



## 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 17 09 92582 007

Manufacturer: Xuzhou Yongkang Electronic Science

Technology Co., Ltd.

4F Building C8, 40 Jingshan Road

Economic and Technological Development Zone

221000 Xuzhou

PEOPLE'S REPUBLIC OF CHINA



**Prolinx GmbH EC-Representative:** 

> Brehmstr. 56 40239 Duesseldorf **GERMANY**

**Product** Vital Signs Monitor,

Category(ies): Handheld Pulse Oximeter, Fingertip Pulse Oximeter,

**Multiparameter Patient Monitor** 

40527686524

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 ovelon 市永康电子科技有限公司

Report No.:

编号 再复审无效

Valid from: Valid until:

2017 12 11 2021-06-29

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2017-12-11 Date.

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123 Page 1 of 2





## **EC Certificate**

**Product Service** 

**Full Quality Assurance System** 

Directive 93/42/EEC on Medical Devices (MDD), Annex if excluding (科技有限公司 (Devices in Class IIa. IIb or III) (Devices in Class IIa, IIb or III) 证件管理专用章

No. G1 17 09 92582 007

Facility(ies):

再复印无效 Xuzhou Yongkang Electronic Science Technology

Co., Ltd.

4F Building C8, 40 Jingshan Road, Economic and Technological Development Zone, 221000 Xuzhou,

PEOPLE'S REPUBLIC OF CHINA