



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 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

Hans-Heiner Junker



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

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Facility(ies):

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