

Declaration of Conformity

Manufacturer: Touchstone International Medical Science Co., Ltd.

Address:

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

Name of authorized EU representative: Shanghai International Holding Corp. GmbH (Europe)

Address of authorized EU representative: Eiffeustraße 80, 20537, Hamburg, GERMANY

Product name: Intraluminal Stapler for Single Use

Model of appliance:

CSC21, CSC25, CSC29, CSC33, CSC21-ET, CSC25-ET, CSC29-ET, CSC33-ET, CSC21-A, CSC25-A, CSC29-A, CSC33-A, ECSC21, ECSC25, ECSC29, ECSC33, CSC29-KOL, CSC29-KOL+, KOL29, KOL29+, CSC33-KOL, CSC33-KOL+, KOL33, KOL33+, CST21, CST25, CST29, CST33, T02005, T03005, T04005, CST29-KOL, CST29-KOL+, CST33-KOL, CST33-KOL+

Product classification: IIb Rule 8 of ANNEX IX GMDN Code: 59875

Conformity assessment route: ANNEX II excluding (4), MDD/93/42/EEC

Declaration of conformity:

We hereby declare that the above mentioned product meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under promise of the manufacturer.

Touchstone International Medical Science Co., Ltd. is exclusively responsible for the Declaration of Conformity.

We follow the applicable directives include:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC concerning medical devices (MDD 93/42/EEC)

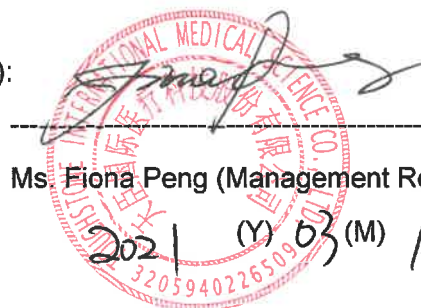
Notified body: TÜV SÜD Product Service GmbH with identification No. 0123
Zertifizierstelle. Ridlerstraße 65. 80339 München. Germany

CE certificate number: G1 005512 0003 Rev.02

Validity period of CE certificate: 2024-05-26

Date of first CE-marking: 2007-08

Top Management (signature):


Ms. Fiona Peng (Management Representative)
2021 (Y) 03 (M) 16 (D)