

OEM and Contract Equipment Manufacturing Environmental, Health, and Safety Specifications

To ensure the marketing of regulatory compliant products around the world, Carestream Health has established the following specifications. Any deviation from these requirements must be reviewed by and approved by Carestream Health.

[SPECIFICATIONS: Standards applicable to all Carestream Health equipment](#)

Materials of Construction:

To ensure compliance to worldwide regulations such as the European Union Restriction on Hazardous Substances (RoHS), Carestream Health has implemented a [Materials Declaration Management Process](#) (EKMD –1752), to be used in conjunction with the [Material Composition Declaration](#) (IPC-1752) form. Supplier is required to evaluate the product being purchased by Carestream Health and complete and return the MCD form. The Supplier may need to contact their sub-contracting suppliers for MCD information.

Energy Efficiency:

Standalone printers, scanners, computers and should be capable of meeting US EPA Energy Star requirements. If not Energy Star capable, Supplier warrants that energy saving features have been incorporated into the product that will reduce energy consumption when not in use. One or more of the following features is acceptable, automatic power off when not in use, programmable night/weekend off or low power modes, or a low power standby mode <20 watts.

Note: A product may be considered “in use” without the physical interaction of the customer (e.g., a direct patient health care product relied upon for the immediate communication of critical patient data). When these features are no longer providing customer functionality, then the energy saving features need to be activated.

External Power Supply Requirements:

For those products containing external power supplies (e.g., AC adapters) with a nameplate output power range of 0 to 250 watts, the following power efficiency/consumption values must be met:

Note: This requirement will be mandatory for all electronic devices that ship to California with external power supplies (e.g. AC adapters).

Power supplies made available, as accessories, service parts or spare parts for products manufactured prior to July 1, 2006 are exempt from Table 1 in California, until June 30, 2009.

Table 1: Minimum Efficiency in Active Mode

Nameplate Output Power	Minimum Active Efficiency
0 to ≤ 1 watt	0.49 * Nameplate Output
>1 to ≤ 49 watts	0.09 * Ln (Nameplate Output) + 0.49
>49 watts	0.84

Max. Energy Consumption-No Load

Nameplate Output Power	Max. No-load power consumption
0 to < 10 watts	0.5 watts
≥ 10 to ≤ 250 watts	0.75 watts

Where Ln (Nameplate Output) = Natural Logarithm of the nameplate output in Watts

For a copy of the test methodology visit: www.energystar.gov/powersupplies
Relevant safety standards for external power supplies include UL-1012, UL-1310

Note: This revised requirement in Table 2 will be mandatory for all electronic devices that ship to California with external power supplies (e.g. AC adaptors) manufactured after January 1, 2008. Power supplies made available as accessories, service parts or spare parts for products manufactured between July 1, 2006 and December 31, 2007 for sale in California, are exempt from table 2, until December 31, 2010.

Table 2: Minimum Efficiency in Active Mode

Nameplate Output Power	Minimum Active Efficiency
< 1 watt	0.5 * Nameplate Output
≥ 1 to < 51 watts	$0.09 * \text{Ln (Nameplate Output)} + 0.5$
>51 watts	0.85

Max. Energy Consumption -No Load

Nameplate Output Power	Max. No-load power consumption
Any Output	0.5 watts

Where Ln (Nameplate Output) = Natural Logarithm of the nameplate output in Watts

For a copy of the test methodology visit www.energystar.gov/powersupplies
Relevant safety standards for external power supplies include UL-1012, UL-1310

Recycled Content in Rigid Containers

For products that have rigid plastic containers (like photochemical bottles and vessels that will hold liquid), this statement applies:

Supplier warrants that rigid plastic containers between 0.03 L and 20 L (8 fluid ounces and 5 gallons) capacity provided with the product are marked with the Society of the Plastic Industry (SPI) code and include a minimum of 25% post consumer resin content.

Test Fixture Equipment and Procedures

The supplier must maintain Test Equipment in accordance with safety agency requirements and approved, documented calibration procedures for Dielectric withstand (**hipot**) and Ground Continuity test fixtures. In addition, approved training procedures must exist for certification of personnel operating these safety test fixtures. These test, calibration and training procedures are to be approved by a *Licensed Safety Professional*.

Product Packaging Requirements

Product packaging must meet the Carestream Health [Packaging Specifications & Declarations](#).

Noise

The product must conform to the following sound power levels measured according to **ISO-7779**:

- Large professional operating systems must be less than 80 dB(A)
- General office systems must be less than 70 dB(A)
- Private office systems or home use must be less than 60 dB(A)

Emissions

In addition, certain products (printers, scanners, etc.) may also have related emissions (heat, ozone, dust, non-ionizing radiation, volatile organic compounds, etc.). The product's specifications document will indicate the acceptable levels for these emissions. For all EMC standards, testing shall be performed by a certified EMC test facility (e.g., NVLAP or A2LA certified).

