



Product Service

Confirmation Statement on validity of EC Certificate (MDD)

pursuant to Directive 93/42/EEC concerning medical devices

No. GCQ 054954 0016 Rev. 00

Manufacturer: AMBULANC (SHENZHEN) TECH. CO., LTD.

3rd and 8th Floor, Block C
Building #5 Skyworth Innovation
Industry Park, Tang Tou 1st Road, Shiyan
Baoan District
518108 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

This Confirmation Statement is only valid in combination with the following EC Certificate (MDD):

G1 054954 0012 Rev. 03

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_054954_0016_Rev_00

Report No.: BJ23087401

Valid until: 2024-05-26

Christoph Dicks
Head of Certification/Notified Body

Issue Date: 2024-03-15

Confirmation Statement on validity of EC Certificate (MDD)

pursuant to Directive 93/42/EEC concerning medical devices

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Product Category(ies): Emergency Ventilator, Transport Ventilator, Ultrasonic Doppler Fetal Monitor, Demand Valve Resuscitator, Inhalation Antalgic Equipment (Sedation System), Nasal Continuous Positive Airway Pressure System, Suction Unit, Emergency Resuscitator, Blender.

Description of Change:

1. Holder address change from:

3rd Floor, Block C, Building #5, Skyworth Innovation Industry Park, Tang Tou 1st Road,Shiyan, Baoan District, 518108, Shenzhen, People's Republic of China

To:

3rd and 8th Floor, Block C, Building #5,Skyworth Innovation Industry Park,Tang Tou 1st Road,Shiyan, Baoan District, 518108, Shenzhen, People's Republic of China

2. Scope change from:

Emergency Ventilator, Transport Ventilator, Ultrasonic Doppler Fetal Monitor, Demand Valve Resuscitator, Inhalation Antalgic Equipment (Sedation System), Nasal Continuous Positive Airway Pressure System, Suction Unit, Emergency Resuscitator, Blender.

To:

Emergency Ventilator, Transport Ventilator, Demand Valve Resuscitator, Inhalation Antalgic Equipment (Sedation System), Nasal Continuous Positive Airway Pressure System, Suction Unit, Emergency Resuscitator, Blender.