

Certificate of Compliance

Certificate: 1182730

Master Contract: 209877

Project: 2144533

Date Issued: March 18, 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'*



Issued by: H. W. 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

PART A:

X-Ray beam limiting device, Type B applied part, Models :
Ralco model P313/A DHHS (Philips model 9890-010-80452) ; 12 V ac/dc; 50/60 Hz .
Ralco model T303/A DHHS (Philips model 9848-600-00172) ; 21÷24 V ac/dc; 50/60 Hz .
Ralco model P303 (Philips model 9890-010-02093) ; 24 V ac/dc ; 50/60 Hz
Provided with one or two laser ,provided with or without timer .

PART B:

X-Ray beam limiting device, model R 302 L/A DHHS, rated 12 or 24 V ac/dc, 50-60 Hz, 9A or 6.5 A, Type B applied part. with one or two laser ,provided with or without timer .

PART C:

X-Ray beam limiting device, models R72 DHHS, rated 12 or 24 V ac/dc, 50-60 Hz, 9A or 6.5 A, Type B , applied part. provided with or without timer and with or without one or two laser module .
Models differs only for accessories: Ex . Double push-button

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PART D:

X-Ray beam limiting device, model R 302/144/A , rated 24 V ac/dc, 50/60 Hz, 8 A, Type B applied part.

PART E:

X-Ray beam limiting device, model R 302 MLPI/A DHHS, rated 12 or 24 V ac/dc, 50/60 Hz, 9A for 12 v.lamp. or 6.5 ÷ 8 A for 24 v. lamp.,24 v. d.c. 0.5 A or 12 V. d.c. 1 A for powered movements, Type B applied part, provided with or without electronic timer, provided with or without laser module.

PART F:

X-Ray beam limiting device, model R 302 ACS/A DHHS, rated 24 V ac, 50/60 Hz, 9A, Type B applied part, provided with or without one or two laser module.

PART G:

X-Ray beam limiting device, model P 232 DHHS, rated 12 or 24 V ac/dc, 50/60 Hz, 9A or 6.5 A, Type B applied part, provided with or without electronic timer, provided with or without laser module

PART H:

X-Ray beam limiting device, model R 221/A DHHS, rated 12 or 24 V ac/dc, 50/60 Hz, 9A or 6.5 A, Type B applied part, provided with or without electronic timer, provided with or without laser module

PART I:

X-Ray beam limiting device, model R 302 MLP/A DHHS, rated 12 or 24 V ac/dc, 50/60 Hz, 9A for 12 v. lamp or 6.5 ÷ 8 A for 24 v. lamp.,24 v. d.c. 0.5 A or 12 V. d.c. 1 A for powered movements, Type B applied part, provided with or without electronic timer, provided with or without laser module .

PART L:

X-Ray beam limiting device, model R 302 /A DHHS, rated 12 or 24 V ac/dc, 50-60 Hz, 9A or 6.5 ÷ 8 A, Type B applied part. provided with or without timer .

X-Ray beam limiting device, model P304/A DHHS, rated 12 or 24 V ac/dc, 50-60 Hz, 9A or 6.5 ÷ 8 A, Type B applied part. provided with or without timer .

X-Ray beam limiting device, model R 302F /A DHHS, rated 12 or 24 V ac/dc, 50-60 Hz, 9A or 6.5 ÷ 8 A, Type B applied part. provided with or without timer .

PART M:

X-Ray beam limiting device, model R 108 DHHS and R108F DHHS, rated 12 or 24 V ac/dc, 50-60 Hz, 9A or 6.5 A, Type B applied part. provided with or without electronic timer, provided with or without one or two laser module

PART N:

X-Ray beam limiting device, model R 302 DACS/A DHHS, rated 24 V ac, 50/60 Hz, 9A, Type B applied part, provided with or without one or two laser module.

PART O:

X-Ray beam limiting device, model R 605 DASM DHHS, rated 24 V ac, 3 A, 50/60Hz (24 V ac, 6.5 A with optional I/O external interface ASR003), Type B applied part.

