

## 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: Eiffestraße 80, 20537, Hamburg, GERMANY

Product name: Linear Cutter and Reloads

Model of appliance:

LC6045, LC6038, LC6025, LN6038, LC8045, LC8042, LC8038, LC10045, LC10038, LCC6045, LCC6038, LCC6025, LNC6038, LCC8045, LCC8042, LCC8038, LCC10045, LCC10038, LC6045L, LC6038L, LC6025L, LN6038L, LC8045L, LC8042L, LC8038L, LC10045L, LC10042L, LC10038L, LCC6045L, LCC6038L, LCC6025L, LNC6038L, LCC8045L, LCC8042L, LCC8038L, LCC10045L, LCC10042L, LCC10038L

Product classification: IIb Rule 8 of ANNEX IX GMDN Code: 59870

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: 2008-08

Top Management (signature):

Ms. Fiona Peng (Management Representative)

2021 (Y) 03 (M) 16 (D)