



Product Service

# CERTIFICATE

No. Q1N 11 02 65773 008

Holder of Certificate: **Frankenman International Ltd.**

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

Facility(ies):

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

Certification Mark:



Scope of Certificate:

Design and Development,  
Production and Distribution of  
Single Use Curved Intraluminal Circular Stapler,  
Single Use Circular Stapler for Rectal Prolapse  
and Haemorrhoids,  
Single Use Reloadable Linear Stapler and Reloads,  
Single Use Reloadable Linear Cutter Stapler and Reloads,  
Single Use Anoscope Kit for CPH,  
Single Use Straight Intraluminal Circular Stapler,  
Single Use Transverse Cutting Linear Stapler and Reloads,  
Single Use Suction And Irrigation System

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.: SH1141104  
Valid from: 2011-04-01  
Valid until: 2014-03-31

Date, 2011-03-28

Hans-Heiner Junker



Page 1 of 1

TÜV SÜD Product Service GmbH  
Zertifizierstelle  
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Germany



Akkreditiert durch  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln  
und Medizinprodukten  
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