This document converts the attached ISO 80369-1:2025 versus 2018 comparison into a DHF impact-and-actions recommendation using the same structure and implementation detail as prior DHF impact assessments prepared for this program.

2. Key Changes Summary

2.1 Non-Interconnectable Requirement (Clause 4 ↔ Clause 5)

Change: Clause 4 (2025) reinforces non-interconnectability across small-bore connector categories as a safeguard against misconnection, framing compliance around objective evidence with Annex B providing acceptability criteria. Using connectors specified in the ISO/IEC 80369 series itself is treated as sufficient proof of conformity, and dimensional checks plus modulus-of-elasticity assessments are clarified as adequate evidence. The 2018 edition (Clause 5) tied compliance to objective evidence through Annex B criteria and manufacturer-defined acceptability criteria, with dimensional checks, modulus of elasticity, and Annex E device/accessory examples per application category.

DHF Impact:

- Non-interconnectability verification protocols must be updated to lead with dimensional and modulus-of-elasticity evidence rather than manufacturer-defined acceptability criteria alone.
- DHF records should explicitly document reliance on standardized ISO/IEC 80369-series connector designs as a conformity pathway where applicable.
- Device files referencing the 2018 edition's Annex E application-category examples need review against the 2025 clause structure.

Recommended Actions:

Action	Timeline	Owner	Priority
Update non-interconnectability verification protocols to prioritize dimensional and modulus-of-elasticity evidence	4 weeks	Design Engineering, Regulatory	**Critical**
Document standardized-connector-design reliance as a conformity pathway in applicable device files	3 weeks	Regulatory Affairs	High
Cross-reference legacy Annex E application-category examples against 2025 clause structure	3 weeks	Quality Systems	Medium

2.2 Small-Bore Connectors for Clinical Applications & New Clinical Applications (Clauses 5, 5.1)

Change: Clause 5 (2025) situates connector requirements within a broader regulatory framework, replacing the 2018 edition's detailed alternative-connector requirements (risk evaluation, engineering analysis, marking, warnings) with informative notes referencing Annex D examples, Annex E design assessments, and Annex F's tie to IMDRF essential principles. New Clause 5.1 (no 2018 equivalent) requires connector designs outside the main application categories to meet Annex C criteria before inclusion in the ISO/IEC 80369 series, offering a single, centralized conformity pathway for novel applications.

DHF Impact:

- Design files that previously relied on 2018 Clause 7's enforceable evaluation, marking, and warning requirements for alternative connectors need a documented rationale for the reduced prescriptive requirements in the 2025 edition.
- A new evaluation and documentation pathway is needed for connector designs outside the defined application categories, tied to Annex C assessment criteria.
- Labeling and IFU content tied to the 2018 edition's explicit warning requirements should be reviewed against the informative-note structure in 2025.

Recommended Actions:

Action	Timeline	Owner	Priority
Document rationale in DHF for the absence of 2018-style enforceable alternative-connector evaluation and labeling requirements	4 weeks	Regulatory Affairs	High
Create an Annex C-based evaluation and documentation pathway for connector designs outside defined application categories	5 weeks	Regulatory, Design Engineering	**Critical**
Review labeling and IFU content previously driven by 2018 Clause 7 warning requirements	4 weeks	Labeling, Regulatory	Medium

2.3 Application-Specific Connector Categories — Respiratory, Enteral, Limb Cuff Inflation, Neural (Clauses 5.2–5.5)

Change: Clause 5.2 (2025) ties respiratory connectors to ISO 80369-2 as the default compliance pathway, replacing the 2018 edition's Clause 6.4 anchoring of neuraxial applications to ISO 80369-6. Clause 5.3 anchors enteral connectors to ISO 80369-3 (Clause 6 alternative-design pathway, versus 2018 Clause 7). Clause 5.4 anchors limb cuff inflation connectors to IEC 80369-5 (Clause 6 alternative pathway, versus 2018 Clause 7). Clause 5.5 (no 2018 equivalent) introduces a new neural-application category anchored to ISO 80369-6 with a Clause 6 alternative-design pathway. Across 5.2–5.4, alternative designs must now prove equivalence via performance tests using reference connectors — a requirement not explicitly stated in the 2018 edition.

DHF Impact:

- Device classification and compliance-verification records for respiratory-application connectors must be updated to reference ISO 80369-2 instead of ISO 80369-6, reflecting the shift from neuraxial to respiratory application context.
- Enteral and limb cuff inflation connector files need their alternative-design compliance clause references updated from Clause 7 to Clause 6, with added reference-connector performance testing documentation.
- A new device-risk file is required for neural-application connectors, with ISO 80369-6-based compliance and Annex-based alternative-design testing.

Recommended Actions:

Action	Timeline	Owner	Priority
Re-map respiratory-application connector files from ISO 80369-6 to ISO 80369-2 compliance basis	5 weeks	Regulatory Affairs	**Critical**