Certificate of Compliance

Certificate: 70056326 **Master Contract:** 209877

Project: 80077452 **Date Issued:** 2023-12-07

Issued To: **RALCO s.r.l.**
Via Dei Tigli 13/G
Biassono, Monza e Brianza, 20853
Italy

Attention: Stefania Conti

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 - C8780 01 - MEDICAL ELECTRICAL EQUIPMENT/SYSTEMS
CLASS - C8780 81 - MEDICAL ELECTRICAL EQUIPMENT/SYSTEMS Certified to US Standards

Medical Electrical Sub-assembly, Automatic X-Ray beam limiting device intended for installation on mammographic equipment, Model/Type: R 915 S DHHS, fixed, rated: 24Vdc, 3A, High luminosity provided by a white LED simulating the X-ray field, the light field is controlled by an electronic timer, Type B applied part (according to clause 4.6).

1. Medical device protection against electric shock: Class I
2. Applied Part protection against electric shock: Applied part Type B (external parts “Lexan and its screws” according to clause 4.6, No marking required as per 7.2.10)
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 operation: 10 to 40°C, 10 to 75% RH, 700 to 1060 hPa
   Storage/ shipping environmental conditions: -40 to +70°C, 10 to 95% RH (not condensing), 500 to 1060 hPa as specified by manufacturer and indicated in the instruction for use

Conditions of Acceptability:

(1) Evaluated to CAN/CSA-C22.2 No. 60601-1:14 and ANSI/AAMI ES60601-1:2005/(R)2012, AND A1:2012, C1:2009 AND A2:2010(R)2012 (CONSOLIDATED TEXT) excluding (Not Evaluated) requirements for Electromagnetic compatibility (Clause 17) and Biocompatibility (Clause 11.7).

(2) SAFETY HAZARDS resulting from the intended physiological function of EQUIPMENT covered by this Standard are not considered.

(3) The X-ray beam limiting device is a sub-assembly intended to be installed in mammography equipment that must be in compliance with the applicable Standards. The beam limiting device is intended to be supplied with 24 V dc from secondary winding of transformer complying to IEC 60601-1 as reported in accompanying documentation and protected by an external fuse.

(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) General standard 60601-1 was evaluated, only as far as applicable to the equipment object of the present report. A re-evaluation of the General standard considering the final installation conditions, is to be considered as part of the end-use mammography equipment.

(6) Applicable collateral (IEC 60601-1-3) and particular standards (IEC 60601-2-45) were partially evaluated, only as far as applicable to the equipment under test of the present report. A re-evaluation of the applicable standards is to be considered as part of the end-use mammography equipment.

(7) 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.

(8) 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.

(9) Mechanical strength of device installation to other equipment shall be ensured in final application (clause 9.8 of IEC 60601-1).

(10) Fuse for power supply protection of the 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.

(11) 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.

APPLICABLE REQUIREMENTS

CSA Standards (CLASS 8780 01):

CAN/CSA-C22.2 No. 60601-1:14 (R2018)	CAN/CSA-C22.2 No. 60601-1:14: Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance (Adopted IEC 60601-1:2005, third edition + Amendment 1:2012)
CAN/CSA-C22.2 NO. 60601-1-6:11 (R2016)	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)
Amendment 1:2015 to CAN/CSA-C22.2 No. 60601-1-6:11 (R2016)	Amendment 1:2015 to 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/Amendment 1:2013)

Additionally considered standards (partially evaluated)

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)
Amendment 1:2015 to CAN/CSA-C22.2 No. 60601-1-3:09 (R2019)	Amendment 1: 2015 to 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/Amendment 1:2013)
CAN/CSA-C22.2 No. 60601-2-45:2011	Medical electrical equipment – Part 2-45: Particular requirements for the basic safety and essential performance of mammographic X-ray equipment and mammographic stereotactic devices (Adopted IEC 60601-2-45:2011, third edition)
Amendment 1: 2017 to CAN/CSA-C22.2 No. 60601-2-45:2011	Amendment 1: 2017 to CAN/CSA-C22.2 No. 60601-2-45:11 Medical electrical equipment – Part 2-45: Particular requirements for the basic safety and essential performance of mammographic X-ray equipment and mammographic stereotactic devices (Adopted IEC 60601-2-45:2011, third edition/Amendment 1:2015 + modification 1:2017)

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

ANSI/AAMI ES60601-1:2005/(R)2012, AND A1:2012, C1:2009(R2012) AND A2:2010(R)2012 (CONSOLIDATED TEXT)	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005+A1:2012, MOD)
IEC 60601-1-6:2010	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
IEC 60601-1-6:2010/A1:2013	Amendment 1:2013 to IEC 60601-1-6:2013 Medical electrical equipment, Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability

Additionally considered standards (partially evaluated)

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 60601-1-3:2008 / A1:2013	Amendment 1:2013 to 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 60601-2-45:2011	Medical electrical equipment – Part 2-45: Particular requirements for the basic safety and essential performance of mammographic X-ray equipment and mammographic stereotactic devices
IEC 60601-2-45:2011 / A1:2015	Amendment 1:2015 to IEC 60601-2-45:2011 Medical electrical equipment – Part 2-45: Particular requirements for the basic safety and essential performance of mammographic X-ray equipment and mammographic stereotactic devices

Notes:

Products certified under Class C878001, C878081 have been certified under CSA's ISO/IEC 17065 accreditation with the Standards Council of Canada (SCC). www.scc.ca

Supplement to Certificate of Compliance

Certificate: 70056326 **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
80077452	2023-12-07	Update cCSAus Certification 70056326 for Automatic X-Ray beam limiting device, Model R 915 S DHHS to cover update to Edition 3.1. and changes to LOCC according to Standard 60601 based on CB acceptance.
70056326	2016-05-23	Original cCSAus Certification of an Automatic X-Ray beam limiting device, Model/Type: R 915 S DHHS, fixed, rated: 24Vdc, 3A, 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: 70199003 **Master Contract:** 209877

Project: 80077448 **Date Issued:** 2024-03-07

Issued To: **RALCO s.r.l.**
Via Dei Tigli 13/G
Biassono, Monza e Brianza, 20853
Italy

Attention: Stefania Conti

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 - C878001 - MEDICAL ELECTRICAL EQUIPMENT/SYSTEMS
CLASS - C878081 - MEDICAL ELECTRICAL EQUIPMENT/SYSTEMS Certified to US Standards

PART A:
Medical Electrical Sub-assembly, Motorized X-Ray beam limiting device, Model/Type: **R 302 MLP/A DHHS**, fixed, rated: 24Vac/dc, 50/60 Hz, 2A, with motor rating: 12Vdc or 24Vdc, 0.5A, Type B applied part (according to clause 4.6), with motorized shutter positioning controlled by potentiometer and adjusted by two knobs on the collimator front panel, high luminosity provided by a white LED simulating the X-ray field, the light field is controlled by an electronic timer,
Optionally provided with:

- RO 242/1: Single laser line to align collimator and detector center: Class 2.
- RO 242/2: Two lasers (one mounted externally) forming a crosshair to center the patient to the detector: Class 2.
- RO 258: Additional variable filtration - manual selection. 4 position rotating wheel with selectable filters (clockwise): (1) empty or (2) 0.1mm Cu+1mm Al or (3) 0.2mm Cu+1mm Al or

(4) 2mm Al.
- RO 258/1: Additional variable filtration - manual selection. 4 position rotating wheel with selectable filters (clockwise): (1) empty or (2) 0.1mm Cu or (3) 0.2mm Cu or (4) 0.3mm Cu.
- RO 305: Additional variable filtration - automatic selection. 4 position rotating wheel with selectable filters (clockwise): (1) empty or (2) 0.1mm Cu+1mm Al or (3) 0.2mm Cu+1mm Al or (4) 2mm Al.
- RO 305/1: Additional variable filtration - automatic selection. 4 position rotating wheel with selectable filters (clockwise): (1) empty or (2) 0.1mm Cu or (3) 0.2mm Cu or (4) 0.3mm Cu.
- RO 314: Camera assembled internally for patient monitoring: analogic interface.
- RO 495 Camera assembled internally for patient monitoring: IP Ethernet interface.
- RO 586 Single laser line to align collimator and detector center: Class 1.
- RO 587/1: Two lasers forming a single line at 1-meter SID: Class 1.
- RO 587/2 Two lasers forming a crosshair to center the patient to the detector: Class 1.