PART P:

X-Ray beam limiting device, model R 72S DHHS, rated 24 -30V AC, 1 A, 50/60Hz or 24 -30V DC, 1A, Type B applied part

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RO 288 component: used as substitution kit of halogen lamp solution. Used on all the X-ray beam limiting devices stated in This Certificate with exclusion of the only model R 605 DASM DHHS.

Note:

The beam limiting devices are to be installed on general-purpose radiology units that must be in 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.
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) and user's guide	Safety of laser products - Part 1: Equipment classification, requirements

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).



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
2144533	March 18, 2009	Part A to Part O: No differences from project 2017249 for the other models. Part P: X-Ray beam limiting device, model R 72S DHHS, rated 24 -30V AC, 1 A, 50/60Hz or 24 -30V DC, 1A, Type B applied part RO 288 component: used as substitution kit of halogen lamp solution. Used on all the X-ray beam limiting devices stated in This Certificate with exclusion of the only model R 605 DASM DHHS. New model: R72S DHHS X-ray beam limiting device
2017249	September , 2008	New model (Part O: R 605 DASM DHHS) added

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1890638

March 26, 2007

Part A:

adding of time board ASR001, used as alternative

Part B:

adding of time board ASR001, used as alternative

Part C:

adding of time board ASR001, used as alternative

Part D:

adding of time board ASR001, used as alternative

Part E:

adding of time board ASR001, used as alternative

Part F:

adding of step motor, used as alternative

Part G:

adding of time board ASR001, used as alternative

Part H:

adding of time board ASR001, used as alternative

Part I:

adding of time board ASR001, used as alternative

Part L:

adding of time board ASR001, used as alternative

adding of new X-Ray beam limiting device, model R302F/A DHHS

Part M :

Adding the suffix DHHS

Part N:

adding of new X-Ray beam limiting device, model R 302 DACS/A DHHS

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1759611 February 21,
2006

PART A :

X-Ray beam limiting device, Type B applied part, Models :
Ralco model P313/A DHHS (Philips model 9890-010-80452) ; 12 V ac/dc; 50/60 Hz .
Ralco model T303/A DHHS (Philips model 9848-600-00172) ; 21÷24 V ac/dc; 50/60 Hz .
Ralco model P303 (Philips model 9890-010-02093) ; 24 V ac/dc ; 50/60 Hz
Provided with one or two laser ,provided with or without timer .

PART B :

X-Ray beam limiting device, model R 302 L/A DHHS, rated 12 or 24 V ac/dc, 50-60 Hz, 9A or 6.5 A, Type B applied part. with one or two laser ,provided with or without timer .

PART C :

X-Ray beam limiting device, models R72 DHHS, rated 12 or 24 V ac/dc, 50-60 Hz, 9A or 6.5 A, Type B , applied part. provided with or without timer and with or without one or two laser module .

Models differs only for accessories: Ex . Double push-button

PART D :

X-Ray beam limiting device, model R 302/144/A , rated 24 V ac/dc, 50/60 Hz, 8 A, Type B applied part.

PART E :

X-Ray beam limiting device, model R 302 MLPI/A DHHS, rated 12 or 24 V ac/dc, 50/60 Hz, 9A for 12 v.lamp. or 6.5 ÷ 8 A for 24 v. lamp.,24 v. d.c. 0.5 A or 12 V. d.c. 1 A for powered movements, Type B applied part, provided with or without electronic timer, provided with or without laser module.

PART F :

X-Ray beam limiting device, model R 302 ACS/A DHHS, rated 24 V ac, 50/60 Hz, 9A, Type B applied part, provided with or without one or two laser module.

