





Product Service

Certificate

No. Q5 032050 0015 Rev. 00

Holder of Certificate: Atom Medical Corporation

2-2-1, Dojo, Sakura-ku, Saitama-shi

Saitama

338-0835 JAPAN

Certification Mark:



Scope of Certificate: Design and Development, Production and

Distribution of Infant Incubator, Infant Radiant Warmer,

Infusion Pump, Nebulizer, Photo Therapy Unit,

Birthing Table, Examination Table, Vacuum Extractor, Electric Suction Unit, Ultrasound Fetal Doppler Phonocardiograph,

Medical Lighting Equipments,

Oxygen Treatment Apparatus, Oxygen Tent,

Stethoscope and Resuscitator

Production and Distribution of Boiling Liquid Sterilizer

Production (labeling only) and Distribution of

Steel Made Surgical Instruments

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5-032050-0015-Rev.00

Report No.: JA1768391

 Valid from:
 2022-12-06

 Valid until:
 2025-05-08

Christoph Dicks

Head of Certification/Notified Body

Date, 2022-12-06







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EN ISO 13485:2016 Applied Standard(s):

Medical devices - Quality management systems -

Requirements for regulatory purposes

(ISO 13485:2016) DIN EN ISO 13485:2016

Atom Medical Corporation Facility(ies):

Bunkyo Green Court Center Office 18F, 2-28-8, Honkomagome, Bunkyo-ku, Tokyo, 113-0021 JAPAN

Distribution of Infant Incubator, Infant Radiant Warmer, Infusion Pump, Nebulizer, Photo Therapy Unit, Birthing Table, Examination Table, Vacuum Extractor, Electric Suction Unit, Ultrasound Fetal Doppler Phonocardiograph, Medical Lighting Equipment, Oxygen Treatment Apparatus, Oxygen Tent, Stethoscope, Resuscitator, Boiling Liquid Sterilizer and Steel made Surgical Instruments

Atom Medical Corporation 2-2-1, Dojo, Sakura-ku, Saitama-shi, Saitama, 338-0835 JAPAN

Design and Development, Production and Distribution of Infant Incubator, Infant Radiant Warmer, Infusion Pump, Nebulizer, Photo Therapy Unit, Birthing Table, Examination Table, Vacuum Extractor, Electric Suction Unit, Ultrasound Fetal Doppler Phonocardiograph, Medical Lighting Equipment, Oxygen Treatment Apparatus, Oxygen Tent, Stethoscope, Resuscitator; Production and Distribution of Boiling Liquid Sterilizer; Production (labeling only) and Distribution of Steel made Surgical Instruments

Atom Medical Corporation Wako Service Center 5-1-63, Niikura, Wako-shi, Saitama, 351-0115 JAPAN

Repair, Storage and Distribution of Infant Incubator, Infant Radiant Warmer, Infusion Pump, Nebulizer, Photo Therapy Unit, Birthing Table, Examination Table, Vacuum Extractor, Electric Suction Unit, Ultrasound Fetal Doppler Phonocardiograph, Medical Lighting Equipment, Oxygen Treatment Apparatus, Oxygen Tent, Stethoscope, Resuscitator, Boiling Liquid Sterilizer and Steel made Surgical Instruments

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