

Certificate of Compliance

Certificate: 2317876

Master Contract: 209877

Project: 2317876

Date Issued: August 9, 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



Hans Werner Zeller
Issued by: Hans Werner Zeller

PRODUCTS

8750 01 MEDICAL ELECTRICAL EQUIPMENT
8750 81 MEDICAL ELECTRICAL EQUIPMENT Certified to US Standard

Manual X –ray beam device (collimator).Model;R108 F DHHS, ; Type B applied part.
Ratings : 20V-30Vac,30VA,50/60 Hz
12V-45Vdc,30 VA

APPLICABLE REQUIREMENTS

CAN/CSA-C22.2 No. 601.1-M90	Medical Electrical Equipment Part 1: General Requirements for Safety.
CSA-C22.2 No. 601.1-B98 Am.1,Am2	Medical Electrical Equipment Part 1: General Requirements for Safety.
CAN/CSA-C22.2 No. 601.1.3-(ed.1)	Medical Electrical Equipment Part 1: General requirements for safety. Collateral standard: General requirements for radiation protection in diagnostic X-ray equipment.

UL Publication 60601-1

Medical Electrical Equipment, Part 1: General Requirements for Safety

IEC Publication 60825-1 (2001)

Safety of laser products - Part 1: Equipment classification, requirements and user's guide

Subjects to the following conditions:

- (1) The equipment has not been investigated for the protection against hazards of explosions in medically used rooms.
- (2) Evaluated to IEC/CSA 601-1 Amendment 2 excluding requirements for Biocompatibility (Clause 48) and Programmable Electronic Systems (IEC 60601-1-4 referenced in sub-clause 52.1).

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).
- 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.

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".



CSA INTERNATIONAL

Supplement to Certificate of Compliance

Certificate: 2317876

Master Contract: 209877

*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
2317876	August 9, 2010	Original Certification of Model R108 F DHHS