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

Product Service

EC Certificate

Production Quality Assurance

Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

No. G2 12 10 50440 019

Manufacturer:

Shenzhen Carewell Electronics Co., Ltd.
1A-2/F, Building 29, District B
Tanglang Industrial Zone
Taoyuan Street
Nanshan
518055 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

EC-Representative:

Shanghai International Trading Corp. GmbH (Hamburg)
Eiffestrasse 80
20537 Hamburg
GERMANY

Product Category(ies):

Diagnostic Ultrasound System, Electrocardiographs, Fetal Dopplers, Dynamic ECG Systems

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class IIb and III devices an additional Annex III certificate is mandatory. See also notes overleaf.

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Valid from: 2013-03-19
Valid until: 2016-03-16

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Date, 2013-03-21

Hans-Heiner Junker

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

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No. G2 12 10 50440 019

Facility(ies):

Shenzhen Carewell Electronics Co., Ltd.
1A-2/F, Building 29, District B, Tanglang Industrial Zone, Taoyuan Street, Nanshan, 518055 Shenzhen, PEOPLE'S REPUBLIC OF CHINA

Shenzhen Carewell Electronics Co., Ltd.
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