PART B:
Medical Electrical Sub-assembly, Motorized X-Ray beam limiting, Model/Type: **R 302 MLPI/A DHHS**, fixed, rated: 24Vac/dc, 50/60 Hz, 2A, with motor rating: 12Vdc or 24Vdc, 0.5A, Type B applied part (according to clause 4.6), with motorized shutter positioning controlled by potentiometer and adjusted by two knobs on the collimator front panel, high luminosity provided by a white LED simulating the X-ray field, the light field is controlled by an electronic timer,
Optionally provided with:
- RO 242/1: Single laser line to align collimator and detector center: Class 2.
- RO 242/2: Two lasers (one mounted externally) forming a crosshair to center the patient to the detector: Class 2.
- RO 258: Additional variable filtration - manual selection. 4 position rotating wheel with selectable filters (clockwise): (1) empty or (2) 0.1mm Cu+1mm Al or (3) 0.2mm Cu+1mm Al or (4) 2mm Al.
- RO 258/1: Additional variable filtration - manual selection. 4 position rotating wheel with selectable filters (clockwise): (1) empty or (2) 0.1mm Cu or (3) 0.2mm Cu or (4) 0.3mm Cu.
- RO 305: Additional variable filtration - automatic selection. 4 position rotating wheel with selectable filters (clockwise): (1) empty or (2) 0.1mm Cu+1mm Al or (3) 0.2mm Cu+1mm Al or (4) 2mm Al.
- RO 305/1: Additional variable filtration - automatic selection. 4 position rotating wheel with selectable filters (clockwise): (1) empty or (2) 0.1mm Cu or (3) 0.2mm Cu or (4) 0.3mm Cu.
- RO 314: Camera assembled internally for patient monitoring: analogic interface.
- RO 495 Camera assembled internally for patient monitoring: IP Ethernet interface.
- RO 586: Single laser line to align collimator and detector center: Class 1.
- RO 587/1: Two lasers forming a single line at 1-meter SID: Class 1.
- RO 587/2 Two lasers forming a crosshair to center the patient to the detector: Class 1.

PART C:
Medical Electrical Sub-assembly, Motorized X-Ray beam limiting, Model/Type: **R 302 MFMLP/A DHHS**, fixed, rated: 24Vac/dc, 50/60 Hz, 2A, with motor rating: 12Vdc or 24Vdc, 0.5A, Type B applied part (according to clause 4.6), with motorized shutter positioning controlled by potentiometer and adjusted by two knobs on the collimator front panel, High luminosity provided by a white LED simulating the X-ray field, the light field is controlled by an electronic timer,
Optionally provided with:

- RO 242/1: Single laser line to align collimator and detector center: Class 2.
- RO 242/2: Two lasers (one mounted externally) forming a crosshair to center the patient
- to the detector: Class 2.
- RO 305/1 Additional variable filtration - automatic selection. 4 position rotating wheel with selectable filters (clockwise): (1) empty or (2) 0.1mm Cu or (3) 0.2mm Cu or (4) 0.3mm Cu.
- RO 586 Single laser line to align collimator and detector center: Class 1.
- RO 587/2 Two lasers forming a crosshair to center the patient to the detector: Class 1.

For all parts indicated above followings apply:

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 (IPX0).
4. Method of Sterilization: None.
5. Suitability for use in an Oxygen Rich Environment: Medical device is not suitable 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 is 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 to 40°C, 10 to 75% RH, 700 to 1060hPa
   Storage/ shipping environmental conditions: -40 to +70°C, 10 to 95%rH (not condensing), 500 to 1060 hPa as specified by manufacturer and indicated in the instruction for use.

Conditions of Acceptability:

(1) Evaluated to CAN/CSA-C22.2 No. 60601-1:14 and ANSI/AAMI ES60601-1:2005/(R)2012, AND A1:2012, C1:2009 AND A2:2010(R)2012 (CONSOLIDATED TEXT), excluding (Not Evaluated) requirements for Electromagnetic compatibility (Clause 17) and Biocompatibility (Clause 11.7).
(2) SAFETY HAZARDS resulting from the intended physiological function of EQUIPMENT covered by this Standard are not considered.
(3) The X-ray beam limiting device is a sub-assembly intended to be installed to X-Ray equipment that must be in compliance with the applicable Standards. The beam limiting device is intended to be supplied with 24Vac/dc, 50/60 Hz, 2A &12 or 24Vdc, 0.5A (motors), from secondary winding of transformer complying to IEC 60601-1 as reported in accompanying documentation and protected by an external fuse.
(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) General standard 60601-1 was evaluated, only as far as applicable to the equipment object of the present report. A re-evaluation of the General standard considering the final installation conditions, is to be considered as part of the end-use X-Ray System.
(6) Applicable collateral (IEC 60601-1-3) and particular standards (IEC 60601-2-54) were partially evaluated, only as far as applicable to the equipment under test of the present report. A re-evaluation of the applicable standards is to be considered as part of the end-use mammography equipment.
(7) 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.
(8) 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.
(9) Mechanical strength of device installation to other equipment shall be ensured in final application (clause 9.8 of IEC 60601-1).
(10) Fuse for power supply protection of the 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.
(11) 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.

APPLICABLE REQUIREMENTS

CSA Standards (CLASS 8780 01):

CAN/CSA-C22.2 No. 60601-1:14 (R2018)	CAN/CSA-C22.2 No. 60601-1:14: Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance (Adopted IEC 60601-1:2005 edition 3.0 + AMENDEMENT 1, 2012-07, MOD)
CAN/CSA-C22.2 NO. 60601-1-6:11 (R2016)	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)
Amendment 1:2015 to CAN/CSA-C22.2 No. 60601-1-6:11 (R2016)	Amendment 1:2015 to 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, Amendment 1:2013)

Additionally considered standards (partially evaluated)

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)
Amendment 1:2015 to CAN/CSA-C22.2 No. 60601-1-3:09 (R2019)	Amendment 1: 2015 to 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, Amendment 1:2013)
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)
CAN/CSA-C22.2 No. 60601-2-54:11 + Update No. 1	Update No 1 - 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)
Amendment 1:2017 to CAN / CSA-C22.2 No. 60601-2-54:11	Amendment 1:2017 to 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 / Amendment 1:2015 + Modification1:2017)

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

ANSI/AAMI ES60601-1:2005/(R)2012, AND A1:2012, C1:2009 AND A2:2010(R)2012 (CONSOLIDATED TEXT)	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005+A1:2012, MOD)
IEC 60601-1-6:2010	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
IEC 60601-1-6:2010 + A1:2013	Amendment 1:2013 to IEC 60601-1-6:2013 Medical electrical equipment, Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability

Additionally considered standards (partially evaluated)

Certificate: 70199003
Project: 80077448

Master Contract: 209877
Date Issued: 2024-03-07

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 60601-1-3:2008 / A1:2013	Amendment 1:2013 to 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
IEC 60601-2-54:2009 / A1:2015	Amendment 1:2015 to 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

Notes:

Products certified under Class C878001, C878081 have been certified under CSA's ISO/IEC 17065 accreditation with the Standards Council of Canada (SCC). www.scc.ca

