



Product Service

Confirmation Statement on validity of EC Certificate (MDD)

pursuant to Directive 93/42/EEC concerning medical devices

No. GCQ 032050 0017 Rev. 00

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

This Confirmation Statement is only valid in combination with the following EC Certificate (MDD): **G1 032051 0076 Rev. 02**

This Confirmation Statement confirms the validity of the aforementioned EC Certificate (MDD). It considers clarification of scope statements, scope reductions and changes to the manufacturer data initiated 26 May 2021 or later.

The conditions laid down in Article 120 (3) of Regulation (EU) 2017/745 on medical devices for placing devices on the market and putting into service apply. For details and confirmation statement validity see: www.tuvsud.com/ps-cert?q=cert:GCQ_032050_0017_Rev._00

Report No.: **JA1768391**

Valid until: **2025-05-26**

Christoph Dicks
Head of Certification/Notified Body

Issue Date: 2022-12-06



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

**Description of
Change:**

Manufacturer change and facility address change