



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. 00**

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

**EC-Representative:** **Atom Medical International Inc.**  
**EU Office**  
Via Libia, 54,  
20081 Abbiategrasso (MI),  
ITALY

**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.:** **JAQ235034809**

**Valid from:** **2019-02-09**  
**Valid until:** **2024-02-08**

**Date,** **2019-01-07**

Stefan Preiß



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## 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 Customer Service Center**  
7-16-1, Sasame, Toda-shi, Saitama, 335-0034 JAPAN

**Atom Medical Corporation Logistic Center**  
14-3, Takeno, Kawagoe-shi, Saitama, 350-0801 JAPAN

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