PART G :

X-Ray beam limiting device, model P 232 DHHS, rated 12 or 24 V ac/dc, 50/60 Hz, 9A or 6.5 A, Type B applied part, provided with or without electronic timer, provided with or without laser module

PART H :

X-Ray beam limiting device, model R 221/A DHHS, rated 12 or 24 V ac/dc, 50/60 Hz, 9A or 6.5 A, Type B applied part, provided with or without electronic timer, provided with or without laser module

PART I :

X-Ray beam limiting device, model R 302 MLP/A DHHS, rated 12 or 24 V ac/dc, 50/60 Hz, 9A for 12 v. lamp or 6.5 ÷ 8 A for 24 v. lamp.,24 v. d.c. 0.5 A or 12 V. d.c. 1 A for powered movements, Type B applied part, provided with or without electronic timer, provided with or without laser module .

PART L :

X-Ray beam limiting device, model R 302 /A DHHS, rated 12 or 24 V ac/dc, 50-60 Hz, 9A or 6.5 ÷ 8 A, Type B applied part. provided with or without timer .

X-Ray beam limiting device, model P304/A DHHS, rated 12 or 24 V ac/dc, 50-60 Hz, 9A or 6.5 ÷ 8 A, Type B applied part. provided with or without timer .

PART M :

X-Ray beam limiting device, model R 108 and R108F, rated 12 or 24 V ac/dc, 50-60 Hz, 9A or 6.5 A, Type B applied part. provided with or without electronic timer, provided with or without one or two laser module

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1691066	June 30, 2005	CSC - Deletion of Factory #1
1691083	June 30, 2005	CSC - Addition of Factory #2 Due to Relocation
1565303	May 28, 2004	<p>Part A: Added suffix DHHS to model P313/A. No differences from edition 2 for the other models.</p> <p>Part B: Model R 302 L/A DHHS. Laser option is permanently installed in equipment. No tests were demanded necessary because the equipment was not changed; the only difference is the name of the model.</p> <p>Part C: Added suffix DHHS to model R72 - R72/170A - R72/170B.</p> <p>Part D: No differences from edition 2 for the other models.</p> <p>Part E: New model. X-Ray beam limiting device, model R 302 MLPI/A DHHS.</p> <p>Part F: New model. X-Ray beam limiting device, model R 302 ACS/A DHHS.</p> <p>Part G: New model. X-Ray beam limiting device, model P 232 DHHS.</p> <p>Part H: New model. X-Ray beam limiting device, model R 221/A DHHS.</p> <p>Part I: New model. X-Ray beam limiting device, model R 302 MLP/A DHHS.</p>
1401467	January 16, 2003	<p>PART A: No variation as to 1182730 revision.</p> <p>PART B: Added suffix DHHS to model R302/A.</p> <p>PART C: X-Ray collimator, model R72 , R72/170A and R72/170B rated 12 or 24 V ac/dc, 50-60 Hz, 9A or 6.5 A, Type B. Models differs only for accessories: model R72 provided with timer and without laser module; model R72/170A provided without timer and laser module; model R72/170B provided without timer and with laser module.</p> <p>PART D: (Added) X-Ray collimator, model R302/144/A, rated 24 V ac/dc, 50-60 Hz, 9A , Type B, provided with laser module.</p>

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1182730 November 8, 2001 Original Certification

PART A:

X-Ray collimators, Type B applied part, Models:

Trade Name	Manufacturer	Model	Rating
Ralco	Ralco	P313/A	12V ac/dc; 50/60 Hz
Ralco	Ralco	T303/A	12V ac/dc; 50/60 Hz
Philips	Ralco	9890-010-80442	21V ac/dc; 50/60 Hz
Philips	Ralco	9848-600-00173	21V ac/dc; 50/60 Hz

PART B:

X-Ray collimator, R302/A, rated 12 or 24Vac/dc, 50-60 Hz, 9A or 6.5 A, Type B applied part.

PART C:

X-Ray collimator, R72 and R72/170 rated 12 or 24Vac/dc, 50-60 Hz, 9A or 6.5 A, Type B applied part.

Model R72 and R72/170 are the same. No timer is provided in model R72/170