Supplement to Certificate of Compliance

Certificate: 70199003 **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
80077448	2024-03-07	Update cCSAus Certification 70199003 for Motorized X-Ray beam limiting device, Model R 302 MLP/A DHHS (Part A) and R 302 MLPI/A DHHS (Part B) to 1) add new model R 302 MFMLP/A DHHS 2) to cover update to Edition 3.1. 3) and cover changes to LOCC according to Standard 60601 based on CB acceptance.
70199003	2019-06-11	cCSAus certification of motorized X-ray beam limiting device, model: R 302 MLP/A DHHS, R 302 MLPI/A DHHS acccording to 60601-1 3.0 Edition, based on CB-Acceptance, (Ref_Test Report_No: DM15S0539936-02-M1)

Certificate of Compliance

Certificate: 70192614 **Master Contract:** 209877

Project: 80077454 **Date Issued:** 2023-03-17

Issued To: **RALCO s.r.l.**
Via Dei Tigli 13/G
Biassono, Monza e Brianza, 20853
Italy

Attention: Stefania Conti

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 - C878001 - MEDICAL ELECTRICAL EQUIPMENT/SYSTEMS
CLASS - C878081 - MEDICAL ELECTRICAL EQUIPMENT/SYSTEMS Certified to US Standards

Medical Electrical Sub-assembly, Automatic X-Ray beam limiting device,
Model/Type: R 225 ACS DHHS, fixed, rated: 24 V AC/DC, 50/60 Hz, 3.5A (with **RO 308**), 24 V AC/DC, 50/60 Hz, 3 A (without **RO 308**), Type B Applied Part, high luminosity provided by a LED.

Optionally provided with one linear laser to align the collimator with the image receptor (**RO 242/1**) and/or provided with or without second laser for cross projection (**RO 242/2**).

Optionally equipped with **RO 308:** external Interface PC board for Can Bus for transmission for analog signals to the PCB on the collimator.

Optionally equipped with **RO 587/1**: Two lasers forming a single line at 1-meter SID and /or **RO 587/2**: Two lasers forming a crosshair to center the patient to the detector.

Optional equipped with **RO 329**: internal proximity sensor.

Optionally equipped with **RO 305**: Additional Variable Filtration - Automatic Selection; filtration values: 0: no filtration, 0.1 mm Cu + 1 mm Al. (Al eq. 3.5 mm), 0.2 mm Cu + 1 mm Al (Al eq. 6.0 mm), 1 mm Al + 1 mm Al support (Al eq. 2.0 mm).
Optionally equipped with **RO 305/1**: Additional Variable Filtration; 0: no filtration, 0.1 mm Cu (Al eq. 2.5 mm), 0.2 mm Cu (Al eq. 5.0 mm), 0.3 mm Cu (Al eq. 7.5 mm).

Optionally equipped with **RO 310**: An Iris option for round field collimation.

Optionally equipped with **RO 544:** Touchscreen display 7", format 16:9 "Intelligence" multifunction – which allows to modify parameter directly by touch screen.

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 (IPX0).
4. Method of Sterilization: None.
5. Suitability for use in an Oxygen Rich Environment: Medical device not suitable 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:
   Operation: 10 to 40°C, 10 to 75% RH, 700 to 1060 hPa as specified by manufacturer and indicated in the instruction for use.
   Storage/ shipping: -40 to +70°C, 10 to 95%rH (not condensing), 500 to 1060 hPa.

Conditions of Acceptability:

(1) Evaluated to CAN/CSA-C22.2 No. 60601-1:14 and ANSI/AAMI ES60601-1:2005/(R)2012, AND A1:2012, C1:2009 AND A2:2010(R)2012 (CONSOLIDATED TEXT) excluding (Not Evaluated) requirements for Electromagnetic compatibility (Clause 17), Biocompatibility (Clause 11.7).

(2) SAFETY HAZARDS resulting from the intended physiological function of EQUIPMENT covered by this Standard are not considered.

(3) The equipment is a sub-assembly intended to be installed in / on X-ray system. The beam limiting device is intended to be supplied with 24 ac/dc from secondary winding of transformer complying with IEC 60601-1 as reported in accompanying documentation and protected by an external fuse.

(4) Applicable collateral and particular standards were partially evaluated, only as far as applicable to the equipment object of the present report. A re-evaluation of the applicable standards is to be considered as part of the end-use X-Ray system.

(5) General standard 60601-1 was evaluated, only as far as applicable to the equipment object of the present report. A re-evaluation of the General standard considering the final installation conditions, is to be considered as part of the end-use X-Ray system.

(6) Interconnection of X-ray beam limiting device with other medical devices, medical used systems or non-medical devices shall additionally be evaluated to the requirements of Clause 16 in the end use application.
(7) The installation of the units shall by performed by Submitter's trained personnel only, according to the installation instructions provided with each unit.
(8) PE connection of the X-ray beam limiting device must be ensured in final application, ground continuity measurement at the end product is required.
(9) Fuse for power supply protection of the x-ray beam limiting device must be provided in the end product (end installation) as specified in the instruction for use. This fuse shall be an approved type acceptable to the authorities where the equipment is sold.
(10) Mechanical strength of device installation to other equipment shall be ensured in final application (clause 9.8 of IEC 60601-1).
(11) 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.

APPLICABLE REQUIREMENTS

CSA Standards:

CAN/CSA-C22.2 No. 60601-1:14 (R2018)	CAN/CSA-C22.2 No. 60601-1:14: Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance (Adopted IEC 60601-1:2005 edition 3.0 + AMENDEMENT 1, 2012-07, MOD)
CAN/CSA-C22.2 NO. 60601-1-6:11 (R2016)	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)
Amendment 1:2015 to CAN/CSA-C22.2 No. 60601-1-6:11 (R2016)	Amendment 1:2015 to 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, Amendment 1:2013)

Additionally considered standards (partially evaluated)

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)
Amendment 1:2015 to CAN/CSA-C22.2 No. 60601-1-3:09 (R2019)	Amendment 1: 2015 to 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, Amendment 1:2013)
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)
CAN/CSA-C22.2 No. 60601-2-54:11 + Update No. 1	Update No 1 - 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)
CAN/CSA-C22.2 NO. 60601-2-54:11 + Update No. 1 + AMD1:2017	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+ Amendment 1:2015)

ANSI/AAMI/IEC Standards:

ANSI/AAMI ES60601-1:2005/(R)2012, AND A1:2012, C1:2009 AND A2:2010(R)2012 (CONSOLIDATED TEXT)	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005+A1:2012, MOD)
IEC 60601-1-6:2010	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
IEC 60601-1-6:2010 (Third Edition) + A1:2013	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability

Additionally considered standards (partially evaluated)

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

Certificate: 70192614
Project: 80077454

Master Contract: 209877
Date Issued: 2023-03-17

IEC 60601-1-3:2008 (Second Edition) + A1:2013	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
IEC 60601-2-54:2009+ AMD1:2015	Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy

Notes:

Products certified under Class C878001, C878081 have been certified under CSA's ISO/IEC 17065 accreditation with the Standards Council of Canada (SCC). www.scc.ca

Supplement to Certificate of Compliance

Certificate: 70192614 **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
80077454	2023-03-17	Update cCSAus Certification 70192614 for Automatic X-Ray beam limiting device, Model R 225 ACS DHHS to cover changes to LOCC according to Standard 60601 Edition 3.1 based on CB acceptance (IMQ IT-20802_M1).
70192614	2019-02-19	Initial cCSAus certification of an Automatic X-ray beam limiting device, model: R 225 ACS DHHS, incl. Touch Screen according to 60601-1 3.1 rd Edition, based on CB-Acceptance, (Ref_Test Report_No: DM17-0014500-01)

Certificate of Compliance

Certificate: 70199006 **Master Contract:** 209877

Project: 80077450 **Date Issued:** 2024-01-24

Issued To: **RALCO s.r.l.**
Via Dei Tigli 13/G
Biassono, Monza e Brianza, 20853
Italy

Attention: Stefania Conti

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 - C878001 - MEDICAL ELECTRICAL EQUIPMENT/SYSTEMS
CLASS - C878081 - MEDICAL ELECTRICAL EQUIPMENT/SYSTEMS Certified to US Standards

Medical Electrical Sub-assembly, Automatic X-Ray beam limiting device, intended for installation on mobile or stationary C-arm image system, Model/Type: R 605 DASM DHHS, R 806 Q DHHS, R 650 QDASM DHHS, fixed, rated: 24 Vdc, 3.5 A (without optional RO 308) or 24 Vdc, 4 A (with optional RO 308), High luminosity provided by a white LED simulating the X-ray field (available only for R 806 Q DHHS and R 650 QDASM DHHS), the light field is controlled by an electronic timer, Type B Applied Part, ,

Optional items (for all models):

- Optional equipped with **RO 308:** External analogic/digital interface in metal housing with 10 meter connecting cable.

Option items for R 605 DASM DHHS only:

- **RO 066:** Fixed aluminum filter: 0.5mm thickness.
- **RO 067:** Fixed aluminum filter: 1mm thickness.
- **RO 246:** Substitution of lead rectangular shutters with one cardiac copper shutter: 1mm thickness.
- **RO 263:** Additional pair of lead rectangular shutters: 3mm thickness (not available with RO 305 or RO 305/1).
- **RO 265:** Substitution of lead rectangular shutters with semitransparent copper shutters: 1mm thickness, open/close 360° rotation.
- **RO 305:** Additional variable filtration - automatic selection. 4 position rotating wheel with selectable filters (clockwise): (1) empty or (2) 0.1mm Cu+1mm Al or (3) 0.2mm Cu+1mm Al or (4) 2mm Al (not available with RO 263).
- **RO 305/1:** Additional variable filtration - automatic selection. 4 position rotating wheel with selectable filters (clockwise): (1) empty or (2) 0.1mm Cu or (3) 0.2mm Cu or (4) 0.3mm Cu (not available with RO 263).

Option items for R 650 QDASM DHHS only:

- **RO 067:** Fixed aluminum filter: 1mm thickness.
- **RO 246:** Substitution of lead rectangular shutters with one cardiac copper shutter: 1mm thickness.
- **RO 263:** Additional pair of lead rectangular shutters: 3mm thickness (not available with RO 305 or RO 305/1).
- **RO 265:** Substitution of lead rectangular shutters with semitransparent copper shutters: 1mm thickness, open/close 360° rotation.
- **RO 305:** Additional variable filtration - automatic selection. 4 position rotating wheel with selectable filters (clockwise): (1) empty or (2) 0.1mm Cu +1mm Al or (3) 0.2mm Cu + 1mm Al or (4) 2mm Al.
- **RO 305/1**: Additional variable filtration - automatic selection. 4 position rotating wheel with selectable filters (clockwise): (1) empty or (2) 0.1mm Cu or (3) 0.2mm Cu or (4) 0.3mm Cu.
- **RO 517**: Additional variable filtration - automatic selection. 4 position rotating wheel with selectable filters (clockwise): (1) empty (2) 0.1mm Cu+1mm Al or (3) 0.2mm Cu+1mm Al or (4) 0.4mm Cu+1mm Al.
- **RO 539**: Additional variable filtration - automatic selection. 4 position rotating wheel with selectable filters (clockwise): (1) empty or (2) 0.1mm Cu or (3) 0.25mm Cu or (4) 0.4mm Cu.
- **RO 571**: Additional variable filtration - automatic selection. 4 position rotating wheel with selectable filters (clockwise): (1) 1.5mm Al or (2) 0.1mm Cu or (3) 0.25mm Cu or (4) 0.3mm Cu.
- **RO 263**: Additional pair of lead rectangular shutters: 3mm thickness.
- **RO 265**: Substitution of lead rectangular shutters with semitransparent copper shutters: 1mm thickness.
- **RO 598**: Substitution of symmetric shutters with two lead asymmetric shutters: 3 mm thickness (not available with RO 263).
- **RO 310**: Round field collimation for image intensifier
- **RO 242/1**: Single laser line to align collimator and detector center: Class 2.
- **RO 242/2**: Two lasers (one mounted externally) forming a crosshair to center the patient to the detector Class 2.
- **RO 586**: Single laser line to align collimator and detector center: Class 1.
- **RO 587/2**: Two lasers (one mounted externally) forming a crosshair to center the patient to the detector: Class 1.

Option items for R 806 Q DHHS only:

- **RO 082:** Glass mirror with minimum internal inherent filtration: 1mm Al equivalent.
- **RO 242/1**: Single laser line to align collimator and detector center: Class 2.
- **RO 242/2**: Two lasers (one mounted externally) forming a crosshair to center the patient to the detector Class 2.
- **RO 305**: Additional variable filtration - automatic selection. 4 position rotating wheel with selectable filters (clockwise): (1) empty or (2) 0.1mm Cu+1mm Al or (3) 0.2mm Cu+1mm Al or (4) 2mm Al.
- **RO 305/1**: Additional variable filtration - automatic selection. 4 position rotating wheel with selectable filters (clockwise): (1) empty or (2) 0.1mm Cu or (3) 0.2mm Cu or (4) 0.3mm Cu.
- **RO 586**: Single laser line to align collimator and detector center: Class 1.
- **RO 587/2**: Two lasers (one mounted externally) forming a crosshair to center the patient to the detector: Class 1.

1. Medical device protection against electric shock: Class I.
2. Applied Part protection against electric shock: Applied part Type B (external metallic enclosure according to clause 4.6).
3. Degree of protection against ingress of water or particulate matter: No degree of protection (IPX0).
4. Method of Sterilization: None.
5. Suitability for use in an Oxygen Rich Environment: Medical device is not suitable 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 is 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:
   Operation: 10 to 40°C, 10 to 75% RH, 700 to 1060 hPa,
   Storage/ shipping: -40 to +70°C, 10 to 95%rH (not condensing), 500 - 1060 hPa as specified by manufacturer and indicated in the instruction for use.

Conditions of Acceptability:

(1) Evaluated to CAN/CSA-C22.2 No. 60601-1:14 and ANSI/AAMI ES60601-1:2005/(R)2012, AND A1:2012, C1:2009 AND A2:2010(R)2012 (CONSOLIDATED TEXT) excluding (Not Evaluated) requirements for Electromagnetic compatibility (Clause 17), Biocompatibility (Clause 11.7).
(2) SAFETY HAZARDS resulting from the intended physiological function of EQUIPMENT covered by this Standard are not considered.
(3) The X-ray beam limiting device is a sub-assembly intended to be installed on stationary or mobile C-arm image system. The beam limiting device is intended to be supplied with secondary winding transformer complying with IEC 60601-1 as reported in accompanying documentation and protected by an external fuse.
(4) Applicable collateral (IEC 60601-1-3:2008+A1:2013) and particular standard (IEC 60601-2-54:2009, AMD1:2015) were partially evaluated, only as far as applicable to the equipment under test of the present report. A re-evaluation of the applicable standards is to be considered as part of the end-use system.

(5) General standard 60601-1 was evaluated, only as far as applicable to the equipment object of the present report. A re-evaluation of the general standard considering the final installation conditions, is to be considered as part of the end-use system.
(6) 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.
(7) The installation of the units shall by performed by Submitter's trained personnel only, according to the installation instructions provided with each unit.
(8) PE connection of the X-ray beam limiting device must be ensured in final application, ground continuity measurement at the end product is required.
(9) Fuse for power supply protection of the x-ray beam limiting device must be provided in the end product (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.
(10) Mechanical strength of device installation to other equipment shall be ensured in final application (clause 9.8 of IEC 60601-1).
(11) 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.

