



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
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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 068644 0013 Rev. 00**

## Manufacturer:

**Vcomin Technology Limited**

2&3 Fl., No 1, Kangzheng Rd.

Buji Town

518110 Shenzhen

PEOPLE'S REPUBLIC OF CHINA

## Facility(ies):

Vcomin Technology Limited

2&3 Fl., No 1, Kangzheng Rd., Buji Town, 518110 Shenzhen,

PEOPLE'S REPUBLIC OF CHINA

## Product Category(ies): **Electrocardiographs, Fetal Dopplers, Fetal Monitors, Patient Monitors and Pulse Oximeters.**

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. See also notes overleaf.

**Report No.:**

GZ19140EXT01

**Valid from:**

2019-05-24

**Valid until:**

2024-04-15

**Date,**

2019-05-24

Stefan Preiß

Head of Certification/Notified Body