









V Series Accessories List

No.	Accessory Name	Picture	Quantity
1	V Paper Filter (Air filter level two)		1pc
2	Intake Window Filter (Air filter level one)		1pc
3	Internal anti-bacterial filter		1pc
4	Humidifier Bottle		1pc
5	starting copacitor		1pc
6	Adult Nasal Cannula		1pc
7	Adult Nasal Cannula		1pc
8	Power Line, optional (1. South Africa) (2. UK) (3. EURO) (4. US) (5. South America)		1pc

9	molecular sieve	 Two cylindrical, silver-colored molecular sieve canisters are shown side-by-side on a wooden surface. Each canister has a blue cap at one end and a silver cap at the other.	1pc
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Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
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

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ CERTIFICADO ◆ CERTIFICAT

A4 / 07.17



Certificate

No. Q5 076260 0009 Rev. 02

Holder of Certificate: **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

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

Certification Mark:



Scope of Certificate: **Design and Development, Production and Service of Oxygen Concentrators and Sleep Apnoea Breathing Therapy Devices.**

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:Q5 076260 0009 Rev. 02](http://www.tuvsud.com/ps-cert?q=cert:Q5_076260_0009_Rev._02)

Report No.: BJ20077701

Valid from: 2020-11-02

Valid until: 2023-10-18

Date, 2020-11-02



Christoph Dicks

Head of Certification/Notified Body