CE Technical Documentation Review CE Technical Documentation Review CE Technical Documentation Review

China

CE Technical Documentation Review Report

(According to IVDD Directive 98/79/EC)

Report No. TFR-BJ-66670 201101

The Manufacturer:

Wenzhou Gaode Medical Instrument Co., Ltd.

Haibin Industrial District, Haibin Street, Longwan, Wenzhou

325024, Zhejiang, P.R.China

Has Established CE Technical Documentation for the Following Products

Single-use Vacuum Tubes for Venous Blood Collection

This report is issued on a voluntary basis. It confirms that the CE technical documentation (no. QR/GDY09-2008, Rev A/0, Date 2010-11-08) of the listed product is complete with regard to the requirements of Annex III section 3 of Directive 98/79/ EC excluding quality system documentation. Detail products covered under the technical documentation are described in this report. This report would be re-assessed before 2012-12-24.

Issue Place:
Medical, Health Service Dept.
TÜV SÜD China, Beijing Branch

Issue Date:
2011-12-24

CE

Any significant changes in design or construction of the product or amendments to the directive or standards applied may render this report invalid. Also, this report is only valid in combination with ISO13485 certificate issued by TÜV SÜD.

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

CERTIFICATE

No. Q1N 11 06 66670 003

Holder of Certificate: **Wenzhou Gaode Medical Instrument Co., Ltd**
Haibin Industrial District
Haibin Street, Longwan
325024 Wenzhou, Zhejiang
PEOPLE'S REPUBLIC OF CHINA

Facility(ies): Wenzhou Gaode Medical Instrument Co., Ltd
Haibin Industrial District, Haibin Street, Longwan, 325024
Wenzhou, Zhejiang, PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

Scope of Certificate: **Design, Development, Production and Distribution of Single-use Vacuum Tubes for Venous Blood Collection**

Applied Standard(s): **EN ISO 13485:2003/AC:2009**
ISO 13485:2003
Medical Devices – Quality Management Systems – Requirements for regulatory purposes

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality system which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: BJ1196804

Valid from: 2011-06-15
Valid until: 2014-05-31

Date, 2011-06-20

Hans-Heiner Junker

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TÜV SÜD Product Service GmbH
Zertifizierstelle
Ridlerstr. 65 · 80339 München
Germany

Akkreditiert durch
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
ZLG-ZQ-999.98.12-46

Report Number: QIP-ASI113909

Audit Date : 15 Sep., 2011
Expiry Date : 14 Sep., 2012

This report is issued by Focus Technology Co., Ltd. (Made-in-China.com) and the supervising inspectorate (SGS-CSTC Standards Technical Services Co., Ltd.) to confirm that:

Company Name	:	**Wenzhou Gaode Medical Instrument Co., Ltd.** 温州市高德医疗器械有限公司
Showroom	:	**http://gaodemedical.en.made-in-china.com/**
Address	:	**No. 168, Haining Road, Haibin Industrial Zone, Wenzhou City, Zhejiang, China**
Product	:	**Blood Collection Tube, Blood Sampling System, Blood Tube, Medical Consumables, Test Tube, etc.**

has been on site audited for the Following Scope of Activity

1. General Information
2. Foreign Trade Capacity
3. Product Research & Development Capacity
4. Quality Management System and Product Certification
5. Working Environment & Energy Saving
6. Photos

General Comments:

Wenzhou Gaode Medical Instrument Co., Ltd. is a manufacturer with 50 employees; it was established in 2003, located in No. 168, Haining Road, Haibin Industrial Zone, Wenzhou City, Zhejiang, China. The workshops occupy an area 3,000 square meters. The company has its own brand “CHGD”. They had passed ISO13485:2003 certification, and already had obtained CE certificate for their products.

Sign for and on behalf of
SGS-CSTC Standards Technical Services Co., Ltd.

SGS-CSTC Standards Technical Services Co.,Ltd.
Consumer Testing Services
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