Certificate of Compliance

Certificate: **70042533** **Master Contract:** **209877**

Project: **70042533** **Date Issued:** **April 29, 2016**

Issued to: **RALCO s.r.l.**
Via Dei Tigli 13/G
20853 Biassono (MB)
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

C US

Issued by: Rami Alareki
Rami Alareki

PRODUCTS

CLASS 8780 01 - MEDICAL ELECTRICAL EQUIPMENT (Canadian adopted IEC 60601-1 3rd edition)
CLASS 8780 81 - MEDICAL ELECTRICAL EQUIPMENT (US Adopted IEC 60601-1 3rd edition)

Automatic X-Ray beam limiting device, Model/Type: R 302 DMLP DHHS, fixed, rated: 24VDC, 1.5A, Type B Applied Part, high luminosity provided by white LED, provided with or without one linear laser to align the collimator with the image receptor (RO242/1), provided with or without second laser for cross projection (RO242/2). Optional provided with LED on front panel (available only for collimators assembled with additional variable filtration RO 258).

1. Medical device protection against electric shock: Class I
2. Applied Part protection against electric shock: Applied part Type B (external housing according to clause 4.6).
3. Degree of protection against ingress of water or particulate matter: No degree of protection
4. Method of Sterilization: None
5. Suitability for use in an Oxygen Rich Environment: Medical device not intended to be used in an Oxygen Rich Environment
6. Suitability to use Medical device in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide: Medical device not suitable for use in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide.

7. Mode of operation: Continuous
8. Environmental Conditions: Normal: 10-40°C, 0-75% RH, 700-1060hPa as specified by manufacturer and indicated in the instruction for use.

APPLICABLE REQUIREMENTS

CSA Standards (CLASS 8780 01):

CAN/CSA-C22.2 No. 60601-1:08	Medical Electrical Equipment - Part 1: General Requirements for basic safety and essential performance (Adopted IEC 60601-1:2005 + CORR.1)
CAN/CSA-C22.2 NO. 60601-1:08 TC 2:2011 (Corrigendum 2)	Technical Corrigendum 2:2011 to CAN/CSA-C22.2 No. 60601-1-08, Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance (Adopted IEC 60601-1:2005, third edition, 2005-12)
CAN/CSA-C22.2 NO. 60601-1-3:09 (R2014)	Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral standard: Radiation protection in diagnostic X-ray equipment (Adopted IEC 60601-1:2008, second edition, 2008-01)
CAN/CSA-C22.2 NO. 60601-1-6:11	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability (Adopted IEC 60601-1-6:2010, third edition, 2010-01)
CAN/CSA-C22.2 NO. 62366:14	Medical devices — Application of usability engineering to medical devices (Adopted IEC 62366 edition 1.0, 2007-10)
CAN/CSA-C22.2 NO. 60601-2-54:11	Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy (Adopted IEC 60601-2-54:2009, first edition, 2009-06)

ANSI/AAMI/ IEC Standards (CLASS 8780 81):

ANSI/AAMI ES60601-1:2005 (R2012) (IEC 60601-1:2005, MOD)	Medical electrical equipment, Part 1: General requirements for basic safety and essential performance
ANSI/AAMI ES60601-1:2005/C1:2009 (R2012) AND A2 (R2012) (COORIGENDUM 1)	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance - Corrigendum 1
IEC 60601-1-3:2008	Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral standard: Radiation protection in diagnostic X-ray equipment
IEC 60601-1-6:2010	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
ANSI/AAMI/IEC 62366:2007	Medical devices – Application of usability engineering to medical

	devices
IEC 60601-2-54:2009	Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy

Subject to the following qualifications:

