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





## **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 005136 0002 Rev. 01

Manufacturer:

Shenzhen Witleaf Medical

Electronics Co., Ltd.

13/F-B2, Block 1 Senyang Science Park

No.7 Road, West District of High-Tech Park

**Guangming District** 518132 Shenzhen

PEOPLE'S REPUBLIC OF CHINA

Product Category(ies): Patient Monitor, Rapid Intervention Capnograph, Fingertip Pulse Oximeter,

Handheld Pulse Oximeter

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:G1 005136 0002 Rev. 01

Report No.:

GZ2035701

Valid from:

2021-04-22

Valid until:

2024-04-14

Date,

2021-04-22

Christoph Dicks

Head of Certification/Notified Body