DHF Impact and Actions Recommendation – ISO 20417:2026

Gap Assessment: ISO 20417:2026 versus ISO 20417:2021

Document Type: Design History File (DHF) Impact Analysis

Standard Reference: ISO 20417:2026 – Medical devices – Information to be supplied by the manufacturer

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1. Executive Summary

ISO 20417:2026 preserves the core 2021 principles of traceability, transparency, and usability, but it introduces broader labeling, packaging, and graphical communication requirements that create meaningful DHF impacts across design inputs, risk management, labeling specifications, IFU structure, and verification records. The attached gap assessment identifies the principal impacts as new graphical-information controls, expanded label-content and packaging rules, revised symbol references, stronger ties between risk management and labeling omissions, new sterile-packaging requirements, and broader IFU requirements for professional and lay users.

Key Impact Areas for DHF:

- Graphical information governance, including symbol explanation and updated referenced symbol standards.
- Expanded label-content architecture for address, model/catalogue number, production identifiers, UDI handling, and material/hazard communication.
- Updated packaging rules, including restructured general packaging content, lay-user packaging clarification, and new sterile-packaging requirements.
- Stronger risk-management linkage for omitted markings, consult-IFU decisions, and home-use/lay-user information design.
- Broader IFU and technical-description content requirements, including split-information control, electronic documentation, readability/accessibility, and lay-user suitability.

- Revised symbol matrices, language/code references, and verification protocols for labels, markings, and packaging.

This document converts the attached ISO 20417:2026 versus 2021 comparison into a DHF impact-and-actions recommendation using the same structure and level of implementation detail as the attached DHF reference example.

2. Key Changes Summary

2.1 Graphical information and symbol-governance expansion

Change: Clause 5 in the 2026 edition expands beyond units of measurement to require governance of graphical information, including use of symbols and pictograms from recognized standards and explanation of those symbols in accompanying information. The comparison specifically cites ISO 7000, ISO 7010, ISO 15223-1:2021 plus Amendment 1:2025, IEC 60417, and IEC/TR 60878:2015 as new referenced sources that were not part of the 2021 clause structure.

DHF Impact:

- Labeling and IFU design controls should now include a formal symbol-governance process, not just unit-of-measure verification.
- DHF traceability should link each graphical symbol to its source standard, intended meaning, and location of explanation in accompanying documentation.
- Verification protocols need to confirm that symbols are both standards-based and adequately explained for intended users.

Recommended Actions:

Action	Timeline	Owner	Priority
Create a controlled symbol and pictogram matrix mapping every label/packaging/IFU symbol to its source standard and meaning	4 weeks	Regulatory / Labeling	Critical
Update IFU and technical-description templates to ensure all symbols are explained in accompanying information	4 weeks	Technical Writing	High
Revise label and packaging verification checklists to include symbol-source and explanation checks	5 weeks	Quality Assurance	High

2.2 Information elements and label-content architecture broaden significantly

Change: The 2026 edition expands clause 5.4 and related label clauses to add full address elements, model and catalogue number associations, production-control identifiers, UDI assignment expectations, and revised rules for dates and product-identity architecture. It also restructures label-content requirements in clause 6.1.3 and 6.1.4, adding transport conditions, e-documentation website addresses, expanded material/hazard symbols, sterilization-method options, quantity or proportion for biological or medicinal substances in direct patient contact, updated expiry/manufacture date expectations, adaptable and patient-matched terminology, and an optional unique version identifier.

DHF Impact:

- Device master records, label specifications, and product-identification logic should be updated to reflect the broader 2026 content architecture.
- Product traceability records must account for revised date, identifier, UDI, model/catalogue, and patient-matched/adaptable device terminology rules.
- Material disclosure, hazardous-substance, nanomaterial, biological-substance, and medicinal-substance labeling decisions require clearer traceability into risk and regulatory files.

Recommended Actions:

Action	Timeline	Owner	Priority
Update label content specifications and device master records for 2026-required identifiers, dates, and model/catalogue associations	5 weeks	Regulatory / Document Control	Critical
Revise label claims matrix to cover hazardous substances, nanomaterials, biological/medicinal content, transport conditions, and e-documentation website references	6 weeks	Regulatory / Product Stewardship	High
Update UDI and production-identifier work instructions, including direct-marking exceptions and version-identifier handling	5 weeks	Quality Systems / Operations	High
Replace outdated terminology in labeling and records with current adaptable and patient-matched device language where applicable	4 weeks	Regulatory / Technical Documentation	Medium

2.3 Manufacturer identification and symbol-reference updates

Change: Clause 6.1.2 is partly revised in 2026 through updated symbol references for the authorized representative, a clarified rule that local address is required only when policy requires it, and removal of

the prior option to replace “EC” with a country code in the authorized-representative symbol context. The comparison notes that the practical DHF effect is primarily on labeling protocols and symbol-usage matrices.

DHF Impact:

- Existing label artwork and symbol libraries should be checked for obsolete authorized-representative symbol references and localized address assumptions.
- Verification procedures and released specifications must align to the amended ISO 15223-1 reference set used in the 2026 edition.
- Country-specific labeling logic should be traceable to applicable policy requirements rather than universal default assumptions.

Recommended Actions:

Action	Timeline	Owner	Priority
Review all manufacturer and authorized-representative labels for outdated symbol references and country-code conventions	4 weeks	Labeling Engineering	High
Update symbol libraries and approval checklists to the amended ISO 15223-1 reference set	3 weeks	Document Control / Regulatory	High
Add policy-based decision logic for local address requirements to labeling review procedures	4 weeks	Regulatory Affairs	Medium

2.4 Packaging requirements are restructured, reduced in some areas, and expanded in others

Change: The 2026 edition revises packaging requirements by narrowing some general-packaging information elements in clause 6.5.1, clarifying lay-user packaging requirements in clause 6.5.2, revising special-condition packaging rules in clause 6.5.3, and introducing a new dedicated clause 6.5.4 for sterile packaging. The comparison notes that 2026 removes some 2021 packaging elements from general packaging, adds optional transport/storage symbols, and moves sterile-packaging identification into a distinct new requirement set.

DHF Impact: