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

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 14 10 89676 002

Manufacturer:

Golden Stapler Surgical Co., Ltd.
Building 7A
Jiangsu Wujin Sci-Tech Pioneer Park
256 Mid Mingxin Road
Hutang Town, Wujin District
213164 Changzhou, Jiangsu Province
PEOPLE'S REPUBLIC OF CHINA

EC-Representative:

Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80
20537 Hamburg
GERMANY

Product Category(ies):

Single use circular stapler,
Single use hemorrhoidal circular stapler,
Single patient use linear stapler and reload,
Single patient use linear cutter and reload,
Single patient use transverse cutter and reload,
Single patient use endo cutter and reload,
Single patient use skin stapler,
Single use abdominal trocar,
Single use purse string device

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.: SH1491201

Valid from: 2014-12-05
Valid until: 2019-12-04

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Date, 2014-12-08

Hans-Heiner Junker

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

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

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