APPLICABLE REQUIREMENTS

CSA Standards (CLASS 8780 01):

CAN/CSA-C22.2 No. 60601-1:14 (R2018)	CAN/CSA-C22.2 No. 60601-1:14: Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance (Adopted IEC 60601-1:2005 edition 3.0 + AMENDEMENT 1, 2012-07, MOD)
CAN/CSA-C22.2 NO. 60601-1-6:11 (R2016)	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)
Amendment 1:2015 to CAN/CSA-C22.2 No. 60601-1-6:11 (R2016)	Amendment 1:2015 to 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, Amendment 1:2013)

Additionally considered standards (partially evaluated)

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)
Amendment 1:2015 to CAN/CSA-C22.2 No. 60601-1-3:09 (R2019)	Amendment 1: 2015 to 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, Amendment 1:2013)
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)

CAN/CSA-C22.2 No. 60601-2-54:11 + Update No. 1	Update No 1 - 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)
Amendment 1:2017 to CAN / CSA-C22.2 No. 60601-2-54:11	Amendment 1:2017 to 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 / Amendment 1:2015 + Modification1:2017)

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

ANSI/AAMI ES60601-1:2005/(R)2012, AND A1:2012, C1:2009 AND A2:2010(R)2012 (CONSOLIDATED TEXT)	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005+A1:2012, MOD)
IEC 60601-1-6:2010	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
IEC 60601-1-6:2010 / A1:2013	Amendment 1:2013 to IEC 60601-1-6:2013 Medical electrical equipment, Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability

Additionally considered standards (partially evaluated)

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 60601-1-3:2008 / A1:2013	Amendment 1:2013 to 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
IEC 60601-2-54:2009 / A1:2015	Amendment 1:2015 to 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

Notes:

Products certified under Class C878001, C878081 have been certified under CSA's ISO/IEC 17065 accreditation with the Standards Council of Canada (SCC). www.scc.ca

Supplement to Certificate of Compliance

Certificate: 70199006 **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
80077450	2024-01-24	Update cCSAus Certification 70199006 for Automatic X-Ray beam limiting device, Model R 605 DASM DHHS to 1) add models from Certificate 70199007, R 806 Q DHHS 2) to add new model R 650 QDASM DHHS 3) to cover update to Edition 3.1. and 4) cover changes to LOCC according to Standard 60601 based on CB acceptance.
70199006	2019-06-11	cCSAus certification of a X-ray beam limiting device, model: R 605 DASM DHHS, according to 60601-1 3.0 Edition, based on CB-Acceptance, (Ref_Test Report_No: DM15S0539936-04-M1)

Certificate of Compliance

Certificate: 70199009 **Master Contract:** 209877

Project: 80077451 **Date Issued:** 2024-03-07

Issued To: **RALCO s.r.l.**
Via Dei Tigli 13/G
Biassono, Monza e Brianza, 20853
Italy

Attention: Stefania Conti

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

C US US

PRODUCTS

CLASS - C878001 - MEDICAL ELECTRICAL EQUIPMENT/SYSTEMS MEDICAL ELECTRICAL EQUIPMENT/SYSTEMS
CLASS - C878081 - MEDICAL ELECTRICAL EQUIPMENT/SYSTEMS Certified to US Standards

PART A:

Medical Electrical Sub-assembly, Manual X-Ray beam limiting device, Model/Type: **R 72 S DHHS**, fixed, rated: 24Vac/dc, 50/60 Hz, 2A, Type B Applied Part (according to clause 4.6), high luminosity provided by a white LED with electronic timer.
Optionally provided with:

- RO 242/1: Single laser line to align collimator and detector center: Class 2.
- RO 242/2: Two lasers (one mounted externally) forming a crosshair to center the patient to the detector: Class 2.
- RO 258: Additional variable filtration - manual selection. 4 position rotating wheel with selectable filters (clockwise): (1) empty or (2) 0.1mm Cu+1mm Al or (3) 0.2mm Cu+1mm Al or (4) 2mm Al.
- RO 258/1: Additional variable filtration - manual selection. 4 position rotating wheel with selectable filters (clockwise): (1) empty or (2) 0.1mm Cu or (3) 0.2mm Cu or (4) 0.3mm Cu.

- RO 586: Single laser line to align collimator and detector center: Class 1.
- RO 587/2: Two lasers (one mounted externally) forming a crosshair to center the patient to the detector: Class 1.

PART B:
Medical Electrical Sub-assembly, Manual X-Ray beam limiting device, Model/Type: **R 108 DHHS**, fixed, rated: 24Vac/dc, 50/60 Hz, 2A, Type B Applied Part (according to clause 4.6), high luminosity provided by a white LED with electronic timer.
Optionally provided with:

- RO 242/1: Single laser line to align collimator and detector center: Class 2.
- RO 258: Additional variable filtration - manual selection. 4 position rotating wheel with selectable filters (clockwise): (1) empty or (2) 0.1mm Cu+1mm Al or (3) 0.2mm Cu+1mm Al or (4) 2mm Al.
- RO 258/1: Additional variable filtration - manual selection. 4 position rotating wheel with selectable filters (clockwise): (1) empty or (2) 0.1mm Cu or (3) 0.2mm Cu or (4) 0.3mm Cu.
- RO 339: Two lasers forming a single line at 1-meter SID: Class 2.
- RO 382: LED on front panel indicating filter presence (only available with RO 258).
- RO 395: Single laser forming a crosshair to center the patient to the detector at a fixed 1-meter SID: Class 2.
- RO 586: Single laser line to align collimator and detector center: Class 1.
- RO 587/1: Two lasers forming a single line at 1-meter SID: Class 1.

PART C:
Medical Electrical Sub-assembly, Manual X-Ray beam limiting device, Model/Type: **R 108 F DHHS**, fixed, rated: 24Vac/dc, 50/60 Hz, 2A, Type B Applied Part (according to clause 4.6), high luminosity provided by a white LED with electronic timer.
Optionally provided with:

- RO 242/1: Single laser line to align collimator and detector center: Class 2.
- RO 258: Additional variable filtration - manual selection. 4 position rotating wheel with selectable filters (clockwise): (1) empty or (2) 0.1mm Cu+1mm Al or (3) 0.2mm Cu+1mm Al or (4) 2mm Al.
- RO 258/1: Additional variable filtration - manual selection. 4 position rotating wheel with selectable filters (clockwise): (1) empty or (2) 0.1mm Cu or (3) 0.2mm Cu or (4) 0.3mm Cu.
- RO 395: Single laser forming a crosshair to center the patient to the detector at a fixed 1-meter SID: Class 2.
- RO 586: Single laser line to align collimator and detector center: Class 1.

PART D:
Medical Electrical Sub-assembly, Manual X-Ray beam limiting device, Model/Type: **R 221/A DHHS**, fixed, rated: 24Vac/dc, 50/60 Hz, 2A, Type B Applied Part (according to clause 4.6), high luminosity provided by a white LED with electronic timer,
Optionally provided with:

- RO 242/1: Single laser line to align collimator and detector center: Class 2.
- RO 242/2: Two lasers (one mounted externally) forming a crosshair to center the patient to the detector: Class 2.
- RO 258: Additional variable filtration - manual selection. 4 position rotating wheel with selectable filters (clockwise): (1) empty or (2) 0.1mm Cu+1mm Al or (3) 0.2mm Cu+1mm Al or (4) 2mm Al.

