



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 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:G10051360002Rev.01](http://www.tuvsud.com/ps-cert?q=cert:G10051360002Rev.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