

Certificate of Compliance

Certificate: 1182730

Master Contract: 209877

Project: 2330993

Date Issued: September 10, 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

PRODUCTS

8750 01 MEDICAL ELECTRICAL EQUIPMENT

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 OR Single LED
20V-30Vac, 30VA, 50/60Hz, 12V-45Vdc, 30VA

Ralco model T303/A DHHS (Philips model 9848-600-00172); 21÷24 V ac/dc; 50/60 Hz . OR Single LED
20V-30Vac, 30VA, 50/60Hz, 12V-45Vdc, 30VA

Ralco model P303 (Philips model 9890-010-02093); 24 V ac/dc; 50/60 Hz. OR Single LED
20V-30Vac, 30VA, 50/60Hz, 12V-45Vdc, 30VA

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, 9 A or 6.5 A, Type B applied part. with one or two laser ,provided with or without timer . OR Single LED

20V-30Vac, 30VA, 50/60Hz, 12V-45Vdc, 30VA

Certificate: 1182730

Project: 2330993



Master Contract: 209877

Date Issued: September 10, 2010

PART C:

X-Ray beam limiting device, models R72 DHHS, rated 12 or 24 V ac/dc, 50-60 Hz, 9 A 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 OR Single LED 20V-30Vac, 30VA, 50/60Hz, 12V-45Vdc, 30VA

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. OR Single LED 20V-30Vac, 30VA, 50/60Hz, 12V-45Vdc, 30VA

PART E:

X-Ray beam limiting device, model R 302 MLPI/A DHHS, rated 12 or 24 V ac/dc, 50/60 Hz, 9 A for 12 V lamp or 6.5÷8 A for 24 V lamp, 24 V dc, 0.5 A or 12 V. dc 1 A for powered movements, Type B applied part, provided with or without electronic timer, provided with or without laser module. OR Single LED 20V-30Vac, 30VA, 50/60Hz, 12V-45Vdc, 30VA . 12Vdc 0.5A (motor) or 24Vdc 1.0A (motor)

PART F:

X-Ray beam limiting device, model R 302 ACS/A DHHS, rated 24 V ac, 50/60 Hz, 9 A, Type B applied part, provided with or without one or two laser module. OR Single LED 20V-30Vac, 30VA, 50/60Hz, 12V-45Vdc, 30VA

PART G:

X-Ray beam limiting device, model P 232 DHHS, rated 12 or 24 V ac/dc, 50/60 Hz, 9 A or 6.5 A, Type B applied part, provided with or without electronic timer, provided with or without laser module. OR Single LED 20V-30Vac, 30VA, 50/60Hz, 12V-45Vdc, 30VA

PART H:

X-Ray beam limiting device, model R 221/A DHHS, rated 12 or 24 V ac/dc, 50/60 Hz, 9 A or 6.5 A. Type B applied part, provided with or without electronic timer, provided with or without laser module. OR Single LED 20V-30Vac, 30VA, 50/60Hz, 12V-45Vdc, 30VA .

PART I:

X-Ray beam limiting device, model R 302 MLP/A DHHS, rated 12 or 24 V ac/dc, 50/60 Hz, 9 A for 12 V lamp or 6.5÷8 A for 24 V lamp, 24 V dc, 1.0 A(motor) or 12 V. dc 0.5 A(motor) for powered movements, Type B applied part, provided with or without electronic timer, provided with or without laser module. OR Single LED 20V-30Vac, 30VA, 50/60Hz, 12V-45Vdc, 30VA .

PART L:

X-Ray beam limiting device, model R 302 /A DHHS, rated 12 or 24 V ac/dc, 50-60 Hz, 9 A or 6.5 ÷ 8 A, Type B applied part, provided with or without timer. OR Single LED 20V-30Vac, 30VA, 50/60Hz, 12V-45Vdc, 30VA .

Certificate: 1182730

Project: 2330993



Master Contract: 209877

Date Issued: September 10, 2010

X-Ray beam limiting device, model P304/A DHHS, rated 12 or 24 V ac/dc, 50-60 Hz, 9 A or 6.5 ÷ 8 A, Type B applied part, provided with or without timer. OR Single LED 20V-30Vac, 30VA, 50/60Hz, 12V-45Vdc, 30VA .

X-Ray beam limiting device, model R 302F /A DHHS, rated 12 or 24 V ac/dc, 50-60 Hz, 9 A or 6.5 ÷ 8 A, Type B applied part, provided with or without timer. OR Single LED 20V-30Vac, 30VA, 50/60Hz, 12V-45Vdc, 30VA .

PART M:

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

OR Single LED 20V-30Vac, 30VA, 50/60Hz, 12V-45Vdc, 30VA .

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. OR Single LED 20V-30Vac, 30VA, 50/60Hz, 12V-45Vdc, 30VA .

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..No light source.

PART P:

X-Ray beam limiting device, model R72 S DHHS, rated 24-30Vac, 1A, 50/60Hz or 24-30Vdc, 1A, Type B applied part. OR Single LED 20V-30Vac, 30VA, 50/60Hz, 12V-45Vdc, 30VA .

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

The RO 333 single LED will be component used as substitution kit of halogen lamp and cluster led solution.

Certificate: 1182730

Project: 2330993



Master Contract: 209877

Date Issued: September 10, 2010

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) 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).



CSA INTERNATIONAL

Supplement to Certificate of Compliance

Certificate: 1182730

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
2330993	2010/09/10	Addition of Single LED as a light source in all the Parts from A-P.(Single) 20V-30Vac, 30VA, 50/60Hz, 12V-45Vdc, 30VA).
2144533	2009/03/18	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 DHHSding new model :R72 S DHHS X-ray beam limiting device .
2017249	2008/09/10	Part A to Part N: No differences from project 1890638 ,for the other models. 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 , /O external interface ASR003), Type B applied part.

Certificate: 1182730

Project: 2330993



Master Contract: 209877

Date Issued: 2010/08/23

Part
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 :

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

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

Certificate: 1182730

Project: 2330993



Master Contract: 209877

Date Issued: 2010/08/23

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 **Part A:**

Added suffix DHHS to model P313/A.
No differences from edition 2 for the other models.

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.

Part C:

Added suffix DHHS to model R72 - R72/170A - R72/170B.

Part D:

No differences from edition 2 for the other models.

Part E:

New model. X-Ray beam limiting device, model R 302 MLPI/A DHHS.

Part F:

New model. X-Ray beam limiting device, model R 302 ACS/A DHHS.

Part G:

New model. X-Ray beam limiting device, model P 232 DHHS.

Part H:

New model. X-Ray beam limiting device, model R 221/A DHHS.

Part I:

New model. X-Ray beam limiting device, model R 302 MLP/A DHHS.

1401467 January 16,
2003

PART A:

No variation as to 1182730 revision.

PART B:

Added suffix DHHS to model R302/A.

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.

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.

Certificate: 1182730

Project: 2330993



Master Contract: 209877

Date Issued: 2010/08/23

1182730 November 8, Original Certification
2001

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