



Product Service

CERTIFICATE

No. Q1N 11 04 55234 015

Holder of Certificate: Suzhou Frankenman Medical Equipment Co., Ltd.

88 Jinfeng Road
215011 Suzhou
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate:

Design and Development,
Production, Distribution of
Disposable Alimentary Canal Staplers/
Single Use Curved Intraluminal Circular Staplers,
Disposable Reloadable Linear Staplers and Reloads/
Single Use Reloadable Linear Staplers and Reloads,
Disposable Reloadable Linear Cutter Staplers
and Reloads/ Single Use Reloadable Linear Cutters
Staplers and Reloads,
Single Use Anoscope Kits for CPH,
Single Use Circular Staplers for Rectal Prolapse
and Haemorrhoids,
Single Use Transverse Cutting Linear Staplers and Reloads,
Single Use Straight Intraluminal Circular Stapler,
Single Use Suction and Irrigation System,
Single Use Endoscopic Linear Cutter Stapler and Reloads,
Single Use Purse String Forceps

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.: SH1108707

Valid from: 2011-06-01

Valid until: 2014-05-31

Hans-Heiner Junker

Date, 2011-05-11



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TÜV SÜD Product Service GmbH
Zertifizierstelle
Ridlerstraße 65 · 80339 München
Germany



Akkreditiert durch
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln
und Medizinprodukten

ZLG-ZQ-999.98.12-46

TÜV®



Product Service

CERTIFICATE

No. Q1N 11 04 55234 015

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

Facility(ies): Suzhou Frankenman Medical Equipment Co., Ltd.
88 Jinfeng Road, 215011 Suzhou, PEOPLE'S REPUBLIC OF
CHINA

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TUV®



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 11 04 55234 016

Manufacturer: Suzhou Frankenman Medical Equipment Co., Ltd.

88 Jinfeng Road
215011 Suzhou
PEOPLE'S REPUBLIC OF CHINA

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

Eiffestrasse 80
20537 Hamburg
GERMANY

Product Category(ies):

Disposable Alimentary Canal Stapler/
Single Use Curved Intraluminal Circular Stapler,
Disposable Reloadable Linear Stapler and Reloads/
Single Use Reloadable Linear Stapler and Reloads,
Disposable Reloadable Linear Cutter Stapler
and Reloads/ Single Use Reloadable Linear Cutter
Stapler and Reloads,
Single Use Circular Stapler for Rectal Prolapse
and Haemorrhoids,
Single Use Transverse Cutting Linear Stapler and Reloads,
Single Use Straight Intraluminal Circular Stapler,
Single Use Suction and Irrigation System,
Single Use Endoscopic Linear Cutter Stapler and Reloads,
Single Use Purse String Forceps

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.: SH1108707

Valid from: 2011-05-09

Valid until: 2015-07-24

Hans-Heiner Junker

Date, 2011-05-11



TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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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 11 04 55234 016

Facility(ies):

Suzhou Frankenman Medical Equipment Co., Ltd.
88 Jinfeng Road, 215011 Suzhou, PEOPLE'S REPUBLIC OF
CHINA