Certificate: USTC/15/FAI/01732

SGS Reference: 619135/01

Certified Product: Convective Air Warming System

Model(s):

Technical Data:

115V~, 12A, 60Hz, 1000W; Type BF applied parts

Manufacturer

Certificate Holder

Adroit Medical Systems, Inc. 1146 Carding Machine Road Loudon, Tennessee 37774 USA

Contract Number: 710317

Adroit Medical Systems, Inc. 1146 Carding Machine Road Loudon, Tennessee 37774

The product is certified according to ISO/IEC Guide 17067, Conformity assessment — Fundamentals of product certification, System 3, and in accordance with the standards indicated on page 2.

This certificate is valid until 13 December 2019 unless the standard in guestion has been amended or superseded with significant changes in requirements, in which case, SGS has the right to shorten the validity of the certificate based on the legislation. This certificate includes the right to use the SGS Product Certification Mark under the condition that changes (if any) will be checked at SGS before the product is brought onto market and that the conditions for the SGS USTC Certification Program are met.

Authorized by

Effective date: 13 December 2016

Suwanee, GA

Certification Manager

Consumer Testing Services, a division of SGS North America Inc. 620 Old Peachtree Road, Ste. 100, Suwanee, GA 30024, USA t +1 770 570 1800 f +1 770 277 1240 www.sgs.com Page 1 of 2





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SGS

Certificate: USTC/15/FAI/01732

SGS Reference: 619135/01

Contract Number: 710317

Certified Product: Convection

Convective Air Warming System

The product is certified according to ISO/IEC Guide 17067, Conformity assessment — Fundamentals of product certification, System 3, and in accordance with the standards indicated on page 2.

Standard for Medical electrical equipment – Part 1: General requirements for basic safety and essential performance ANSI/AAMI ES60601-1:2005 + A1:2012 + C1:2009 and A2:2010

Standard for Medical electrical equipment – Part 1: General requirements for basic safety and essential performance CAN/CSA-C22.2 No. 60601-1:14

Standard for Medical electrical equipment – Part 2-35: Particular requirements for basic safety and essential performance of heating devices using blankets, pads or mattresses and intended for heating in medical use IEC 80601-2-35:2009

Standard for Medical electrical equipment – Part 2-35: Particular requirements for basic safety and essential performance of heating devices using blankets, pads or mattresses and intended for heating in medical use CAN/CSA C22.2 No. 80601-2-35:12

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