(1) Evaluated to CAN/CSA-C22.2 No. 60601-1:08 and ANSI/AAMI ES60601-1:2005 (IEC 60601-1:2005, MOD) excluding requirements for Electromagnetic compatibility (Clause 17).
(2) SAFETY HAZARDS resulting from the intended physiological function of EQUIPMENT covered by this Standard are not considered.
(3) The X-ray beam limiting devices are to be installed on general-purpose radiology units that must be in compliance with the applicable Standards. After installation, the medical system shall be evaluated to the requirements of the applicable standards.
(4) The installation of the units shall by performed by Submitter's trained personnel only, according to the installation instructions provided with each unit.
(5) Interconnection of X-ray beam limiting device with other medical devices, medical used systems or non-medical devices shall be evaluated to the requirements of Clause 16 in the end use application.
(6) PE connection of the X-ray beam limiting device has to be ensured in final application, PE measurement to provide compliance with this standard is required.
(7) Fuse for power supply protection of the x-ray beam limiting device has to be provided in the end equipment (end installation) as specified in the instruction for use. This fuse must be an approved type acceptable to the authorities where the equipment is sold.
(8) Mechanical strength of device installation to other equipment shall be ensured in final application (clause 9.8 of IEC 60601-1).
(9) Storage/ shipping environmental conditions: -40- +70°C, 10-95%rH (not condensing), 500- 1060hPa.
(10) Safety Risk Management: A risk management process complying with the requirements of standard ISO 14971 was inspected during the evaluation of this medical device and/or additional considerations were taken into account since the subject legacy medical device was evaluated to the previous edition of this standard. The risk management decisions affecting the testing requirements have been taken into consideration during the evaluation of this medical device. Changes/Updates in risk management documents during the lifecycle of this medical device that affect the safety of this medical device shall be communicated to the CSA Group as a condition for continued compliance.

MARKINGS

The manufacturer is required to apply the following markings:

- Products shall be marked with the markings specified by the particular product standard.
- Products certified for Canada shall have all Caution and Warning markings in both English and French.

Additional bilingual markings not covered by the product standard(s) may be required by the Authorities Having Jurisdiction. It is the responsibility of the manufacturer to provide and apply these additional markings, where applicable, in accordance with the requirements of those authorities.

Certificate: 70042533 **Master Contract:** 209877

Project: 70042533 **Date Issued: April 29, 2016**

The products listed are eligible to bear the CSA Mark shown with adjacent indicators 'C' and 'US' for Canada and US (indicating that products have been manufactured to the requirements of both Canadian and U.S. Standards) or with adjacent indicator 'US' for US only or without either indicator for Canada only.

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 applicable mark / / with optional reference to Standard, CAN/CSA-C22.2 No. 60601-1:08 and ANSI/AAMI ES60601-1:2005 (IEC 60601-1:2005, MOD).
- Manufacturer's identification: Name and/or CSA file number 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).
- Marking on the unit that indicates the manufacturing location if the equipment is manufactured at more than one factory location.
- Complete electrical ratings; as applicable in volts (V), Frequency (DC), and amperes (A).

On the Equipment Interior:

- The IEC 60417-5019 "Protective earth" symbol adjacent to protective earth terminal.

Supplement to Certificate of Compliance

Certificate: 70042533 **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
70042533	April 29, 2016	Original cCSAus Certification of an Automatic X-Ray beam limiting device, Model/Type: R 302 DMLP DHHS, fixed, rated: 24VDC, 1.5A, Type B Applied Part, CAN/CSA-C22.2 No. 60601-1:08 and ANSI/AAMI ES60601-1:2005 (IEC60601-1:2005, MOD)

Certificate of Compliance

Certificate: **70018475** **Master Contract:** **209877**

Project: **70018475** **Date Issued:** March 24, 2015

Issued to: **RALCO s.r.l.**
Via Dei Tigli 13/G
20853 Biassono (MB)
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: Rami Alareki
Rami Alareki

PRODUCTS

CLASS 8780 01 - MEDICAL ELECTRICAL EQUIPMENT (Canadian adopted IEC 60601-1 3rd edition)
CLASS 8780 81 - MEDICAL ELECTRICAL EQUIPMENT (US Adopted IEC 60601-1 3rd edition)

Automatic X-Ray beam limiting device, Model/Type: P 225 ACS DHHS, Fixed, rated: 24VDC, 1.5A and 12VDC, 2A for LED, Type B applied part.

1. Medical device protection against electric shock: Class I
2. Applied Part protection against electric shock: Applied part Type B (touchable enclosure housing).
3. Degree of protection against ingress of water or particulate matter: No degree of protection
4. Method of Sterilization: None
5. Suitability for use in an Oxygen Rich Environment: Medical device not intended to be used in an Oxygen Rich Environment
6. Suitability to use Medical device in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide: Medical device not suitable for use in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide.
7. Mode of operation: Continuous
8. Environmental Conditions: Normal: 10-40°C, 0-75% RH, 700-1060hPa as specified by manufacturer and indicated in the instruction for use.

