Medical CE & FDA Technical Compliance Register: Carton Labeling Standards for North American Importers

REGULATORY DIRECTIVES

This compliance register codifies the mandatory carton labeling standards governing the importation of aesthetic medical devices into the North American market. The document serves as the authoritative OEM reference for labeling architecture, regulatory symbology, traceability protocols, and importer identification obligations under U.S. FDA 21 CFR Part 801 and Health Canada SOR/98-282. All carton labeling must be approved by the OEM Regulatory Affairs department prior to production release. Non-conforming labels constitute grounds for shipment rejection and may trigger customs holds or regulatory action against the importer of record.



DEVICE IDENTIFICATION

The outer carton label must present the device identification block in a fixed, legible sequence. The following elements are mandatory: (1) device trade name; (2) model and configuration code; (3) unique device identifier (UDI) in both human-readable and machine-readable (GS1-128) formats; (4) serial number and lot/batch number; (5) manufacturing date in YYYY-MM format; (6) country of origin. The label substrate must be a minimum 80 gsm synthetic stock with permanent acrylic adhesive, resistant to moisture, abrasion, and alcohol wipe-down. Barcode symbology must meet GS1 General Specifications and pass ISO/IEC 15416 verification at grade B or higher.

HARDWARE SPECS SUMMARY

Carton dimensions, gross weight, and handling symbology are governed by the OEM packaging master record. The label must declare net weight, gross weight, and carton count in a multi-unit shipment. Fragile, this-side-up, and keep-dry pictograms must conform to ISO 780. Stacking limits must be printed where the OEM packaging engineer certifies a maximum stack height. Lithium battery content, if applicable, requires UN 3481 marking and Class 9 hazard labeling on the outer carton.

Parameter	Specification
Label Substrate	80 gsm synthetic stock, permanent acrylic adhesive, moisture/abrasion/alcohol resistant
UDI Barcode Symbology	GS1-128, ISO/IEC 15416 grade B minimum
Device Identification Block	Trade name, model/configuration code, UDI (human-readable + machine-readable), serial, lot/batch, MFG date (YYYY-MM), country of origin
Handling Pictograms	ISO 780 compliant (fragile, this-side-up, keep-dry); stacking limit per OEM packaging master
Hazard Marking	UN 3481 + Class 9 lithium battery label where applicable
Prescription Statement	21 CFR 801.109 statement, minimum 6-point sans-serif, front panel
Importer of Record Block	Legal name, registered address, FDA establishment registration number; Health Canada importer name/address and device license

	number
CE Mark Policy	Displayed only with EU authorized representative block; prohibited on North American-only cartons
Record Retention	Label approvals, barcode verification reports, GUDID confirmations retained for device retention period

TISSUE SAFETY PROTOCOLS

Although carton labeling does not directly govern clinical use, the label carries the mandatory contraindication symbol set and the prescription-device statement required by 21 CFR 801.109. The statement "Caution: Federal law restricts this device to sale by or on the order of a licensed practitioner" must appear in a minimum 6-point sans-serif font on the front panel. The label must also direct the user to the accompanying instructions for use and to the OEM's clinical training portal before first treatment.

COMPLIANCE VERIFICATION

Each carton label must carry the importer of record block: legal name,

registered business address, and FDA establishment registration number. For Health Canada, the importer name and address and the device license number must appear. The CE mark, where applicable, is printed only when the EU authorized representative block is present; North American-only cartons must not display CE marking. UDI records must be transmitted to the FDA GUDID database prior to first commercial shipment, and the label must be reconciled against the GUDID record during incoming inspection.

APPLICATION VIEW

Correct carton labeling is the first regulatory control point in the North American distribution chain. Importers must retain label approval records, barcode verification reports, and GUDID submission confirmations for the device retention period. The OEM recommends a 100% label inspection at the point of carton sealing and an annual audit of label artwork against current regulatory listings. Deviations must be reported through the OEM quality management system within five business days.