- RO 258/1: Additional variable filtration - manual selection. 4 position rotating wheel with selectable filters (clockwise): (1) empty or (2) 0.1mm Cu or (3) 0.2mm Cu or (4) 0.3mm Cu.
- RO 314: Camera assembled internally for patient monitoring: analogic interface.
- RO 339: Two lasers forming a single line at 1-meter SID: Class 2.
- RO 382: LED on front panel indicating filter presence (only available with RO 258).
- RO 495 Camera assembled internally for patient monitoring: IP Ethernet interface.
- RO 586: Single laser line to align collimator and detector center: Class 1.
- RO 587/1: Two lasers forming a single line at 1-meter SID: Class 1.
- RO 587/2: Two lasers (one mounted externally) forming a crosshair to center the patient to the detector: Class 1.
- RO 588: Additional variable filtration - manual selection. 4 position rotating wheel with selectable filters: (1) empty or (2) 1mm Al or (3) 1mm Al+0.1mm Cu or (4) 1mm Al+0.2mm Cu.

PART E:
Medical Electrical Sub-assembly, Manual X-Ray beam limiting device, Model/Type: **R 302/A DHHS**, fixed, rated: 24Vac/dc, 50/60 Hz, 2A, Type B Applied Part (according to clause 4.6), high luminosity provided by a white LED with electronic timer,
Optionally provided with:

- RO 242/1: Single laser line to align collimator and detector center: Class 2.
- RO 242/2: Two lasers (one mounted externally) forming a crosshair to center the patient to the detector: Class 2.
- RO 258: Additional variable filtration - manual selection. 4 position rotating wheel with selectable filters (clockwise): (1) empty or (2) 0.1mm Cu+1mm Al or (3) 0.2mm Cu+1mm Al or (4) 2mm Al.
- RO 258/1: Additional variable filtration - manual selection. 4 position rotating wheel with selectable filters (clockwise): (1) empty or (2) 0.1mm Cu or (3) 0.2mm Cu or (4) 0.3mm Cu.
- RO 339: Two lasers forming a single line at 1-meter SID: Class 2.
- RO 586: Single laser line to align collimator and detector center: Class 1.
- RO 587/1: Two lasers forming a single line at 1-meter SID: Class 1.
- RO 587/2: Two lasers (one mounted externally) forming a crosshair to center the patient to the detector: Class 1.

PART F:
Medical Electrical Sub-assembly, Manual X-Ray beam limiting device, Model/Type: **P 313/A DHHS**, fixed, rated: 24Vac/dc, 50/60 Hz, 2A, Type B Applied Part (according to clause 4.6), high luminosity provided by a white LED with electronic timer,
Optionally provided with:

- RO 242/1: Single laser line to align collimator and detector center: Class 2.
- Variable filtration - manual selection. 1 mm Al support + 0.1 mm Cu, 1 mm Al support + 0.2 Cu, 2 mm Al support.

PART G:
Medical Electrical Sub-assembly, Manual X-Ray beam limiting device, Model/Type: **R 225 DHHS**, fixed, rated: 24Vac/dc, 50/60 Hz, 2A, Type B Applied Part (according to clause 4.6), high luminosity provided by a LED with electronic timer,

Optionally provided with:

- RO 242/1: Single laser line to align collimator and detector center: Class 2.
- RO 242/2: Two lasers (one mounted externally) forming a crosshair to center the patient to the detector: Class 2.
- RO 258: Additional variable filtration - manual selection. 4 position rotating wheel with selectable filters (clockwise): (1) empty or (2) 0.1mm Cu+1mm Al or (3) 0.2mm Cu+1mm Al or (4) 2mm Al.
- RO 258/1: Additional variable filtration - manual selection. 4 position rotating wheel with selectable filters (clockwise): (1) empty or (2) 0.1mm Cu or (3) 0.2mm Cu or (4) 0.3mm Cu.
- RO 495 Camera assembled internally for patient monitoring: IP Ethernet interface.
- RO 586: Single laser line to align collimator and detector center: Class 1.
- RO 587/2: Two lasers (one mounted externally) forming a crosshair to center the patient to the detector: Class 1.

For all parts indicated above followings apply:

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 (IPX0).
4. Method of Sterilization: None.
5. Suitability for use in an Oxygen Rich Environment: Medical device is not suitable 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 is 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 to 40°C, 10 to 75% RH, 700 to 1060hPa
   Storage/ shipping environmental conditions: -40 to +70°C, 10 to 95%rH (not condensing), 500 to 1060 hPa, as specified by manufacturer and indicated in the instruction for use.

Conditions of Acceptability:

(1) Evaluated to CAN/CSA-C22.2 No. 60601-1:14 and ANSI/AAMI ES60601-1:2005/(R)2012, AND A1:2012, C1:2009 AND A2:2010(R)2012 (CONSOLIDATED TEXT) excluding (Not Evaluated) requirements for Electromagnetic compatibility (Clause 17) and Biocompatibility (Clause 11.7).
(2) SAFETY HAZARDS resulting from the intended physiological function of EQUIPMENT covered by this Standard are not considered.
(3) The X-ray beam limiting device is a sub-assembly intended to be installed to X-Ray equipment that must be in compliance with the applicable Standards. The beam limiting device is intended to be supplied with 24Vac/dc, 50/60 Hz, 2A from secondary winding of transformer complying to IEC 60601-1 as reported in accompanying documentation and protected by an external fuse.
(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) General standard 60601-1 was evaluated, only as far as applicable to the equipment object of the present report. A re-evaluation of the General standard considering the final installation conditions, is to be considered as part of the end-use X-Ray system.
(6) Applicable collateral (IEC 60601-1-3) and particular standards (IEC 60601-2-54) were partially evaluated, only as far as applicable to the equipment under test of the present report. A re-evaluation of the applicable standards is to be considered as part of the end-use mammography equipment.
(7) 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.
(8) PE connection of the X-ray beam limiting device has to be ensured in final application, ground continuity measurement at the end product is required.
(9) Mechanical strength of device installation to other equipment shall be ensured in final application (clause 9.8 of IEC 60601-1).
(10) Fuse for power supply protection of the x-ray beam limiting device has to be provided in the end product (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.
(11) 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.

APPLICABLE REQUIREMENTS

CSA Standards (CLASS 8780 01):

CAN/CSA-C22.2 No. 60601-1:14 (R2018)	CAN/CSA-C22.2 No. 60601-1:14: Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance (Adopted IEC 60601-1:2005 edition 3.0 + AMENDEMENT 1, 2012-07, MOD)
CAN/CSA-C22.2 NO. 60601-1-6:11 (R2016)	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)
Amendment 1:2015 to CAN/CSA-C22.2 No. 60601-1-6:11 (R2016)	Amendment 1:2015 to 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, Amendment 1:2013)

Additionally considered standards (partially evaluated as described in summary of testing section)

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)
Amendment 1:2015 to CAN/CSA-C22.2 No. 60601-1-3:09 (R2019)	Amendment 1: 2015 to 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, Amendment 1:2013)
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)
CAN/CSA-C22.2 No. 60601-2-54:11 + Update No. 1	Update No 1 - 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)
Amendment 1:2017 to CAN / CSA-C22.2 No. 60601-2-54:11	Amendment 1:2017 to 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 / Amendment 1:2015 + Modification1:2017)

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

ANSI/AAMI ES60601-1:2005/(R)2012, AND A1:2012, C1:2009 AND A2:2010(R)2012 (CONSOLIDATED TEXT)	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005+A1:2012, MOD)
IEC 60601-1-6:2010	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
IEC 60601-1-6:2010 / A1:2013	Amendment 1:2013 to IEC 60601-1-6:2013 Medical electrical equipment, Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability

Additionally considered standards (partially evaluated as described in summary of testing section)

