

POSI

CERTIFICATE

This is to certify that the Quality Management System of
Yuyao Guangjing Medical Instrument Co.,Ltd.

Business license number: 913302815953640483
 Registered Address: No. 126, Hou Zhongcun Road, Muhu Village,
 Ditang Street, Yuyao City
 Audit Address: No. 24, Guangming East Road, Lishan Village, Ditang
 Street, Yuyao City

applicable to
 production and sale of bite block, disposable
 tourniquet and snap tourniquet

has been assessed and registered by POSI against the provisions of
ISO13485:2016

This registration is subject to the company maintaining a quality management system,
 to the above standard, which will be monitored by POSI.

Please consult the website: www.posicert.com

The certificate information is also available on the CNCA official website: <http://cx.cnca.cn>.



General Manager

Certificate Registration No: 381190028R0S

Initial issue date: 2019.09.17

Issue date: 2019.09.17

Valid until: 2022.09.16



Shanghai POSI Certification Co., Ltd.

Room 1002A, No.1500, Century Avenue, Pudong New Area, Shanghai, China. Email: info@posicert.com



Declaration of Conformity

Declaration of conformity in accordance with the requirements for manufacturing single use tourniquets in accordance with the medical device's directive 93/42/EEC

Manufacturer:

Yuyao Guangjing Medical Instruments Co., Ltd
Ditang Street, Yuyao City, Ningbo, ROC

Product Classification/Classification Rule: Class I / Rule 1

Conformity Assessment Route: ANNEX VII

GMDN code: 35844

Products:

Snap Tourniquet **GJ030-100 GJ030-200 GJ030-300 GJ031-100 GJ031-200**

Standards used for compliance in the specified directive:

EN ISO 14971:2012

EN ISO 15223-1:2016

EN 1041:2013

EN ISO 10993-1:2010

EN ISO 10993-5: 2009

EN ISO 10993-10: 2013

Declaration:

As the authorised representative, I declare under our sole responsibility that the products that are listed for use and detailed on page 1 fully comply and will continue to comply with the Medical Device Directive 93/42/EEC.

Yuyao Guangjing Medical Instruments Co., Ltd representative:

Signature:

Name: XUHANXIONG

Position:

DATE: 2022-08-11

