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 71164 006

Manufacturer:

Shenzhen Basda Medical Apparatus Co., Ltd.
A1402 & A1403
Longgang Tianan Cyber Park 3#
Longgang Central City
518172 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

EC-Representative:

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

Product Category(ies):

Magnetic Resonance Imaging 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.: 7484000500

Valid from: 2015-03-20
Valid until: 2020-03-19

Date, 2015-03-12

Hans-Heiner Junker

616807

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

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Facility(ies):

Shenzhen Basda Medical Apparatus Co., Ltd.
A1402 & A1403, Longgang Tianan Cyber Park 3#, Longgang Central City, 518172 Shenzhen, PEOPLE'S REPUBLIC OF CHINA

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