

MEDICAL DEVICE LABELING AND MARKING

Guide for Medical Device Manufacturers

ETL Certification Labeling, IEC 60601-1 Product Markings, Warnings, Safety Signs, and Accompanying Documentation

Treat the two labeling layers as separate and complementary requirements. The ETL Certification Mark indicates certification status; it does not replace the equipment identification, ratings, safety signs, warnings, or accompanying information required for the completed medical device.

1. Build the ETL Certification Label

Direct-imprint labels are created by the manufacturer or its printer. Separable Intertek Labels are supplied as needed and contain only the certification elements specified.

Required certification elements

- ETL Certification Mark: Use only the exact mark configuration authorized for the product, based on the applicable report type, Listing, Classification, or Recognized Component, and the intended market, including the applicable C and/or US designations
- Control number: Use the number assigned to the approved applicant and manufacturing-site combination; place it directly beneath or close to the mark.
- Standards wording: Reproduce the wording in Section 1 of the Certification Report exactly. Do not substitute a different identifier or designation.

Any additional product information required by the applicable standard must be provided on the manufacturer's product label or in another location specified by the standard. Intertek separable labels do not provide or replace this required information.

2. Choose the Labeling Method

Direct Imprint

- The marking may be provided by an adhesive label, metal nameplate, laser marking, stamping, or another method permitted for the application.
- Must meet any material requirements stated in the Certification Report and remain visible after installation.
- Artwork must be submitted to Intertek for review before use.

Intertek Label

- Printed by Intertek using the approved mark, control number, and standards wording.
- Requires an approved Listing Report and an assigned manufacturing-site control number before ordering.
- Any other required device information belongs on a separate product label.

3. Follow the Approval Sequence

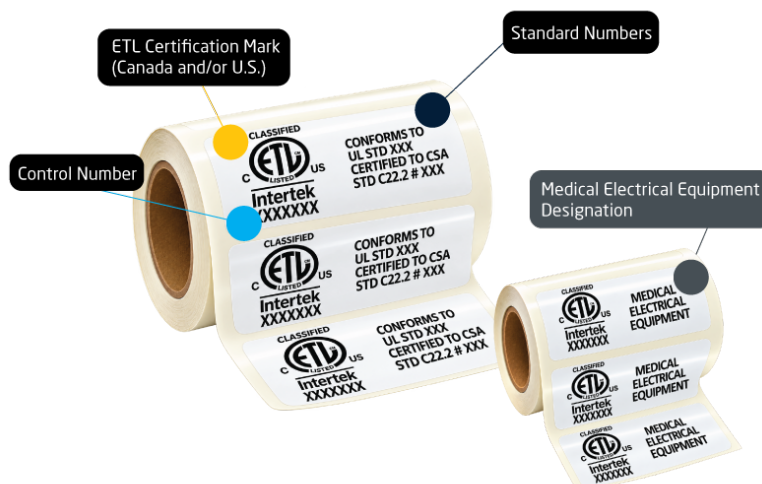
- Provide the report number or draft Sections 1.0 and 2.0 for a new report.
- Receive the required mark configuration, control number, and standards wording.
- Submit direct-imprint artwork to the certification team for review.

- Wait for written approval and completion of the Certification Report.
- Apply the mark and ship only after the signed Authorization to Mark is issued for the approved factory location.

4. Avoid common ETL Mark errors

- Do not stretch, redraw, crop, or resize individual elements of the mark.
- Do not omit the control number or place it where it appears unrelated to the mark.
- Do not apply labels before written approval or use a mark configuration not shown on the Authorization to Mark.
- Do not describe a product as 'UL Certified by Intertek' or 'CSA Certified by Intertek.' Testing to a UL or CSA standard does not authorize use of another organization's certification mark.
- Update the label when report changes affect the authorized mark (listing vs. classification report type) or standards wording.

NOTE: If labels are purchased through Intertek and are intended to include the designation "Medical Electrical Equipment," specify this requirement when placing the order. The applicable standards must also use the "Medical Electrical Equipment" title consistently.



IEC 60601-1 MARKING CHECKLIST

Finished Medical Devices

Use this checklist as an early design review. Exact requirements depend on the equipment, applied parts, intended environment, risks, applicable collateral and particular standards, and the markets where the product will be sold.

A. Markings on the outside of the equipment

- Identification and traceability: manufacturer or responsible organization, model/type reference, serial or lot identification, and other required identifiers.
- Electrical information: supply rating, frequency, power input, duty or operating mode, and fuse or protective-device information where applicable.
- Protection and classification: Class II, applied-part type, ingress protection, protective earth or potential-equalization terminals, and other applicable symbols.
- Equipment-specific safety markings: hazardous voltage, emergency stop, moving parts, hot surfaces, pressure systems, overflow hazards, transport instability, prohibited pushing/sitting/stepping, safe working load, or patient-mass limits when applicable.
- Multiple socket-outlets, separating transformer assemblies, and other ME SYSTEM elements require their own applicable markings.

B. Markings inside the equipment

- Identify hazardous voltages, stored energy, capacitors or connected circuits that can remain hazardous, and relevant mains terminals.
- Provide markings needed for safe servicing, connection, replacement, or adjustment by qualified personnel.
- Apply any required national certification marking to pressure vessels or pipes where applicable.

C. Controls, Indicators, and Instruments

- Make the function of controls and indicators clear and consistent with the instructions for use.
- Mark scales, units, settings, operating states, and direction of adjustment where needed for safe use.
- Clearly identify temperature-setting changes and other adjustments that can create a hazardous output.

D. Warnings, Safety Signs, and Symbols

- Use warnings for residual risks that cannot be adequately controlled through design or protective measures.
- Place the warning where the user encounters the hazard or direct the user clearly to the relevant accompanying information.
- Use standardized symbols and safety signs where required. Explain unfamiliar symbols in the accompanying documents.
- Make markings conspicuous, legible, understandable to the intended user, and sufficiently durable for the expected cleaning, disinfection, handling, and service conditions.

E. Instructions for Use

- State intended use, patient population and user profile, operating environment, known contraindications, and the meaning of warnings and symbols.
- Include safe installation, operation, connection, transport, storage, cleaning, disinfection, maintenance, and disposal instructions as applicable.
- Address equipment specific risks such as accessible parts, hot or cold applied parts, moving equipment, overflow, lifting, instability, patient-support loading, and the need for more than one person to move equipment.
- For ME SYSTEMS and network-connected equipment, include the information necessary for safe connection, configuration, and use.

F. Technical description

- Describe isolation and disconnection means, protective measures, essential performance, environmental limits, and information needed for safe service or integration.
- Disclose relevant transient-current behavior, capacitor-discharge provisions, and other technical safety information where applicable.
- Ensure the label, risk management file, test documentation, instructions for use, and technical description tell the same safety story.

Practical Pre-Submission Review

- Map every applicable IEC 60601-1 Clause 7 and Annex C item to the label, equipment, IFU, or technical description.
- Review collateral and particular standards for additional markings and warnings.
- Confirm translations, symbol explanations, contrast, size, location, and durability.
- Verify that production artwork matches the evaluated configuration and approved certification report.
- Treat labeling changes as controlled design changes and assess their impact before release.

How Intertek can support you

Intertek can review label concepts and artwork, identify applicable medical electrical equipment marking requirements, evaluate durability and legibility, align labeling with the risk management file and accompanying documents, and support testing and ETL certification for North American market access.