



Certificate of Compliance

Certificate: 2783117

Master Contract: 262528

Project: 2783117

Date Issued: 2015-04-24

Issued to: RICHWAY&FUJIBIO Inc.
1314 S. King St., Suite 520 Honolulu
Hawaii 96814
USA

Attention: Mr. Hoon-Hee Lee

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:  Antonio Joo

PRODUCTS

CLASS 8780 01 - MEDICAL ELECTRICAL EQUIPMENT

CLASS 8780 81 - MEDICAL ELECTRICAL EQUIPMENT (Certified to US Standards)

Medical Electrical Equipment: Heating Mat, Model: BIOMAT PROFESSIONAL (Basic), BIOMAT SINGLE (Alternate), ORGONE BIOMAT PROFESSIONAL (Alternate), ORGONE BIOMAT SINGLE (Alternate), Cord-connected: Non-detachable cord, Transportable, Rated: 120 Vac, 60 Hz, 180 W.

1. Medical device protection against electric shock: Class II
2. Applied Part protection against electric shock: Type BF
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: 5-40 °C, 15-93 % RH, 700-1 060 hPa



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APPLICABLE REQUIREMENTS

CSA Standards:

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	Medical Electrical Equipment - Part 1-6: General Requirements for Basic Safety and Essential Performance – Collateral standard: Usability
CAN/CSA-C22.2 No. 60601-1-11:11	Medical Electrical Equipment - Part 1-11: General Requirements for Basic Safety and Essential Performance – Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
CAN/CSA-IEC 62366:14	Medical devices – Application of usability engineering to medical devices

ANSI/AAMI Standards:

ANSI/AAMI ES60601-1:2005 / (R)2012, AND A1:2012, C1:2009 / (R)2012 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).
ANSI/AAMI HA60601-1-11:2011	Medical Electrical Equipment - Part 1-11: General Requirements for Basic Safety and Essential Performance – Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment



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
2783117	2015-04-24	Original Certification.