Manufacturing:

Supplier warrants that, during their manufacturing operations, which produce products (including packaging) for Carestream Health, no ozone depleting substances (such as chlorofluorocarbons, methyl chloroform and carbon tetrachloride) are used.

Communication Procedures

The Supplier is obligated to communicate to Carestream Health or respond to Carestream Health's concerns including the following areas:

- **Product Changes:**
Appropriate notification of changes, which could impact the safety, electromagnetic compatibility or environmental performance of the product (including the discontinuance of products or parts).
- **Modifications or Recalls**
Safety, electromagnetic compatibility or environmental related modifications and recalls that affect existing products provided to Carestream Health are identified to Carestream Health.
- **Resolution of Concerns/Corrective Action**
Supplier must respond in writing within 10 days to all Carestream Health requests for corrective action for potential safety, electromagnetic compatibility or environmental related issues discovered by CARESTREAM HEALTH, or our customers, that are determined to be the Supplier's responsibility. For Contract Equipment Manufacturers, this includes taking immediate steps to contain the problem within any work-in-process.

PRODUCT SPECIFIC REQUIREMENTS:

Specific EHS requirements, such as these that follow, must be further specified within the Carestream Health Product Specifications Document (PSD), Carestream Health engineering drawing, contract or purchase order. In some cases, Supplier must provide information to Carestream Health based on a specific product and its application.

Additional Requirements for Creating EHS Product Specifications

These items must be included in the Product Specifications Document (PSD). In some instances, these may be found in the "Quality" specifications section. Regulatory standards that the product is expected to meet must be specified by Carestream Health, including any critical components, spare parts,

consumables, and accessories as well as the intended usage and intended equipment configurations. Media and Consumables required as part of an Equipment Product must comply with **Carestream Health Chemical Specifications and Declarations**. If Product Safety (PS) and Electromagnetic Compatibility (EMC) requirements and other regulatory or standards requirements are not specifically defined by Carestream Health, Supplier will provide Carestream Health with all applicable standards for the product.

These standards can include, but are not limited to:

- Product safety: UL, CSA, IEC standards, EU Product Safety Directives
- Electromagnetic compatibility (EMC): FCC, C-tick, IEC standards, EU EMC Directive
- Ergonomic: ZH1/618, MPR II
- Environmental: US EPA Energy Star
- Noise emissions levels (sound pressure and sound power) as tested according to ISO 7779

Ionizing/Non-Ionizing Radiation

Products that emit ionizing (alpha, beta, gamma or x-ray) or non-ionizing radiation (ultrasonic, ultraviolet, infrared, radiofrequency, microwave radiation, intense visible light or magnetic fields) will require approval of Carestream Health's EHS Organization.

Lasers

Products containing lasers require a Center for Devices and Radiological Health (CDRH) report and Carestream Health EHS Organization approval. A CDRH report must be filed before sale of a laser or product containing a laser takes place in the United States.

Compliance Evidence:

Compliance Evidence documenting that the product meets these performance specifications must be provided to Carestream Health (Declarations of Conformity, test certificates, test reports, Material Safety Data Sheets, etc.), evaluated, and accepted by Carestream Health's EHS Organization. For those products that are provided under the Carestream Health identity, separate Carestream Health compliance documentation must be developed prior to sale.

Batteries

Battery requirements including restricted materials, labeling and recovery vary by country. For products placed on the market in the European Union, batteries must comply to the **European Battery Directive 91/157/EEC**. Supplier must disclose the presence of all batteries and provide any additional information upon request from Carestream Health. Lead-acid batteries used to provide memory backup in computers and nickel-cadmium (Ni-Cd) batteries or mercury containing batteries used as a power source or to provide memory backup capability must be appropriately marked, easily customer removable, and managed within established recovery/recycling programs. Additional battery specifications are **Carestream Health Battery Specifications and Declarations**.

End-of-Life Product Management:

Carestream Health and the Supplier must agree on the end-of-life management of the product. In some instances, the Supplier may accept the product back for remanufacturing or parts reclamation. In other instances, Carestream Health may take the product and remanufacture or reclaim parts from the product (either directly or by a third party). Depending on the local applicable end-of-life laws, the product may be placed in the municipal waste stream for disassembly and recycling. In certain countries, the manufacturer or importer (i.e. Carestream Health or their dealer/distributor) is expected to pay a disposal fee prior to marketing the product or is expected to include the cost of disposal in the sale price of the product or has the ability to charge the final customer for the disposal of the product.