

Safety Traceability Requirements for Carestream Health Suppliers

Issued: 17 Dec 2007

Last Review: 16 Oct 2020

Next review: 01Oct 2022

1.0 Product Specification:

SPECIFICATION CONTROL:

Contact the specification owner for additional information: Manager, Equipment Compliance and Commercialization

2.0 Special Requirements:

Description	Plastic & Foam	Wire Harness	Circuit Boards	Safety Label
Requirements	Materials must be identifiable to safety agency inspectors.	Must be identifiable as having been produced under the UL Recognized Wire Harness Manufacturer's Program and CSA Certified Wire Harness Program.	Must be identifiable as having been produced under the UL Recognized Component Printed Wiring Program.	Must be identifiable as having been produced under the UL and CSA Marking and Labeling System approval programs.
Required Information from supplier with each shipment	1. Molder name 2. Carestream Health part number 3. Raw material manufacturer name 4. Plastic manufacturer type designation (e.g., "Cycoloy C6200") 5. Month and year molded 6. UL Recognized Molder program number, if applicable In addition, for parts with metallic (EMI) coating, identify the applicator, the process used and the metallic (EMI) coating material used.	Wire Harness label on the shipping container or on each harness	Mark parts according to UL Printed Wiring Program (e.g. Manufacturer's name or trademark and board type.)	Manufacturer's identity (e.g., name or trademark) and manufacturer's label type (e.g. Type 123).
Acceptable methods to provide traceability to Carestream Health	Molded on each part or "Stuffer sheet" containing the 6 items above in the smallest shipping container or Label on every shipping container stating the 6 items above.	Label on each harness Label the smallest deliverable package. Label the shipping box for the harnesses contained in the box.	Mark parts according to UL Printed Wiring Program requirements.	For CSA approved labels, place identifier on each label. For UL approved labels, place the identifier on each label or smallest delivered package.
Related supplier safety expectations	1. Parts will be produced under the UL Recognized Fabricated Parts Program. 2. If not, contact the Carestream Health Commodity Manager.	1. Harnesses will be produced under the UL Recognized Wiring Harness Manufacturer program and be CSA Certified. 2. If not, contact the Carestream Health Commodity Manager.	1. Parts will be produced under the UL Recognized Printed Wiring Board program. 2. If not, contact the Carestream Health Commodity Manager	1. Safety labels will be approved to UL/CSA "Marking and Labeling System" requirements. 2. If not, contact the Carestream Health Commodity Manager.



Carestream Health Inc.

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3.0 Carestream Health's Responsibility:

- Call out regulatory compliance and traceability requirements on engineering drawings.
- Provide written authorization and updated engineering drawings prior to the supplier making changes.

4.0 Revision History EKSP-1628_10162020.docx

Date	Revision	By
17 Sep 2015	Update format. Update owner in Section 1.0	J. Shipkowski
16 Oct 2020	Updated Review Date	Said Hassani

END