Certificate: 70199009
Project: 80077451

Master Contract: 209877
Date Issued: 2024-03-07

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 60601-1-3:2008 / A1:2013	Amendment 1:2013 to 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
IEC 60601-2-54:2009 / A1:2015	Amendment 1:2015 to 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

Notes:

Products certified under Class C878001, C878081 have been certified under CSA's ISO/IEC 17065 accreditation with the Standards Council of Canada (SCC). www.scc.ca

Supplement to Certificate of Compliance

Certificate: 70199009 **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
80077451	2024-03-07	Update cCSAus Certification 70199009/revision 80041859 for Manual X-Ray beam limiting device, Models R 72 S DHHS (Part A), R 108 F DHHS (Part B), R 221/A DHHS (Part C), R 108 DHHS (Part D), R 302/A DHHS (Part E), R 302/144/A DHHS (Part F), R 302 L/A DHHS (Part G), P 313/A DHHS (Part H) and R 225 DHHS (Part I) to cover update to Edition 3.1. and changes to LOCC according to Standard 60601 based on CB acceptance.
80041859	2020-05-11	Update cCSAus Certification 70199009 for Manual X-Ray beam limiting device, to update LOCC for the enclosure of the collimator model P 313/A DHHS according to 60601 Third Edition
70199009	2019-05-21	cCSAus certification of a Manual X-ray beam limiting device, model: R 108 F DHHS, R 108 DHHS, R 72 S DHHS , R 221/A DHHS, R 225 DHHS, R 302/A DHHS, R 302/144/A DHHS, R 302 L/A DHHS, P 313/A DHHS according to 60601-1 3.0 Edition, based on CB-Acceptance, (Ref_Test Report_No: DM15S0539936-01-M1 and DM15S0539936-02-M1)

Certificate of Compliance

Certificate: 70042533 **Master Contract:** 209877

Project: 80077449 **Date Issued:** 2024-03-07

Issued To: **RALCO s.r.l.**
Via Dei Tigli 13/G
Biassono, Monza e Brianza, 20853
Italy

Attention: Stefania Conti

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

C US

US

PRODUCTS

CLASS - C878001 - MEDICAL ELECTRICAL EQUIPMENT/SYSTEMS MEDICAL ELECTRICAL EQUIPMENT/SYSTEMS
CLASS - C878081 - MEDICAL ELECTRICAL EQUIPMENT/SYSTEMS Certified to US Standards

Medical Electrical Sub-assembly, Automatic X-Ray beam limiting device, Model/Type: **R 302 DMLP DHHS**, fixed, rated: 24Vac/dc, 50/60 Hz, 2A, Type B Applied Part (according to clause 4.6), with motorized shutter positioning controlled by potentiometer and adjusted remotely or by two knobs on the collimator front panel, high luminosity provided by white LED with electronic timer,
Optionally provided with:

- RO 242/1: Single laser line to align collimator and detector center: Class 2.
- RO 242/2: Two lasers (one mounted externally) forming a crosshair to center the patient to the detector: Class 2.
- RO 258: Additional variable filtration - manual selection. 4 position rotating wheel with selectable filters (clockwise): (1) empty or (2) 0.1mm Cu+1mm Al or (3) 0.2mm Cu+1mm Al or (4) 2mm Al.
- RO 258/1: Additional variable filtration - manual selection. 4 position rotating wheel with selectable filters (clockwise): (1) empty or (2) 0.1mm Cu or (3) 0.2mm Cu or (4) 0.3mm Cu.

- RO 305 Additional variable filtration - automatic selection. 4 position rotating wheel with selectable filters (clockwise): (1) empty or (2) 0.1mm Cu+1mm Al or (3) 0.2mm Cu+1mm Al or (4) 2mm Al.
- RO 305/1 Additional variable filtration - automatic selection. 4 position rotating wheel with selectable filters (clockwise): (1) empty or (2) 0.1mm Cu or (3) 0.2mm Cu or (4) 0.3mm Cu.
- RO 382: LED on front panel (available only for collimators assembled with RO 258).
- RO 495 Camera assembled internally for patient monitoring: IP Ethernet interface.
- RO 514: Additional variable filtration - automatic selection. 4 position rotating wheel with selectable filters, (clockwise): (1) empty or (2) 0.1mm Cu+1mm Al or (3) 0.2mm Cu+1mm Al or (4) 1.5mm Cu.
- RO 586: Single laser line to align collimator and detector center: Class 1.
- RO 587/2: Two lasers (one mounted externally) forming a crosshair to center the patient to the detector: Class 1.

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 (IPX0).
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 to 40°C, 10 to 75% RH, 700 to 1060hPa
   Storage/ shipping environmental conditions: -40 to +70°C, 10 to 95%rH (not condensing), 500 to 1060 hPa, as specified by manufacturer and indicated in the instruction for use.

Conditions of Acceptability:

(1) Evaluated to CAN/CSA-C22.2 No. 60601-1:14 and ANSI/AAMI ES60601-1:2005/(R)2012, AND A1:2012, C1:2009 AND A2:2010(R)2012 (CONSOLIDATED TEXT) excluding (Not Evaluated) requirements for Electromagnetic compatibility (Clause 17) and Biocompatibility (Clause 11.7).
(2) SAFETY HAZARDS resulting from the intended physiological function of EQUIPMENT covered by this Standard are not considered.
(3) The X-ray beam limiting device is a sub-assembly intended to be installed to X-Ray equipment that must be in compliance with the applicable Standards. The beam limiting device is intended to be supplied with 24Vac/dc, 50/60 Hz, 2A from secondary winding of transformer complying to IEC 60601-1 as reported in accompanying documentation and protected by an external fuse.
(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) General standard 60601-1 was evaluated, only as far as applicable to the equipment object of the present report. A re-evaluation of the General standard considering the final installation conditions, is to be considered as part of the end-use X-Ray system.

(6) Applicable collateral (IEC 60601-1-3) and particular standards (IEC 60601-2-54) were partially evaluated, only as far as applicable to the equipment under test of the present report. A re-evaluation of the applicable standards is to be considered as part of the end-use mammography equipment.
(7) 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.
(8) 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.
(9) Mechanical strength of device installation to other equipment shall be ensured in final application (clause 9.8 of IEC 60601-1).
(10) Fuse for power supply protection of the 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.
(11) 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.

APPLICABLE REQUIREMENTS

CSA Standards (CLASS 8780 01):

CAN/CSA-C22.2 No. 60601-1:14 (R2018)	CAN/CSA-C22.2 No. 60601-1:14: Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance (Adopted IEC 60601-1:2005 edition 3.0 + AMENDEMENT 1, 2012-07, MOD)
CAN/CSA-C22.2 NO. 60601-1-6:11 (R2016)	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)
Amendment 1:2015 to CAN/CSA-C22.2 No. 60601-1-6:11 (R2016)	Amendment 1:2015 to 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, Amendment 1:2013)

Additionally considered standards (partially evaluated as described in summary of testing section)

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)

Amendment 1:2015 to CAN/CSA-C22.2 No. 60601-1-3:09 (R2019)	Amendment 1: 2015 to 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, Amendment 1:2013)
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)
CAN/CSA-C22.2 No. 60601-2-54:11 + Update No. 1	Update No 1 - 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)
Amendment 1:2017 to CAN / CSA-C22.2 No. 60601-2-54:11	Amendment 1:2017 to 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 / Amendment 1:2015 + Modification1:2017)

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

ANSI/AAMI ES60601-1:2005/(R)2012, AND A1:2012, C1:2009 AND A2:2010(R)2012 (CONSOLIDATED TEXT)	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005+A1:2012, MOD)
IEC 60601-1-6:2010	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
IEC 60601-1-6:2010 + A1:2013	Amendment 1:2013 to IEC 60601-1-6:2013 Medical electrical equipment, Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability

Additionally considered standards (partially evaluated as described in summary of testing section)

