

ISO 15223-1

Medical devices — Symbols to be used with information to be supplied by the manufacturer —
General requirements

Condensed Practical Reference & Field Checklists

Prepared for teams preparing labeling, packaging, and instructions for use (IFU) for medical devices — including refurbished equipment being relabeled or re-exported.

***Important note on scope and use:** This document is an original, independently written condensed overview and practical checklist tool. It summarizes, in the author's own words, the general purpose and categories of symbols standardized by ISO 15223-1 for quick field reference. It is **not a reproduction of the official standard text or its symbol graphics**, is not a substitute for it, and must not be used as the sole basis for final label approval. The precise graphical form of each symbol, and the full current list, must be taken from the current officially licensed ISO 15223-1 text (and the ISO 7000/IEC 60417 symbol registers it draws from), together with applicable regional labeling regulation (e.g. EU MDR labeling annex, destination-country requirements).*

1. About This Standard

ISO 15223-1 standardizes the graphical symbols manufacturers may use on medical device labels, packaging, and accompanying documents in place of (or alongside) written text — each symbol has a defined meaning, and a defined reference number back to its source (many originate in the general ISO 7000 or IEC 60417 symbol registers, with some device-specific symbols defined directly in this standard). The goal is a common visual language understood across countries and languages, reducing reliance on translation for safety-critical information.

1.1 Why it matters for a refurbishment/export business

- Correct, standardized symbol use is expected by most regulatory frameworks (including the ones covered in the companion regional regulatory guide) and by institutional buyers used to seeing internationally recognized marks.
- For bilingual (Persian/English, or other regional-language) labeling, standardized symbols reduce how much safety-critical text must be translated and fit onto limited label space.
- When refurbishing and relabeling equipment, incorrect or invented symbols (or reusing a symbol with the wrong meaning) can create genuine safety-communication risk, not just a cosmetic/branding issue.
- Buyers and regulators may specifically check for the presence of expected symbols (manufacturer identity, date of manufacture, sterility status where relevant, single-use status) as a basic credibility signal during evaluation.

2. Common Symbol Categories (Conceptual Overview)

The table below describes, in general terms, the categories of information ISO 15223-1 provides standardized symbols for. Exact graphical designs are not reproduced here — always source the official symbol graphic from the current standard or a licensed symbol library rather than recreating it freehand.

Symbol category	General meaning
Manufacturer identity	Identifies the legal manufacturer of the device, typically paired with name/address in accompanying documentation.
Authorized representative	Identifies a manufacturer's authorized representative in a given regulatory region, where the manufacturer itself is based elsewhere.
Date of manufacture	Indicates when the device was produced.
Use-by / expiry date	Indicates the date after which the device (or a component with a shelf life, e.g. a battery or consumable) should not be used.
Batch/lot code	Identifies the production batch for traceability.
Serial number	Identifies an individual unit uniquely, important for traceability of refurbished units.
Catalog/reference number	Identifies the manufacturer's model/catalog reference.
Sterile / non-sterile status	Indicates whether the device (or packaging) is sterile, and by what method where relevant, or explicitly non-sterile.
Single use / do not reuse	Indicates a device is intended for one use only and should not be reprocessed or reused.
Do not resterilize	Indicates a device should not be resterilized, distinct from single-use marking.
Caution / consult instructions for use	Signals the user must refer to the accompanying documentation for important safety information not otherwise conveyed by the label alone.
Temperature limit / humidity limit / keep dry	Storage and transport condition limits.
Fragile / handle with care, this way up	General handling symbols for packaging and transport.
Unique Device Identifier (UDI) marking	Indicates presence of a UDI carrier (barcode/data matrix) used for traceability under various regional regulatory frameworks.
Importer / distributor	Identifies the importer or distributor responsible for the device in a given market, distinct from the manufacturer.

3. Practical Considerations for Refurbished Equipment Labeling

- **Do not alter the original manufacturer's serial number or model identity** when relabeling a refurbished unit — instead, add clearly distinguishable refurbisher information (company name, refurbishment date, refurbisher's own reference number) alongside, not in place of, the original.
- **Clarify responsibility on the label** — if your company is acting as an importer, distributor, or refurbisher rather than the original manufacturer, the correct corresponding symbol/role should be used, not the manufacturer symbol.
- **Bilingual labeling** should pair standardized symbols with text in both languages where space allows, rather than relying on symbols alone to replace translated safety text — symbols support, but do not fully substitute for, clear language-appropriate instructions for use.
- **Consistency across the fleet** — use the same symbol conventions across all refurbished units of a given type, so clinical staff build reliable pattern recognition rather than encountering inconsistent labeling from batch to batch.

4. Practical Field Checklists

Use these as a starting self-assessment tool before finalizing labels/packaging artwork. They do not replace a formal regulatory labeling review for your specific destination market.

A. Label Content Checklist	
Check Item / Action	Status
■ Manufacturer identity clearly indicated (name/address or standardized symbol with accompanying text).	Y / N / NA
■ Refurbisher/distributor/importer role clearly distinguished from the original manufacturer where applicable.	Y / N / NA
■ Model/catalog reference and serial number present and legible, matching internal traceability records.	Y / N / NA
■ Date of manufacture (original) and date of refurbishment both indicated where relevant.	Y / N / NA
■ Sterility status correctly indicated if applicable to the device/accessory.	Y / N / NA
■ Single-use / reusable status correctly and unambiguously indicated.	Y / N / NA
■ Storage/transport condition symbols (temperature, humidity, handling) included where relevant to the device.	Y / N / NA
■ "Consult instructions for use" symbol included wherever safety-critical information exists only in the IFU, not on the label itself.	Y / N / NA

B. Symbol Accuracy & Consistency Checklist

Check Item / Action	Status
■ Each symbol used sourced from an official/licensed symbol reference, not freehand-recreated from memory.	Y / N / NA
■ Each symbol's meaning double-checked against its intended use (symbols are not used decoratively or for an unrelated meaning).	Y / N / NA
■ No invented or non-standard symbols used for safety-critical information.	Y / N / NA
■ Symbol usage consistent across all units of the same device type/batch.	Y / N / NA
■ Symbol size and placement meet minimum legibility requirements for the label size used.	Y / N / NA

C. Multi-Language & Regional Fit Checklist

Check Item / Action	Status
■ Text accompanying symbols provided in all languages required by the destination market.	Y / N / NA
■ Any region-specific labeling requirement (e.g. specific importer marking, UDI requirements, local language mandate) checked against the companion regional regulatory guide for your target country.	Y / N / NA
■ Label reviewed by someone fluent in the destination language for translation accuracy, not machine translation alone.	Y / N / NA
■ Final label proof reviewed against a physical or high-resolution mockup before mass printing, to confirm legibility at actual size.	Y / N / NA

Reminder: always obtain the official graphical symbol designs from the current ISO 15223-1 text or a licensed symbol library, and have final label/IFU artwork reviewed against the destination market's specific labeling regulation before production.