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Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
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ZLG-BS-244.10.08



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 076260 0010 Rev. 00

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

**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.:

BJ19777071

Valid from:

2020-03-02

Valid until:

2024-05-26

Date,

2020-03-02

Christoph Dicks

Head of Certification/Notified Body