

## SHOTUNE KNOWLEDGE SERIES

### Issue 1: EU MDR Portfolio Heatmaps - Turning Certificates and Risk into an Executive Dashboard

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#### Why Portfolio Visibility Is the First Governance Gap

In most large MedTech organizations, MDR risk is still understood at the product team level, not at the level where capital and commercial bets are made.

Executives see long lists of SKUs, certificates, and remediation projects - but not a single view of **where MDR pressure intersects with revenue, margin, and strategic markets**.

The result is familiar: MDR shows up as a series of local fires instead of a portfolio pattern.

A portfolio level MDR heatmap is designed to change that. It converts regulatory noise into an executive instrument panel, showing exactly where certificate cliffs, evidence gaps, and quality exposures will hit P&L, tenders, and strategic accounts.

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#### 1. What an MDR Portfolio Heatmap Actually Is

An MDR portfolio heatmap is not a prettier RAID log.

It is an integrated, comparative view across product families of:

- **Certificate status and expiry waves (MDD and MDR)** - where transition and surveillance cycles actually cluster.
- **Revenue and margin per SKU or product family** - so small regulatory issues on big lines don't hide in the noise.
- **Evidence maturity** - CER robustness, PMCF sufficiency, PMS signal profile, and residual risk alignment.
- **Quality and audit exposure** - inspection history, CAPA trend, supplier documentation strength, manufacturing complexity.
- **Strategic importance** - role in tenders, key accounts, flagship platforms, and future digital or service roadmaps.

The output is not a score for its own sake; it is a simple classification:

**Which products are stable, at risk, or unsustainable under MDR - and on what time horizon.**

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#### 2. Why 2026-2027 Demands This View

Over 2026-2027, three forces collide for enterprise MedTech:

- **MDR transition deadlines and surveillance cycles** compress timelines and leave less room for slow remediation.

- **Notified Body capacity** remains constrained and selective in key device classes, creating real bottlenecks.
- **Portfolio rationalization** pressure grows as evidence, PMCF, and quality costs rise faster than price and volume.

Without a portfolio heatmap, companies discover these forces one incident at a time: clustered certificate expirations, late NB findings, and unplanned SKU withdrawals.

With a heatmap, leadership can treat MDR as a **capital allocation question - deciding, in advance, where to invest, defend, exit, or redesign.**

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### 3. Core Dimensions of an Effective Heatmap

A SHOTUNE style MDR portfolio heatmap scores each product family across five dimensions:

#### 1. Regulatory Trajectory

- MDD vs MDR status, certificate expiry date, NB relationship complexity, and open deficiencies.

#### 2. Evidence Maturity

- Strength and recency of CER, clarity and sufficiency of PMCF, PMS/PSUR signal profile, and alignment with residual risk.

#### 3. Quality & Supply Exposure

- Audit and inspection history, CAPA volume and recurrence, supplier documentation depth, and manufacturing complexity.

#### 4. Commercial Criticality

- Revenue, margin, growth, strategic accounts, tender dependence, and replacement difficulty.

#### 5. Strategic Fit

- Role in future platform strategy, digital roadmap, and competitive positioning.

**The goal is not perfect data. The goal is directional clarity executives can trust enough to make different decisions on Monday morning.**

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### 4. How the Heatmap Changes Decisions

Once the portfolio is visualized, patterns that were invisible in siloed reports become hard to ignore:

- High revenue / high risk products that need immediate remediation, NB planning, or design strategy - not another status slide.
- Low margin / high burden SKUs where MDR and PMCF cost exceed strategic value, making them candidates for orderly exit or bundling.
- "Hidden gems" with strong evidence and low MDR risk that can support growth, platform strategies, or acquisition theses.

Used well, the heatmap enables:

- Forward planned certificate and evidence investment instead of last-minute firefighting.
- Data driven SKU rationalization instead of blanket cuts that damage key markets.
- Clear internal narratives for BU heads, Finance, and investors about where MDR spend is protecting enterprise value - and where it is not.

In other words, MDR stops being a background compliance project and becomes what it already is in reality: a portfolio strategy lever that leadership can see, debate, and deliberately pull.

Respectfully,

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