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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 071165 0013 Rev. 02

Manufacturer:

Sino-Hero (Shenzhen) Bio-Medical Electronics Co., LTD.
A area, Second Floor, First Building
Tongkangfu Industrial Park
Yingrenshi Community, Shiyan Sub-district
Bao'an District
518108 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

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.

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Valid from: 2019-10-30
Valid until: 2024-05-26

Date, 2019-10-30

Christoph Dicks
Head of Certification/Notified Body

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

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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Facility(ies):

Sino-Hero (Shenzhen) Bio-Medical Electronics Co., LTD.
A area, Second Floor, First Building, Tongkangfu Industrial Park,
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518108 Shenzhen, PEOPLE'S REPUBLIC OF CHINA

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