

CERTIFICATE ◆ 认证证书 ◆ CERTIFICATE ◆ 认证证书 ◆

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>.



Joe Zhou
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



TIFIKAT ◆ CERTIFICATE ◆ ZERTIFIKAT ◆ CERTIFICA



Verification of Conformity

Applicant: YUYAO GUANGJING MEDICAL INSTRUMENT CO., LTD.
 Address: Ditang Street, Yuyao City, Ningbo, China
 Product(s): Medical Tourniquet
 Type(s): Snap, Buckle Hole, TPE
 Product Classification: Class I

The submitted technical files including test report of the above products have been reviewed against the self declaration requirements of conformity for CE marking according to Medical Device Directive (93/42/EEC).

Standard(s) used for showing compliance with the essential requirements in the specified directive(s):
 Standard(s): EN ISO 14971:2012; EN ISO 15223-1:2016;
 EN 1041:2013 ; EN ISO10993-1:2010;
 EN ISO 10993-5:2009; EN ISO 10993-10:2013

The review result of the technical files and test report support the self declaration for the devices listed above. Where the manufacturer affix's the CE marking to the product listed they must ensure that all the requirements of the appropriate EU directive(s) have and continue to be met.

SUNGO Certification Company Limited

