Certificate of Compliance

Certificate: 80236397 **Master Contract:** 305413

Project: **80236397** **Date Issued:** April 16, 2025

Issued to: **Korea Auto Controls Co., Ltd.**
66, Geonji-ro 250beon-gil,
Seo-gu Incheon, Incheon 22837
South Korea

Attention: **Jin-kyu Choi**

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: Albert Li
Albert Li, Certifier

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)

Component type Medical footswitch, portable cord-connected, Model: HRF-HD62, HRF-HD6, HRF-HD6P, HRF-M3, HRF-M8-F, HRF-M7-F, HRF-M5-F

Rated: 60Vdc or 25Vac, 1A

1. Type of protection against electric shock: To be determined in end-use product
2. Degree of protection against electric shock:, No applied part
3. Degree of protection against ingress of water: IPX 8
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. Degree of safety of application in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide: Equipment 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°C -40°C, 20% RH -60% RH, 70-106kPa.
   Transport and storage: -25°C to 70°C, 20-85% RH, 70-106kPa.

Condition of acceptability:

1. Evaluated to IEC 60601-1:2005 + A2:2020 excluding (not evaluated) requirements for Electromagnetic compatibility (Clause 17), Biocompatibility (Clause 11.7) and Usability (Clause 12.2). These exclusions shall be evaluated in the end product/device.

2. 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.

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. Equipment needs to be re-evaluated in combination with end product.

6. Korea Auto Controls Co., Ltd provide information for the end product manufacturer. The end use manufacturer has to incorporate the necessary information within their user manual. Accompanying documents has to be evaluated with the end product.

7. The subject models are evaluated only as components of other Medical equipment, where the suitability of the combination is to be determined by the Accepting NCB.

8. The circuit isolation of two means of protection (2MOP) to the mains circuit shall be provided for footswitch in the end product. Footswitch evaluated for 2 MOPP for secondary voltage of 25Vac

9. Connection and anchorage of a flexible cord of footswitches must fulfil the requirements for power supply cords in Cl. 8.11.3 at both ends of the cable to the end device.

10. Risk Controls/ Engineering Considerations for component footswitch:

For use only in or with complete equipment where the acceptability of the combination is to be determined by CSA Group, when installed in an end-product, consideration must be given to the following: End product Risk Management Process to include consideration of requirements specific to the footswitch. End product Risk Management Process to consider the need for simultaneous fault condition testing.

11. Usability is not evaluated in this report and has to be evaluated in the end product.

APPLICABLE REQUIREMENTS

Edition 3.2

CSA Standards:

CAN/CSA-C22.2 No. 60601-1:14 + AMD 2:2022	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 edition 3.0/Amendment 2:2020)

ANSI/AAMI Standards:

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).

Reference standards

IEC 60601-1:2005 +A2:2020	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

Subject to the following qualifications:

(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) The user replaceable mains (line) fuse must be an approved type acceptable to the authorities where the equipment is sold.

(4) Evaluated to CAN/CSA-C22.2 No. 60601-1:14 + A2:2022 and ANSI/AAMI ES60601-1:2005/A2: 2021 excluding (Not Evaluated) requirements for Electromagnetic compatibility (Clause 17), Biocompatibility (Clause 11.7)

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

(6) 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.

(7) 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.

Supplement to Certificate of Compliance

Certificate: 80236397 **Master Contract:** 305413

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
80236397	April 16, 2025	Original Certification.