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 60601-1-3:2008 / A1:2013	Amendment 1:2013 to 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

Certificate: 70042533
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Date Issued: 2024-03-07

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
IEC 60601-2-54:2009 / A1:2015	Amendment 1:2015 to 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

Notes:

Products certified under Class C878001, C878081 have been certified under CSA's ISO/IEC 17065 accreditation with the Standards Council of Canada (SCC). www.scc.ca

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
80077449	2024-03-07	Update cCSAus Certification 70042533 for Automatic X-Ray beam limiting device, Model R 302 DMLP DHHS to cover update to Edition 3.1. and changes to LOCC according to Standard 60601 based on CB acceptance.
70042533	2016-04-29	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: 70046215 **Master Contract:** 209877

Project: 80077455 **Date Issued:** 2023-03-17

Issued To: **RALCO s.r.l.**
Via Dei Tigli 13/G
Biassono, Monza e Brianza, 20853
Italy

Attention: Stefania Conti

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

C US

US

PRODUCTS

CLASS - C878001 - MEDICAL ELECTRICAL EQUIPMENT/SYSTEMS
CLASS - C878081 - MEDICAL ELECTRICAL EQUIPMENT/SYSTEMS Certified to US Standards

Medical Electrical Sub-assembly, Automatic X-Ray beam limiting device,
Model/Type: R 221 ACS DHHS, fixed, rated: 24 V AC/DC, 50/60 Hz, 3.5A, Type B Applied part, high luminosity provided by LED.
Optionally provided with or without one linear laser to align the collimator with the image receptor (**RO 242/1**), provided with or without second laser for cross projection (**RO 242/2**).
Optional equipped with **RO 308:** external Interface PC board for Can Bus for transmission for analog signals to the PCB on the collimator.
Optional equipped with **RO 587/1**: Two lasers forming a single line at 1-meter SID and / or **RO 587/2**: Two lasers forming a crosshair to center the patient to the detector.
Optionally equipped with **RO 305**: Additional Variable Filtration - Automatic Selection; filtration values: 0: no filtration, 0.1 mm Cu + 1 mm Al. (Al eq. 3.5 mm), 0.2 mm Cu + 1 mm Al (Al eq. 6.0 mm), 1 mm Al + 1 mm Al support (Al eq. 2.0 mm).

Optionally equipped with **RO 305/1**: Additional Variable Filtration; 0: no filtration, 0.1 mm Cu (Al eq. 2.5 mm), 0.2 mm Cu (Al eq. 5.0 mm), 0.3 mm Cu (Al eq. 7.5 mm).
Optionally equipped with **RO 329**: Internal proximity sensor.
Optional equipped with **RO 544:** Touchscreen display 7", format 16:9 "Intelligence" multifunction – which allows to modify parameter directly by touch screen.

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 (IPX0).
4. Method of Sterilization: None.
5. Suitability for use in an Oxygen Rich Environment: Medical device not suitable 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:
   Operation: Normal: 10 to 40 °C, 10 to 75 % RH, 700 to 1060 hPa as specified by manufacturer and indicated in the instruction for use.
   Storage/ shipping environmental conditions: -40 to +70 °C, 10 to 95 %rH (not condensing), 500 to 1060 hPa.

Conditions of Acceptability:

(1) Evaluated to CAN/CSA-C22.2 No. 60601-1:14 and ANSI/AAMI ES60601-1:2005/(R)2012, AND A1:2012, C1:2009 AND A2:2010(R)2012 (CONSOLIDATEDTEXT) excluding (Not Evaluated) requirements for Electromagnetic compatibility (Clause 17), Biocompatibility (Clause 11.7).

(2) SAFETY HAZARDS resulting from the intended physiological function of EQUIPMENT covered by this Standard are not considered.

(3) The equipment is a sub-assembly intended to be installed in / on X-ray system. The beam limiting device is intended to be supplied with 24 ac/dc from secondary winding of transformer complying with IEC 60601-1 as reported in accompanying documentation and protected by an external fuse.

(4) Applicable collateral and particular standard were partially evaluated, only as far as applicable to the equipment object of the present report. A re-evaluation of the applicable standards is to be considered as part of the end-use X-Ray system.

(5) General standard 60601-1 was evaluated, only as far as applicable to the equipment object of the present report. A re-evaluation of the General standard considering the final installation conditions, is to be considered as part of the end-use X-Ray system.

(6) Interconnection of X-ray beam limiting device with other medical devices, medical used systems or non-medical devices shall be additionally evaluated to the requirements of Clause 16 in the end use application.

(7) The installation of the units shall by performed by Submitter's trained personnel only, according to the installation instructions provided with each unit.

(8) PE connection of the X-ray beam limiting device shall be ensured in final application, ground continuity measurement at the end product is required.

(9) Fuse for power supply protection of the x-ray beam limiting device shall be provided in the end product (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.

(10) Mechanical strength of device installation to other equipment shall be ensured in final application (clause 9.8 of IEC 60601-1).

(11) 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.

APPLICABLE REQUIREMENTS

CSA Standards:

CAN/CSA-C22.2 No. 60601-1:14 (R2018)	CAN/CSA-C22.2 No. 60601-1:14: Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance (Adopted IEC 60601-1:2005 edition 3.0 + AMENDEMENT 1, 2012-07, MOD)
CAN/CSA-C22.2 NO. 60601-1-6:11 (R2016)	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)
Amendment 1:2015 to CAN/CSA-C22.2 No. 60601-1-6:11 (R2016)	Amendment 1:2015 to 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, Amendment 1:2013)

Additionally considered standards (partially evaluated)

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)
Amendment 1:2015 to CAN/CSA-C22.2 No. 60601-1-3:09 (R2019)	Amendment 1: 2015 to 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, Amendment 1:2013)

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)
CAN/CSA-C22.2 No. 60601-2-54:11 + Update No. 1	Update No 1 - 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)
Amendment 1:2017 to CAN/CSA-C22.2 No. 60601-2-54:11	Amendment 2:2019 to 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 + Amendment 2:2018)

ANSI/AAMI/IEC Standards:

ANSI/AAMI ES60601-1:2005/(R)2012, AND A1:2012, C1:2009 AND A2:2010(R)2012 (CONSOLIDATED TEXT)	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005+A1:2012, MOD)
IEC 60601-1-6:2010 (Third Edition) + A1:2013	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability

Additionally considered standards (partially evaluated)

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 60601-1-3:2008 (Second Edition) + A1:2013	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
IEC 60601-2-54:2009, AMD1:2015	Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy

Certificate: 70046215
Project: 80077455

Master Contract: 209877
Date Issued: 2023-03-17

Notes:

Products certified under Class C878001, C878081 have been certified under CSA's ISO/IEC 17065 accreditation with the Standards Council of Canada (SCC). www.scc.ca

Supplement to Certificate of Compliance

Certificate: 70046215 **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
80077455	2023-03-17	Update cCSAus Certification 70046215/revision 70192615 for Automatic X-Ray beam limiting device, Model R 221 ACS DHHS to cover changes to LOCC according to Standard 60601 Edition 3.1. based on CB acceptance (IMQ IT-20803_M1).
70192615	2019-02-19	Update cCSAus certification 70046215 of an Automatic X-ray beam limiting device, model: R 221 ACS DHHS, incl. Touch Screen according to 60601-1 3.1 rd Edition, based on CB-Acceptance, (Ref_Test Report_No: DM17-0014500-01)
70046215	2015-12-04	Original cCSAus Certification of an Automatic X-Ray beam limiting device, Model/Type: R 221 ACS DHHS, fixed, rated: 24Vdc, 2A, Type B Applied Part, CAN/CSA-C22.2 No. 60601-1:08 and ANSI/AAMI ES60601-1:2005 (IEC60601-1:2005, MOD)