

Certificate of Compliance

Certificate: 2155461

Master Contract: 209877

Project: 2155461

Date Issued: June 8, 2009

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



Issued by: Hans Werner Zeller

Authorized by: M.H.J. Hoendervangers
Area Director Europe



PRODUCTS

CLASS 8750 01 MEDICAL ELECTRICAL EQUIPMENT

CLASS 8750 81 MEDICAL ELECTRICAL EQUIPMENT-Certified to US Standards

For details related to rating, size, configuration, etc. reference should be made to the CSA Certification Record or the descriptive report.

X-Ray beam limiting device, model R225 ACS DHHS, rated 24 V ac, 50/60 Hz, 3A, Type B applied part, provided with timer and laser module.

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.

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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.
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.

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).

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	June 8, 2009	Original cCSAus Certification of X-Ray beam limiting device, model R225 ACS DHHS.