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

APPLICABLE REQUIREMENTS

CSA Standards:

CAN/CSA-C22.2 No. 60601-1:08	Medical Electrical Equipment - Part 1: General Requirements for basic safety and essential performance (Adopted IEC 60601-1:2005 + CORR.1)
CAN/CSA C22.2 NO. 60601-1-2:08 (R2014)	Medical Electrical Equipment part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic Compatibility - Requirements and Tests adopted IEC 60601-1-2:(07) 3rd edition
CAN/CSA-C22.2 NO. 60601-1-3:09 (R2014)	Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral standard: Radiation protection in diagnostic X-ray equipment (Adopted IEC 60601-1:2008, second edition, 2008-01)
CAN/CSA-C22.2 NO. 60601-1-6:11	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability (Adopted IEC 60601-1-6:2010, third edition, 2010-01)
CAN/CSA-IEC 62366:14	Medical devices — Application of usability engineering to medical devices (Adopted IEC 62366:2007)
CAN/CSA-C22.2 NO. 60601-2-54:11	Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy (Adopted IEC 60601-2-54:2009, first edition, 2009-06)

ANSI/AAMI Standards:

ANSI/AAMI ES60601-1:2005 (R2012) (IEC 60601-1:2005, MOD)	Medical electrical equipment, Part 1: General requirements for basic safety and essential performance
ANSI/AAMI/IEC 60601-1-2:2007 (R2012)	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
IEC 60601-1-3:2008	Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral standard: Radiation protection in diagnostic X-ray equipment
IEC 60601-1-6:2010	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability

Certificate: 70018475 **Master Contract:** 209877

Project: 70018475 **Date Issued:** March 24, 2015

ANSI/AAMI/IEC 62366:2007	Medical devices – Application of usability engineering to medical devices
IEC 60601-2-54:2009	Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy

Subject to the following qualifications:

(1) Evaluated to CAN/CSA-C22.2 No. 60601-1:08 and ANSI/AAMI ES60601-1:2005.
(2) SAFETY HAZARDS resulting from the intended physiological function of EQUIPMENT covered by this Standard are not considered.
(3) The X-ray beam limiting devices are to be installed on general-purpose radiology units that must be in compliance with the applicable Standards. After installation, the medical system shall be evaluated to the requirements of the applicable standards.
(4) The installation of the units shall by performed by Submitter's trained personnel only, according to the installation instructions provided with each unit.
(5) Interconnection of X-ray beam limiting device with other medical devices, medical used systems or non-medical devices shall be evaluated to the requirements of Clause 16 in the end use application.
(6) PE connection of the X-ray beam limiting device has to be ensured in final application, PE measurement to provide compliance with this standard is required.
(7) Extended environmental conditions Normal: 10-40 °C, 0-75% rH, 700-1060 hPa.
(8) Mechanical strength of device installation to other equipment shall be ensured in final application (clause 9.8 of IEC 60601-1).
(9) Fuse for power supply protection of the x-ray beam limiting device, rated T 4 A, has to be provided in the end equipment (end installation) as specified in the instruction for use MTP225 DHHS – ACS_DHHS date of issue: 2014-09-25. This fuse must be an approved type acceptable to the authorities where the equipment is sold.
(10) Safety Risk Management: A risk management process complying with the requirements of standard ISO 14971 was inspected during the evaluation of this medical device and/or additional considerations were taken into account since the subject legacy medical device was evaluated to the previous edition of this standard. The risk management decisions affecting the testing requirements have been taken into consideration during the evaluation of this medical device. Changes/Updates in risk management documents during the lifecycle of this medical device that affect the safety of this medical device shall be communicated to the CSA Group as a condition for continued compliance.

MARKINGS

The manufacturer is required to apply the following markings:

- Products shall be marked with the markings specified by the particular product standard.
- Products certified for Canada shall have all Caution and Warning markings in both English and French.

Additional bilingual markings not covered by the product standard(s) may be required by the Authorities Having Jurisdiction. It is the responsibility of the manufacturer to provide and apply these additional markings, where applicable, in accordance with the requirements of those authorities.

The products listed 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.

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 applicable mark / US / C US with optional reference to Standard, CAN/CSA-C22.2 No. 60601-1:08 and ANSI/AAMI ES60601-1:2005.
- Manufacturer's identification: Name and/or CSA file number 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 (V), Frequency (DC), and amperes (A).

On the Equipment Interior:

- The IEC 60417-5019 "Protective earth" symbol adjacent main protective earth terminal.

