

## 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 13 07 85300 003

Manufacturer:

**Hunan Accurate Bio-Medical** 

Technology Co., Ltd.

M8-613, No.8, Lutian Road Changsha National Hi-Tech Industrial Development Zone

410205 Changsha, Hunan Province PEOPLE'S REPUBLIC OF CHINA

**EC-Representative:** 

**Shanghai International Holding** 

Corp. GmbH (Europe)

Eiffestraße 80 20537 Hamburg GERMANY

Product Category(ies):

**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. See also notes overleaf.

Report No.:

748467736

Valid from:

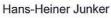
2013-10-10

Valid until:

2018-10-09

Date, 2013-10-15

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TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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Facility(ies):

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