ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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 14 08 71165 008

**Manufacturer:**

**Sino-Hero (Shenzhen) Bio-Medical Electronics Co., LTD.**
Unit 608, 6/F., First Building
Zhongxing Industrial Park
Chuangye Road
Nanshan District
518054 Shenzhen City
PEOPLE'S REPUBLIC OF CHINA

**EC-Representative:**

**Shanghai International Holding Corp. GmbH (Europe)**
Eiffestraße 80
20537 Hamburg
GERMANY

**Product Category(ies):**

**Patient Monitor, Full Digital Ultrasonic Diagnostic System, Central Monitoring System Software, Electrocardiograph, Pulse Oximeter Probes, Pulse Oximeter, Infusion Pumps and Syringe Pumps**

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.:** 748485937

**Valid from:** 2014-11-19
**Valid until:** 2019-11-18

**Date,** 2014-10-21

Hans-Heiner Junker

TÜV SÜD 616748

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





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