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 16 07 91561 004

Manufacturer:

PROMISE TECHNOLOGY CO., LTD.
3/F, East-Asia Building
Jida Jiuzhou Avenue
519015 Zhuhai, Guangdong
PEOPLE'S REPUBLIC OF CHINA

EC-Representative:

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

Product Category(ies):

B-Ultrasound Diagnostic System, Patient Monitor, Dynamic ECG Systems, Electrocardiograph, Pulse Oximeter, and Ambulatory Blood Pressure Monitor

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.: 7484032215

Valid from: 2016-09-19
Valid until: 2020-06-25

04052767033315

Date, 2016-09-19

Stefan Preiß

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

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Facility(ies):

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Guangdong, PEOPLE'S REPUBLIC OF CHINA