Certificate of Compliance

Certificate: 70092922 **Master Contract:** 266310

Project: 80104537 **Date Issued:** 2021-11-10

Issued To: **Akrus GmbH & Co., KG**
Otto-Hahn-Strasse 3
Elmshorn, Schleswig-Holstein, 25337
Germany

Attention: Scott Kottwitz

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: *Santhosh Kumar Reddy Velim*
Santhosh Kumar Reddy Veliminate


PRODUCTS

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

APPLICABLE REQUIREMENTS

Medical Electrical Equipment, Mobile Mammography Chair, Model/Type: ak 5010 MBS **/ REF: 277000XXX**, cord-connected: Internally powered (Battery operated), mobile, rated: 24 VDC battery
Battery (BAJ1): 24 VDC / 2.9 Ah
Charger (CHJ2): 100 - 240 V ~, 50/60 Hz, max. 400 mA

XXX: can be range between 000 – 999; designates customer specific information.

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 (ED1,5 min / 13,5min)
8. Environmental Conditions: Normal: 10 – 40 °C, max 50 % RH, 700 - 1060 hPa

Conditions of Acceptability:

(1) This report describes the certification of the Medical Electrical Equipment or the Medical Electrical System with a North American Certified power supply cord set as indicated in the CSA description report.

(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) Evaluated to CAN/CSA-C22.2 No. 60601-1:14 and ANSI/AAMI ES60601-1:2005/(R)2012, AND c1:2009 AND a2:2010(r)2012 (Consolidated text - edition 3.1) excluding (Not Evaluated) requirements for Electromagnetic compatibility (Clause 17), Biocompatibility (Clause 11.7)

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

(5) 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.

(6) 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.

APPLICABLE REQUIREMENTS

CSA Standards:

CAN/CSA-C22.2 No. 60601-1: 08 + AMD1:2014	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 + AMD1***:2015***	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 + A1:2013 – edition 3.1 This consolidated version consists of the third edition (2010) and its amendment 1 (2013-10)).

ANSI/AAMI Standards:

ANSI/AAMI ES60601-1:2005/(R)2012, AND C1:2009 AND A2:2010(R)2012 (Consolidated text - edition 3.1)	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005+A1:2012, MOD).
IEC 60601-1-6:2006+ ***A1:2013***	Medical electrical equipment, Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability

MARKINGS

The manufacturer is required to apply the following markings:

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

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

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

On the Equipment Exterior:
Equipment is plainly marked in a permanent manner in a place where the details will be readily visible after installation with the following:

- The CSA applicable mark / / with optional reference to Standard, CAN/CSA-C22.2 No. 60601-1:14 and ANSI/AAMI ES60601-1:2005/(R)2012, AND C1:2009 AND A2:2010(R)2012
- Manufacturer's identification: Name and/or CSA file number on the same label as the CSA Mark. The name and/or trademark should appear elsewhere on the equipment if only the file number is used on this label.
- Catalogue/Model/Type designation.
- Date of manufacture: Month and year of manufacture or date code. If a serial number is used instead of date of manufacture, a record of serial numbers shall be kept traceable to date of manufacture. (Not related to date of sale).

- Complete electrical ratings; in volts (V), hertz (Hz), and amperes (A), Volt-amperes (VA) or Watts (W) with the IEC 60417-5032 alternating current symbol adjacent to the marked AC voltage and dc current symbol IEC 60417-5031 marked adjacent to DC input rating for each model.
- The IEC 60417-5840 "Type B" symbol for degree of protection against electric shock; If there is more than one applied part with different degrees of protection, the relevant symbols shall be clearly marked on such applied parts or on or near relevant outlets.
- Interchangeable fuses accessible only with the aid of a tool shall be identified either by (voltage, current, operating speed, and breaking capacity) next to the fuse, or by at least a reference traceable in the Technical Manual.
- On the power supply cord or on the equipment there is a tag or label indicating that "GROUNDING RELIABILITY CAN ONLY BE ACHIEVED WHEN EQUIPMENT IS CONNECTED TO AN EQUIVALENT RECEPTACLE MARKED 'HOSPITAL ONLY' OR 'HOSPITAL GRADE' " or equivalent wording.
- Protection against ingress protection according to IEC 60529, IPX5 rating for charger and battery.

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: 70092922 **Master Contract:** 266310

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
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