Impact of variation in risk classification criteria on the implementation of Reliance

Fatemeh Razjouyan

Senior Director of regulatory policy, international and harmonization; Medtronic

June 2026, Mexico City

Same device, different risk class

What does this mean for reliance?

Reference Authority

Device classified as **moderate risk**

Reliance pathway?

Relying Authority

Same device classified as **higher risk**

Classification divergence does not automatically prevent reliance, but it may affect the extent and type of reliance that is appropriate

Reliance is built on trust in reference authority

Device authorization is work product, but trust is grounded in system that produced it

Regulatory framework

Does reference authority have a comparable legal/regulatory framework? Is it subject to good regulatory practices?

Regulatory controls

How are devices classified, reviewed, authorized, and monitored, including change management & postmarket surveillance?

Competence & processes

Are there transparent, science-based processes, qualified reviewers, QMS, and consistent decision-making?

Outputs available for reliance

Are assessment reports, certificates, decisions, audit reports, or postmarket surveillance information available and usable?

Device-specific applicability

Is the device same or sufficiently similar? Is the intended use aligned? Are any classification or evidence gaps material, and how can they be addressed?

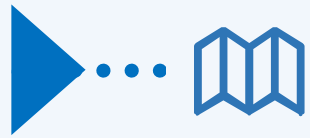
TRUST THE SYSTEM. VERIFY APPLICABILITY.

IMDRF Reliance Playbook (N89) frames reliance as an assessment of the authority, its framework, and its regulatory outputs.

Use structured questions to decide how much reliance is appropriate.

Why risk classification matters for reliance

Risk classification helps determine level of reg control behind authorization being leveraged



Conformity assessment (CA) pathway: Was the device subject to notification, registration, self-declaration, abridged review, or full review?

Evidence & documentation expectations: What clinical, performance, SW, usability, risk management, or bench evidence was expected & reviewed?

Postmarket & lifecycle controls: Are vigilance, postmarket surveillance, adverse events reporting, corrective actions & lifecycle obligations comparable?

Change management: Would future changes require notification, review, approval, or no regulatory action?

Risk classification drives the conformity assessment pathway, including level of review, evidence expectations, and lifecycle controls applied by the reference authority.

Classification misalignment: not a dead end

How should regulators respond when classification does not align?

Situation

- Similar device classified differently across jurisdictions due to different classification criteria or interpretations
- Reference authority applied a lower-risk pathway
- Relying authority has additional local requirements

Impact on reliance

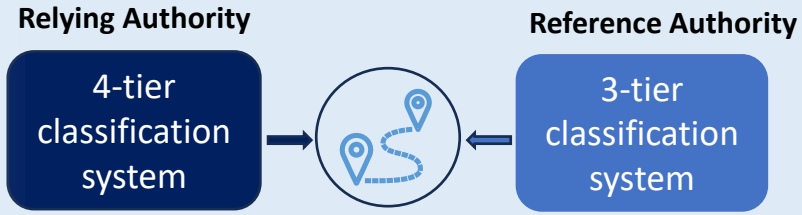
- The reference authorization may not fully align with relying authority's expected level of control
- Some evidence or review outputs may be unavailable
- Reliance benefits may be reduced if local expectations are unclear

Practical solution

- Conduct a classification & CA crosswalk and evidence gap assessment
- Supplement with targeted supplementary evidence, RWE, or postmarket surveillance
- Use an abridged pathway rather than defaulting to full review

IMDRF N89 example

Different classification systems can still support reliance when relying authority understands reference authority's risk-based conformity assessment approach



1 Map classification systems

- A 4-tier classification system may not directly align with a 3-tier system
- Map both classification criteria & associated CA requirements

2 Compare CA requirements

- Identify what requirements apply by class: notification/listing, declaration of conformity, technical review, and postmarket controls

3 Define the scope of reliance

- Choose appropriate level of reliance based on confidence in reference authority's classification approach, CA framework & regulatory controls, while confirming what device-specific evidence or outputs exist

Classification and CA differences should define the scope and extent of reliance, not automatically prevent reliance

How about lower-risk devices?

WHO GMRF supports proportionate pathways for lower-risk devices using lighter controls, such as notification/listing, DoC, QMS obligations, and postmarket oversight.

Why?

To focus premarket review resources on higher-risk devices while maintaining oversight.

IMDRF/GRRP WG/N89 FINAL: 2026 - Playbook for Medical Device Regulatory Reliance Programs, Section 5.4 (Example)

From classification misalignment to a reliance decision

A structured assessment helps determine whether reliance can proceed, and at what level

1. **Confirm sameness**
   - Is the device the same as or sufficiently similar to the one reviewed by the reference authority?
   - If significant differences exist, reliance may be limited or not appropriate
2. **Map classification**
   - How does reference authority's classification map to relying authority's classification?
   - Identify whether the difference is administrative or material
3. **Compare conformity assessment & regulatory controls**
   - Was the reference pathway sufficient for the relying authority's expected level of control?
   - Determine whether the prior review, certification, or other regulatory output can be leveraged
4. **Assess evidence gaps**
   - Are any regulatory expectations (e.g., clinical, performance, QMS) unmet?
   - Request targeted supplementary information if needed
5. **Select reliance pathway**
   - What level of reliance is appropriate?
   - Recognition, verification, abridged review, targeted review, or standard review

The goal is not identical classification. The goal is confidence that the reference review is sufficient for the relying authority's decision.

Decision rule:

Same or sufficiently similar device + **trusted reference system** + **Classification / conformity assessment gaps addressed** = **Reliance pathway can proceed**


Muchas
Gracias!