

1.0. Comparison Table: below describes the alignment clause-by-clause between the two versions of the standard. Status is **Full** / **Part** / **Not**.

2025 Clause	Requirement	2018 Clause	Requirement	Alignment	Remarks
4 Small-bore connector non-interconnectable requirement	The 2025 text reinforces the principle of non-interconnectability across small-bore connector categories, framing it as a safeguard against misconnections. Compliance is tied to objective evidence, with Annex B providing the acceptability criteria. In practice, using connectors specified in the ISO/IEC 80369 series itself is treated as sufficient proof of conformity. Regulators also clarified that dimensional checks and modulus of elasticity assessments are adequate to demonstrate non-interconnectable characteristics. Overall, the guidance reflects a streamlined, evidence-based approach: conformity is proven through standardized connector designs and measurable physical properties, reducing ambiguity in compliance.	5 SMALL-BORE CONNECTOR incompatibility	The 2018 text underscores the principle of non-interconnectability across small-bore connector categories, framing it as a risk-reduction measure. Compliance was tied to objective evidence, not only through Annex B criteria but also through manufacturer-defined acceptability criteria. Dimensional checks and modulus of elasticity were considered sufficient proof of non-interconnectable characteristics, while Annex E provided examples of medical devices and accessories for each application category. Overall, the guidance reflects a risk-based, evidence-driven approach: conformity demonstrated through measurable properties, manufacturer accountability, and clear device categorization.	Part	2025 (4) clarifies that small-bore connectors must be non-interconnectable unless specified otherwise in the ISO and IEC 80369 series, and it emphasizes confirming compliance through objective evidence in Annex B, while 2018 (5) required confirming that risks are reduced to acceptable levels for the acceptability criteria.
5 Small-bore connectors for clinical applications	The 2025 text situates connector requirements within a broader regulatory framework. Notes point to supporting guidance in A.2.4, examples of intended device applications in Annex D, and design assessments summarized in Annex E. Importantly, Annex F ties the document to IMDRF essential principles and labeling guidance, signaling alignment with global regulatory expectations. Overall, the clause reflects a more integrated compliance model—technical standards reinforced by explanatory annexes and harmonized with international regulatory principles.	7 Alternative SMALL-BORE CONNECTORS	The 2018 text allowed for alternative small-bore connector designs but placed strict conditions on their use. Such designs had to be evaluated for non-interconnectability, risk acceptability, engineering analysis, and material compliance. Devices incorporating them required clear labeling—using ISO symbols or safety signs—and explicit warnings in accompanying documents about potential misconnections and patient harm. Importantly, compliance claims were limited: an alternative design could claim conformance to the specific document but not to the broader ISO 80369 series. Overall, the clause reflects a cautious, risk-management approach—permitting innovation but demanding objective evidence, transparent labeling, and manufacturer accountability.	Part	2025 (5) removes the detailed requirements for alternative small-bore connector designs, risk evaluation, engineering analysis, marking, and warnings that were present in 2018 (7), replacing them with only informative notes referencing guidance, examples, and regulatory alignment. 2018 (7) mandated evaluation per Clause 5 for non-interconnectability, engineering analysis per D.3, compliance with Clause 4 materials, specific marking (ISO 15223-1:2016 or ISO 7010-M002), and a warning in the accompanying documents, plus objective evidence that risks were reduced per Annex B. 2025 (5) provides only references to guidance and rationale in A.2.4, examples in Annex D, design assessments in

2025 Clause	Requirement	2018 Clause	Requirement	Alignment	Remarks
			to mitigate foreseeable hazards.		Annex E, and IMDRF principles in Annex F, omitting all enforceable requirements for alternative connector evaluation and labelling.
5.1 Small-bore connectors for new clinical applications	The 2025 text addresses connector designs outside the main application categories, requiring them to meet Annex C criteria before inclusion in the ISO/IEC 80369 series. Compliance is demonstrated directly through Annex C assessments, signaling a streamlined pathway: alternative or new connector designs are validated against a single annex rather than dispersed requirements. This reflects regulators' intent to centralize conformity checks, ensuring consistency and clarity for novel applications while maintaining patient safety.			Not	New Requirement
5.2 Small-bore connectors for respiratory applications	The 2025 text ties respiratory connectors directly to ISO 80369-2, positioning it as the default compliance pathway. Alternative designs are permitted under Clause 6 but must prove equivalence through ISO 80369-2 performance tests using reference connectors. This reflects regulators' intent to anchor respiratory connector safety in a standardized benchmark, while still allowing innovation if supported by objective test evidence. The approach balances flexibility with rigor: conformity is either built-in through standardized designs or demonstrated through comparative testing.	6.4 Neuraxial APPLICATIONS	The 2018 text anchors neuraxial connectors to ISO 80369-6 as the default compliance pathway, while allowing alternatives under Clause 7 if justified. Documentation had to demonstrate conformity either through direct adherence to ISO 80369-6 or by applying its performance tests to alternative designs. Regulators emphasized flexibility but insisted that risk acceptability and standardized testing remain central. This reflects a balanced compliance model: innovation permitted, but only when backed by objective evidence and aligned with established test methods.	Part	2025 (5.2) shifts the focus from neuraxial applications to respiratory applications and changes the compliance standard from ISO 80369-6 to ISO 80369-2, while retaining the requirement for documentation inspection.
5.3 Small-bore connectors for enteral applications	The 2025 text anchors enteral connectors to ISO 80369-3 as the primary compliance route, with Clause 6 providing the pathway for alternative designs. Documentation must demonstrate conformity either through direct adherence to ISO 80369-3 or by applying its performance tests to alternative connectors using reference designs. This reflects regulators' intent to standardize enteral	6.2 Enteral APPLICATIONS	The 2018 text positioned ISO 80369-3 as the default compliance route for enteral connectors, while allowing alternatives under Clause 7 if justified. Documentation had to demonstrate conformity either through direct adherence to ISO 80369-3 or by applying its performance tests to alternative designs. Regulators emphasized flexibility but insisted that risk acceptability and	Part	2025 (5.3) modifies the compliance clause by referencing Clause 6 instead of Clause 7 as in 2018 (6.2), and it specifies that performance tests must be applied using appropriate reference connectors, which was not explicitly stated in 2018.