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 15 01 45163 023

Manufacturer:

Shenzhen Biocare Bio-Medical Equipment Co., Ltd.

#A735,7/F, Block A
Shenzhen Mingyou Industrial Products
Exhibition & Procurement Center
Baoyuan Road, Xixiang Sub-district
Bao'an District
518102 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

EC-Representative:

Shanghai International Holding Corp. GmbH (Europe)

Eiffestraße 80
20537 Hamburg
GERMANY

Product Category(ies):

Digital Electrocardiograph, Patient Monitor, B-Ultrasonic Diagnostic Equipment, Doppler Fetal Heart Rate Detector, Infusion Pump, Syringe Pump, Fingertip Pulse Oximeter, Handheld Pulse Oximeter, Fetal/Maternal Monitor, Fetal Monitor, Color Doppler Ultrasound System, Central Monitoring System.

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.: BJ1489604-2

Valid from: 2015-03-31
Valid until: 2020-03-19

573539

Date, 2015-04-07

Hans-Heiner Junker

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

TÜV®

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 15 01 45163 023

Facility(ies):

Shenzhen Biocare Bio-Medical Equipment Co., Ltd.
#A735,7/F, Block A, Shenzhen Mingyou Industrial Products, Exhibition & Procurement Center, Baoyuan Road, Xixiang Sub-district, Bao'an District, 518102 Shenzhen, PEOPLE'S REPUBLIC OF CHINA

Shenzhen Biocare Bio-Medical Equipment Co., Ltd.
2/F West, 4th Block, Dayang Road South, Fuyong Sub-district, Bao'an District, 518103 Shenzhen, PEOPLE'S REPUBLIC OF CHINA

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

TÜV®