ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ 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 04 87949 002

Manufacturer:

Beijing Safe Heart Technology Ltd.
Room 101, Unit 6, Building No.6
No.88 Kechuang 6th Street
Beijing Economic-Technological Development Area
101111 Beijing
PEOPLE'S REPUBLIC OF CHINA

EC-Representative:

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

Product Category(ies):

Patient Monitor, 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.: BJ1478601

Valid from: 2014-07-03
Valid until: 2019-07-02

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Date, 2014-07-04

Hans-Heiner Junker

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

TÜV®

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Facility(ies):

Beijing Safe Heart Technology Ltd.
Room 101, Unit 6, Building No.6, No.88 Kechuang 6th Street,
Beijing Economic-Technological Development Area, 101111
Beijing, PEOPLE'S REPUBLIC OF CHINA

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