Certificate of Compliance

Certificate:	70092922	**Master Contract:**	266310
Project:	80271017	**Date Issued:**	2026-02-02
Issued to:	**Akrus GmbH & Co. KG** **Otto-Hahn-Strasse 3** **Elmshorn, Schleswig-Holstein** **25337** **Germany** **Attention:** Roman Gartz	**Issued by:**	*Moamin Alabdullah* Moamin Alabdullah

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.

PRODUCTS

Class 8780 01 MEDICAL ELECTRICAL EQUIPMENT/SYSTEMS - Medical Equipment/Medical System
Class 8780 81 MEDICAL ELECTRICAL EQUIPMENT/SYSTEMS - Certified to US Standards

Medical Electrical Equipment, Mobile Mammography Chair, cord-connected: Internally powered (Battery operated), mobile, Battery (BAJ1): 24 VDC / 2.9 Ah Charger (CHJ2): 100 - 240 V ~, 50/60 Hz, max. 400 mA.

Model(s)	Voltage (VDC)
REF: 277000XXX, ak 5010 MBS	24

XXX: can be range between 000 – 999; designates customer specific information which does not affect safety and performance of the medical electrical equipment.

1. Medical device protection against electric shock: Internally powered
2. Applied Part protection against electric shock: Type B
3. Degree of protection against ingress of water or particulate matter: IPX5 for charger and battery
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: Non-continuous S3 – 10% (1'/ 9').
8. Environmental Conditions: Normal: 10 – 40 °C, **30%** –**75%** RH, 700 - 1060 hPa

APPLICABLE REQUIREMENTS

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

Amendment 2:2022 to CAN/CSA-C22.2 No. 60601-1:14 - Amendment 2:2022 to 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 2:2020)

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)

Amendment 2:2021 to CSA-C22.2 No. 60601-1-6:11 - Amendment 2:2021 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 2:2020)

ANSI/AAMI ES60601-1:2005 / (R)2012, AND A1:2012, C1:2009(R2012) and A2:2010(R)2012 (Consolidated Text) - Amendment 1:2012 to ANSI/AAMI ES60601-1:2005 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005+A1:2012, MOD).

ANSI / AAMI ES60601-1:2005 / A2:2021 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance - Amendment 2 (IEC 60601-1:2005 / A2:2020).

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

IEC 60601-1-6:2010 / A2:2020 - Amendment 2:2020 to IEC 60601-1-6:2013 - Medical electrical equipment, Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability

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Project: 80271017 **Date Issued**: 2026-02-02

Conditions Of Acceptability

1. Evaluated to CAN/CSA-C22.2 No. 60601-1:14(R2018), Amendment 2:2022 to CAN/CSA-C22.2 No. 60601-1:14; ANSI/AAMI ES60601-1:2005 / (R) 2012, AND A1:2012, C1:2009 (R2012) and A2:2010(R)2012 (Consolidated Text) and ANSI/AAMI ES60601-1:2005/A2: 2021, excluding (Not Evaluated) requirements for Electromagnetic compatibility (Clause 17), Biocompatibility (Clause 11.7).
2. A Medical Electrical Equipment or Medical Electrical System for shipping to outside of North America and not provided with a North American power supply cord set as described in the report, is certified as a component or a sub-assembly, and this certification does not cover the power supply cord set.
3. SAFETY HAZARDS resulting from the intended physiological function of EQUIPMENT covered by this Standard are not considered.
4. Interconnection of this medical 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.
5. 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. During the evaluation of this medical device, the risk management decisions affecting the test requirements have been taken into consideration. Changes/Updates in risk management documents that affect the safety of this medical device during its lifecycle shall be communicated to the CSA Group as a condition for continued certification.
6. Accessories have not been evaluated and are therefore not eligible to bear the CSA mark.
7. The BAJ1 battery can only be charged with the CHJ2 charger. The battery must be removed from the mammography chair for charging. It is not possible to charge the battery while it is installed in the mammography chair.
8. Some mechanical tests were carried out by CSA Group Europe GmbH. See resp. measurement tables.
9. There are two versions of the mammography chair. One is designed for people up to 135 kg and the other version is designed for people up to 250 kg. The two devices differ only in the linear actuator of the device (Megamat MCZ, see images). Relevant tests were carried out with both devices, see resp. measurement tables.
10. The supplementary information of some tables consider a number for one or more test equipment(s). For example: Test equipment: 11; each number represents a test equipment of the Test equipment list (see the end of this report).
11. Due to changes of the installed lifting column of the company Rose & Krieger to ensure conformity with the IEC 60601-1, this report applies for mammography chairs with the serial number of the lifting columns Type Number: 101-016 (1500 N): 348 014233 0100 or higher and serial number of the lifting columns Type Number: 101-017 (3000 N): 348 012062 0100 or higher. See table 9.2.3.2 Over-travel end stop test.
12. The Charger CHJ2 has an IPX5 protection level and is only approved for IEC 60601-1 3rd Ed. Due to this, the tests after 168 h humidity preconditioning (leakage current tests and dielectric strength tests) were carried out.
13. The lifting column is referred in various documents as lifting pole.

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Notes:

Products certified under Class(es) 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

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The products listed, including the latest revision described below, are eligible to be marked in accordance with the referenced Certificate.

Product Certification History

Project	Date	Description
80271017	2026-02-02	Update of cCSAus Certification 70092922 (80104537) for Medical Electrical Equipment, Mobile Mammography Chair, Model/Type: ak 5010 MBS, according to 60601-1 AMD2
80104537	2021-11-10	Update of cCSAus Certification 70092922 for Mobile Mammography Chair, Model/Type: ak 5010 MBS, to cover change in type reference number REF: 277000000 to REF: 277000XXX (administrative change).
70092922	2018-06-08	cCSAus certification for mammography chair ak 5010 MBS according to 60601-1:2005+AM1:2012