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 12 02 75893 003

Manufacturer:

Dimetek Digital Medical Technologies, Ltd.
3/F-A2, A/B Block Unit 8
Xing Hua Building, Nanhai Rd.
Nanshan
518067 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

EC-Representative:

Jade Technologie France, Ltd.
1 Allée Barbara
77600 Bussy Saint Georges
FRANCE

Product Category(ies):

Micro Ambulatory ECG Recorder

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.: SZ120610101

Valid from: 2012-05-30
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Date, 2012-06-01

Hans-Heiner Junker

382382

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

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

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Facility(ies):

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