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 06 76260 007

Manufacturer:

Shenyang Canta Medical Tech.Co.,Ltd.
No.76-39 Shenbei Road
Daoyi Economic Development Zone
Shenbei New District
110136 Shenyang
PEOPLE'S REPUBLIC OF CHINA

EC-Representative:

Wellkang Ltd t/a Wellkang Tech Consulting
Suite B, 29 Harley Street
London
W1G 9QR
UNITED KINGDOM

Product Category(ies):

Oxygen Concentrator for Medical Use,
Sleep Apnoea Breathing Therapy Devices.

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.: BJ1677707

Valid from: 2016-10-19
Valid until: 2021-10-18

Date, 2016-08-22

Stefan Preiß

0405276871386S

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

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Facility(ies):

Shenyang Canta Medical Tech.Co.,Ltd.
No.76-39 Shenbei Road, Daoyi Economic Development Zone,
Shenbei New District, 110136 Shenyang, PEOPLE'S REPUBLIC OF CHINA

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