



Product Service

# EC - CERTIFICATE

## Production Quality Assurance System

(Annex V of the Directive 93/42/EEC on Medical Devices)

No. G2S 09 03 65773 005

**Manufacturer:** **Frankenman International Ltd.**

Suite B, 13F  
Wing Tat Commercial Building  
121-125 Wing Lok Street  
Sheung Wan  
HONG KONG

**EC-Representative:** **Shanghai International Trading Corp. GmbH (Hamburg)**

Eiffestrasse 80  
20537 Hamburg  
GERMANY

**Product Category(ies):** **Single Use Anoscope Kit for CPH**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture according to Annex V, section 3 of the Directive 93/42/EEC on Medical Devices. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective product / product categories and conforms to the provisions of this Directive. It is subject to periodical surveillance. See also notes overleaf.

**Report No.:** SH0941102

**Valid until:** 2014-04-16

**Date,** 2009-04-17

Hans-Heiner Junker



TÜV SÜD Product Service GmbH is Notified Body according to Council Directive 93/42/EEC concerning medical devices with identification no. 0123.

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**Facility(ies):**

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