

Certificate of Compliance

Certificate: 2155461

Master Contract: 209877

Project: 2330992

Date Issued: August 23, 2010

Issued to: RALCO s.r.l.
Via Dei Tigli 13/G
20046 Biassono (MI)
ITALY

Attention: Mr. Giovanni Pagani

The products listed below are eligible to bear the CSA Mark shown with adjacent indicators 'C' and 'US' for Canada and US or with adjacent indicator 'US' for US only or without either indicator for Canada only



H. - W. Zeller
Issued by: H.- W. Zeller

CSA PRODUCT CLASS

8750 01 MEDICAL ELECTRICAL EQUIPMENT

8750 81 MEDICAL ELECTRICAL EQUIPMENT Certified to US Standard

X-Ray beam limiting device, model R225 ACS DHHS, rated 20V-30Vac,30VA,50/60 Hz ,12V-45Vdc, 30VA,Type B applied part, provided with timer and laser module.

CONDITIONS OF ACCEPTABILITY

The beam limiting devices are to be installed on general-purpose radiology units that must be tested for compliance with the applicable Standards.

APPLICABLE REQUIREMENTS

CAN/CSA-C22.2 No. 601.1-M90(1997) Medical Electrical Equipment Part 1: General Requirements for Safety.

CSA-C22.2 No 601.1-B98 Am.2 Medical Electrical Equipment Part 1: General Requirements for Safety.

CAN/CSA-C22.2 No. 601.1.3-98 Medical Electrical Equipment Part 1: General requirements for safety.
Collateral standard: General requirements for radiation protection in diagnostic X-ray equipment.

CAN/CSA-C22.2 No. 601.2.32 Medical Electrical Equipment Part 2: Particular requirements for the safety of associated equipment of X-ray equipment

UL Publication 60601-1 Medical Electrical Equipment, Part 1: General Requirements for Safety

IEC Publication 601-1 (1988) Safety of Medical Electrical Equipment, Part I, General Requirements for Safety

IEC 601-1 Amendment 1 (1991)

IEC 601-1 Amendment 2 (1995)

IEC Publication 601-1-3 (1998) Medical Electrical Equipment Part 1: General requirements for safety.
Collateral standard: General requirements for radiation protection in diagnostic X-ray equipment.

IEC Publication 60825-1 (2001) Safety of laser products - Part 1: Equipment classification, requirements and user's guide

MARKINGS

On the Equipment Exterior:

Equipment is plainly marked in a permanent manner in a place where the details will be readily visible after installation with the following:

- the CSA Mark with the C US indicator adjacent to it and the optional reference to CAN/CSA Standard C22.2 No. 60601.1, UL 60601-1, or IEC/EN 60601-1.
- Manufacturer's identification: Name and/or CSA file number "209877" on the same label as the CSA Mark.
- The name and/or trademark should appear elsewhere on the equipment if only the file number is used on this label.
- Catalogue/Model/Type designation.
- Date of manufacture: Month and year of manufacture or date code. If a serial number is used instead of date of manufacture, a record of serial numbers shall be kept traceable to date of manufacture (not related to date of sale).
- Complete electrical ratings in volts, hertz and amperes, except for P313/A, T303/ A, P303 and P304.
- For UL 2601-1: Marking on the unit that indicates the manufacturing location if the equipment is manufactured at more than one factory location.
- The "Type B" symbol for degree of protection against electric shock.
- For equipment incorporating laser source: marking in according to IEC 60825-1 Standard requirements.

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Additional markings:

- All words comprising the text of the marking, excluding the signal word are in letters not less than 1.6mm (1/16 inch) high, based upon uppercase.
- The signal word is in letters at least 2.8mm (7/64 inch).

Marking method: The above markings are made via silk screening, die stamping, molding or on CSA certified or UL recognized adhesive nameplate material compatible with the surface used, or other equivalent permanent means that can pass the label rub test under Clause 6.1.

Note 1: Bilingual Markings for products with CSA Mark or CSA Mark and the C US indicator.

Note 2: Jurisdictions in Canada may require these markings to be also in French. It is the responsibility of the Customer to provide bilingual marking, where applicable, in accordance with the requirements of the Provincial Regulatory Authorities. It is the responsibility of the Customer to determine this requirement and have bilingual wording added to the "Markings".

ACCOMPANYING DOCUMENTS:

An operating manual is provided that specifies proper operating procedures for the equipment, recommended accessories, proper cleaning and operator maintenance procedures, maintenance information and particular technical characteristics



CSA INTERNATIONAL

Supplement to Certificate of Compliance

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*The products listed, including the latest revision described below,
are eligible to be marked in accordance with the referenced Certificate.*

Product Certification History

Project	Date	Description
2155461	2009/05/05	Original Certification.
2330992	2010/08/23	Update to report 2155461 to add halogen lamp or Single LED as light field source.