- New MDR certificates issued in the first wave of transitions, which begin their own expiry cycles around 2026–2028.
- Evidence remediation projects (CER, PMCF, PMS) that are still catching up with MDR expectations, especially for legacy devices.

On paper, everything is "on track."
In practice, as deadlines approach, several high-revenue families hit:

- Tight NB scheduling windows.
- Unresolved questions about evidence sufficiency.
- Internal resource collisions across Regulatory, Clinical, Quality, and Operations.

Without a plan, executives are forced into one of three bad options: emergency resourcing, fragmented derogation requests, or last-minute SKU withdrawal.

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2. Renewal waves: planning the work, not just the dates

The alternative to a certificate cliff is deliberate renewal waves.

Instead of treating each device in isolation, leadership groups product families into a small number of waves over 2025–2028, based on:

- Risk class and NB complexity. Higher-risk and more complex devices (Class III, implantable IIb) are prioritized earlier.
- Revenue and strategic importance. Products that anchor tenders, platforms, or key accounts get early, reserved capacity.
- Evidence and QMS readiness. Devices with stronger evidence and fewer QMS gaps can be scheduled closer to deadlines; weaker ones need earlier attention.
- Overlap and dependencies. Families sharing components, suppliers, or clinical data are sequenced together where possible.

Each renewal wave has:

- A defined set of product families.
- A targeted NB plan and internal resource plan.
- Clear evidence deliverables (CER, PMCF, PMS integration) and QMS milestones.

This creates a multi-year calendar where leadership can see when each wave enters pre-submission, submission, review, and post-approval — and where the bottlenecks and white space truly are.

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3. SKU triage: exit, defend, or transform

Not every product should make the MDR journey. Extensions make it tempting to defer tough calls, but doing so loads risk into the back end of the timeline.

A disciplined triage framework considers:

- Economic profile. Revenue, margin, working capital footprint, and contribution to platform or portfolio economics.
- Evidence cost. Depth of legacy data, gaps vs MDR expectations, and likely PMCF investment.
- QMS and supplier complexity. Sites, suppliers, and historical issues that drive remediation effort.
- Strategic relevance. Alignment with future technology and market direction, including AI, SaMD and new standards.

From this analysis, each product family falls into one of three buckets:

1. **Defend** – High-value, strategically important lines where MDR investment is clearly justified.
2. **Transform** – Products that should be redesigned, repositioned, bundled, or migrated into a new platform before full MDR investment.
3. **Exit** – Low-margin / high-burden products where MDR and PMCF cost outweigh future return; plan for orderly withdrawal, communication, and substitution.

The earlier these calls are made, the more leverage companies retain over pricing, customer communication, and NB engagement.

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4. Practical levers to avoid the 2026–2027 bottleneck

4.1 Lock NB strategy early

- Confirm which NBs will cover which segments of the portfolio and risk classes; avoid late "NB shopping" when capacity is tight.
- Reserve NB capacity for high-value families in early waves, especially Class III and implantable IIb devices.

4.2 **Front-load evidence and QMS work where it matters most**

- Use portfolio heatmaps and governance councils to identify high-revenue / high-risk families.
- Prioritize CER upgrades, PMCF design, PMS integration, and QMS remediation for these families in 2025–2026, not 2027.

4.3 **Align supply, pricing, and portfolio plans**

- Match inventory and pricing strategies to the renewal-wave plan to avoid either stock-outs or write-offs at certificate end.
- Incorporate MDR renewal scenarios into long-term pricing and contract discussions, particularly in multi-year tenders.

4.4 **Make MDR a standing portfolio topic**

- Integrate MDR renewal waves and SKU triage into quarterly portfolio reviews and board discussions, not just RA/QA updates.
- Track a small set of MDR portfolio KPIs: exposure by year, evidence readiness by wave, and value at risk.

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5. How SHOTUNE helps clients de-risk the cliff

In practice, SHOTUNE's work on the MDR bottleneck starts with the same question every executive team has:

"Where are we likely to feel this crunch first, and what options do we really have?"

Typical steps:

1. Map certificates and value. Build a portfolio heatmap showing MDD/MDR status, renewal dates, revenue, and evidence/QMS maturity.
2. Design renewal waves. Group products into 3–5 waves with clear assumptions about NB and internal capacity.
3. Run SKU triage. Apply the Defend / Transform / Exit framework to clarify where capital and attention should concentrate.
4. Integrate with governance. Plug the renewal-wave and triage plan into MDR decision councils and executive reporting.

The goal is not to eliminate all MDR risk — that is impossible.
The goal is to decide where to absorb it, where to reduce it, and where to walk away, while there is still time to shape the outcome.

Between now and 2028, the choice for most portfolios is simple:
experience MDR as a series of certificate emergencies or use the extension window **to turn it into a deliberate restructuring of where and how you compete.**

Respectfully,

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