Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 032051 0076 Rev. 01

Manufacturer: **Atom Medical Corporation**
18-15, Hongo 3-chome, Bunkyo-ku
Tokyo
113-0033 JAPAN

Product Category(ies): **Infant Incubator, Infant Radiant Warmer, Infusion Pump, Nebulizer, Resuscitator and Phototherapy Unit**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: **JAQ235039245**

Valid from: **2020-01-08**
Valid until: **2024-02-08**

Date, **2020-01-08**

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT
TÜV SÜD
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(Devices in Class IIa, IIb or III)

No. G1 032051 0076 Rev. 01

Facility(ies):

Atom Medical Corporation
18-15, Hongo 3-chome, Bunkyo-ku, Tokyo, 113-0033
JAPAN

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

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

-/-

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