Supplement to Certificate of Compliance

Certificate: 70018475 **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
70018475	March 24, 2015	Original cCSAus Certification of an Automatic X-Ray beam limiting device, Model/Type: P 225 ACS DHHS, Fixed, rated: 24VDC, 1.5A and 12VDC, 2A for LED, Type B applied part. CAN/CSA-C22.2 No. 60601-1:08 and ANSI/AAMI ES60601-1:2005 (IEC60601-1:2005, MOD)

Certificate of Compliance

Certificate: 2463785 **Master Contract:** 209877

Project: 2553726 **Date Issued:** November 15, 2012

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

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
Hans-Werner Zeller

PRODUCTS

CLASS 8780-01 - MEDICAL ELECTRICAL EQUIPMENT/SYSTEMS (Adopted IEC 60601-1, 3rd Edition)
CLASS 8780-81 - MEDICAL ELECTRICAL EQUIPMENT/SYSTEMS (Certified to U.S. Standards)

X-Ray beam limiting device, models R225/R225 DHHS, rated 12-45 VDC, 30 VA or 20-30 VAC, 50/60 Hz, 30 VA, Type B applied part, provided with electronic timer and with 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.

When the beam limiting device is used in combination with the final end-product the equipment shall be subject to the applicable risk management evaluation on the system-level. Component certification so risk management was not evaluated.

The units are installed by the Submitter's trained personnel only, according to the installation instructions provided with each unit.

External over current protection, rated T 3.15 A maximum, has to be provided in the end equipment (end installation) as specified in the installation instruction MTR225 DHHS – date of issue: 2011-03-08.

APPLICABLE REQUIREMENTS

CSA Standards:

CAN/CSA-C22.2 No. 60601-1-08	Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance (Adopted IEC 60601-1:2005, third edition, 2005-12) which incorporates Corrigendum 1:2006
CAN/CSA-C22.2 NO. 60601-1-08 TC 2:2011 (Corrigendum 2)	Technical Corrigendum 2:2011 to CAN/CSA-C22.2 No. 60601-1-08, Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance (Adopted IEC 60601-1:2005, third edition, 2005-12)
CAN/CSA C22.2 60601-1-2-08	Medical Electrical Equipment part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic Compatibility - Requirements and Tests adopted IEC 60601-1-2:(07) 3rd edition
CAN/CSA-C22.2 NO. 60601-1-3-09	Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral standard: Radiation protection in diagnostic X-ray equipment (Adopted IEC 60601-1:2008, second edition, 2008-01)
CAN/CSA-C22.2 NO. 60601-2-54-11	Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy (Adopted IEC 60601-2-54:2009, first edition, 2009-06)

Reference Standards:

IEC 60601-1:2005	Medical electrical equipment, Part 1: General requirements for basic safety and essential performance
ANSI/AAMI ES60601-1:2005 (IEC 60601-1:2005, MOD)	Medical electrical equipment, Part 1: General requirements for basic safety and essential performance
ANSI/AAMI ES60601-1:2005/C1:2009	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance - Amendment 1
ANSI/AAMI/IEC 60601-1-2:2007	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
IEC 60601-1-3:2008	Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment
IEC 60601-2-54:2009	Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy

Certificate: 2463785 **Master Contract:** 209877

Project: **2553726** **Date Issued: November 15, 2012**

Supplement to Certificate of Compliance

Certificate: 2463785 **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
2553726	November 15, 2012	Update to report 2463785 to correct Critical components list.
2463785	April 12, 2012	Original Certification of X-Ray beam limiting device, models R225/R225 DHHS.

Certificate of Compliance

Certificate: 1182730 **Master Contract:** 209877

Project: 70000318 **Date Issued:** 2013-04-24

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: A.SINGH
A.SINGH

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

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 .

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 **Master Contract:** 209877

Project: 70000318 **Date Issued:** 2013-04-24

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) IEC 601-1 Amendment 1 (1991) IEC 601-1 Amendment 2 (1995)	Safety of Medical Electrical Equipment, Part I, General Requirements for Safety
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).

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
70000318	2013-04-24	Update to the report 1182730 to add alternative motor. No tests required necessary.
2546819	2012-08-24	Addition of alternate component Electronic timer board GC-338 to Part B,C,E,G,H,I,L,M .No additional tests required.
2330993	2010/08/23	Addition of Single LED as a light source in all the Parts from A-P (Single LED 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.

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

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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

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.

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