Report Description	Gap assessment showing ISO 20417:2026 versus ISO 20417 2021.
Industry Type	Medical device
Document Type	Pre-audit record
Summary of changes	with many clauses restated or only editorially clarified. Core principles of **traceability, transparency, and usability** are preserved. However, the 2026 edition introduces **expanded labeling, packaging, and graphical communication requirements**, which create notable gaps in documentation, risk management, and design history file (DHF) updates.

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

2026 Clause	Requirement	2021 Clause	Requirement	Alignment	Remarks
5 Information elements to be established	The 2026 update highlights a dual emphasis: standardized measurements and clear graphical communication. Numeric values must align with SI units or recognized conventions, reinforcing consistency through ISO 80000-1. Meanwhile, symbols and pictograms are encouraged but cannot remain ambiguous—they must be drawn from established standards (ISO 7000, ISO 7010, ISO 15223-1, IEC 60417, IEC/TR 60878) and explained in accompanying documentation. Compliance is ultimately verified by inspecting both the manufacturer's information and its	**5** Information elements to be established **5.1** Units of measurement	The 2021 text reflects a streamlined approach: manufacturers were expected to present numeric parameters in SI units, or in units dictated by product/group standards or clinical convention. ISO 80000-1 was cited as the reference for applying SI multiples, reinforcing alignment with international measurement practices. Conformance was checked simply by inspecting the supplied information, showing a focus on basic consistency and clarity of unit usage rather than the broader graphical and explanatory requirements that	Part	2026 (5) adds requirements for graphical information, specifying that symbols must be explained in accompanying information and lists additional standards (ISO 7000, ISO 7010, ISO 15223-1:2021+Amd 1:2025, IEC 60417, IEC/TR 60878:2015) not mentioned in 2021 (5.1), which only covered units of measurement; the DHF must update the information supplied by the manufacturer to include graphical explanations and verify compliance with the new standards.

2026 Clause	Requirement	2021 Clause	Requirement	Alignment	Remarks
	supporting explanations, reflecting a broader drive toward harmonization and transparency in technical communication.		appeared in later revisions.		
5.3 Language and country identifiers	The 2026 update continues to stress clarity in multilingual documentation but presents the guidance in a streamlined way. The focus is on ensuring that each language section is unmistakably tied to its content, so users can easily navigate multilingual materials. Manufacturers retain flexibility: they may use either the plain text name of the language or ISO 639 codes. The examples—“English” vs. “en,” “Français” vs. “fra,” “Русский” vs. “ru”—illustrate that both native script and standardized codes are	**5.3** Language and country identifiers **5.3.1** Language identifiers	In the 2021 version, the clause on multilingual information is really about clarity and consistency. The commentary takeaway is that manufacturers are expected to make sure each language section is unmistakably identified, either by spelling out the language name or by using standardized ISO 639 codes. The examples (“English,” “Français,” “Русский” or their codes) show the flexibility allowed, but the underlying principle is usability—readers should never be left guessing which	Part	2026 (5.3) retains the requirement for the language name to be clearly linked to the language used but simplifies the identification method by removing the specific references to ISO 639-1, ISO 639-2, and ISO 639-3, now only stating 'the language codes in accordance with ISO 639'; the DHF must update the language identifier documentation to reflect this change in standard references.

2026 Clause	Requirement	2021 Clause	Requirement	Alignment	Remarks
	acceptable, provided they are applied consistently.		language they're looking at. Conformance is checked simply by inspecting the documentation, so the requirement is practical and easy to verify.		
5.3.2 Country identifiers	The 2026 version reinforces the same principle as earlier editions: when manufacturers provide contact details across multiple countries, each country must be clearly identified to avoid confusion. The standard continues to allow either ISO 3166-1 codes or the country name in the local language, keeping the balance between global consistency and local clarity. Conformity is checked simply by inspecting the supplied information to ensure countries are labeled in	**5.3.2** Country identifiers	The 2021 update makes it clear that when manufacturers list contact details for multiple countries, each country must be identified in a way that avoids confusion. The standard allows either ISO 3166-1 codes or the country name in the local language, striking a balance between global uniformity and local readability. Compliance is checked simply by reviewing the supplied information to confirm that the country identifiers are present and clear.	Full	2026 (5.3.2) restates 2021 with no change to intent or parameter values; no DHF impact.