



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 054954 0012 Rev. 03

Manufacturer:

AMBULANC (SHENZHEN) TECH. CO., LTD.

3rd Floor, Block C, Building #5

Skyworth Innovation Industry Park

Tang Tou 1st Road,Shiyan, Baoan District

518108 Shenzhen

PEOPLE'S REPUBLIC OF CHINA

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.

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. 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:G10549540012Rev.03

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Date, 2020-09-24

Christoph Dicks

Head of Certification/Notified Body