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Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
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ZLG-BS-244.10.08



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 005512 0003 Rev. 02**

**Manufacturer:**

**Touchstone International  
Medical Science Co., Ltd.**

278 Dongping Street, Suzhou Industrial Park  
215123 Suzhou  
PEOPLE'S REPUBLIC OF CHINA

**Product Category(ies):** **Linear Cutter and Reloads,  
Linear Stapler and Reloads,  
Tissue-Selecting Therapy Stapler,  
Curved Linear Cutter and Reloads,  
Intraluminal Stapler for Single Use,  
Auto Purse String Clamp for Single Use,  
PPH Stapler and Purse Sets for Single Use,  
Endoscopic Linear Cutter and Single Use Loading  
Unit, Circumcision Stapler for Single Use**

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. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:G10055120003Rev.02](http://www.tuvsud.com/ps-cert?q=cert:G10055120003Rev.02)

**Report No.:**

SH21484EXT01

**Valid from:**

2021-03-10

**Valid until:**

2024-05-26

**Date,**

2021-03-10

Christoph Dicks  
Head of Certification/Notified Body