



## BSS MEDICAL SUPPLY CO., LIMITED

Document Number : CE-DC-001

Version: A/1

### EC Declaration of Conformity

*Manufacturer:*

*whose single Authorized Representative:*

BSS MEDICAL SUPPLY CO., LIMITED

No.18, Shabian Road, Torch Hi-tech Industry Zone,

Zhonggshan, China.

info@bssmedical.com

Wellkang Ltd.

Suite B, 29 Harley Street

LONDON, W1G 9QR, U.K.

info@bssmedical.com

We, the manufacturer, herewith declare that the products

**Disposable ECG electrode  
B1,B2,B3,B4,B5,B6,B7,B8,B9,B10,B11,  
B12,B13,B15,B16,B17,B18,B19,B20,B22,B24**

**GMDN Code:11425**

meet the provisions of the Council Directive 93/42/EEC which apply to them.

The medical device has been assigned to class I according to Annex IX of the Directive 93/42/EEC. It bears the mark



Conformity assessment procedure: Annex VII of Directive 93/43/EEC

This Declaration of conformity is valid in connection with the release document for the respective batch of produced devices.

The above mentioned declaration of conformity is exclusively under the responsibility of

Company: BSS MEDICAL SUPPLY CO., LIMITED

Address: No.18, Shabian Road Torch Hi-tech Industry Zone, Zhongshan, China.

ZHONGSHAN2018/01/01

Place, date



Legally binding signature, Function



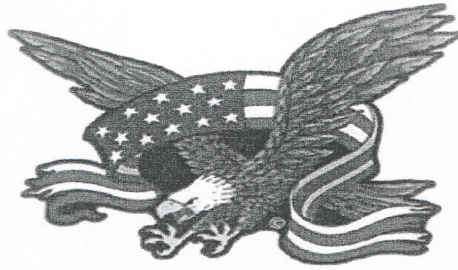
No.18,Shabian Road, Torch Hi-tech Industry Zone, Zhongshan, China

+86 760 85280100

www.bssmedical.com

info@bssmedical.com

**BSS-----Nothing Less Than Perfect!**



## Fiscal Year 2019 CERTIFICATION OF REGISTRATION

This certifies that:

**BSS MEDICAL SUPPLY CO., LIMITED**

**No. 18, Shabian Road Torch Hi-Tech Industry Zone, Zhongshan,  
Guangdong, China**

has completed the FDA Establishment Registration (as manufacturer , foreign exporter, contract manufacturer ) and Device Listing with the US Food & Drug Administration, through

U.S. Agent for FDA  
Communications:

**SUNGO TECHNICAL SERVICE INC.**  
6050 W EASTWOOD AVE APT 201, CHICAGO,  
ILLINOIS 60630, USA  
Telephone: +1-855-957-7779 / E-mail: US.FDA@sungogroup.com

**Owner/Operator Number: 10058649**

**Device Listing#: See annex**



*SUNGO Technical Service Inc. will confirm that such registration remains effective upon request and presentation of this certificate until the end of the calendar year stated above, unless said registration is terminated after issuance of this certificate. SUNGO Technical Service Inc. makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. This certificate does not denote endorsement or approval of the certificate-holder's device or establishment by the U.S. Food and Drug Administration. SUNGO Technical Service Inc. assumes no liability to any person or entity in connection with the foregoing.*

*Pursuant to 21 CFR 807.39, "Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding." The U.S. Food and Drug Administration does not issue a certificate of registration, nor does the U.S. Food and Drug Administration recognize a certificate of registration, SUNGO Technical Service Inc. is not affiliated with the U.S. Food and Drug Administration.*



Executive Director  
Issued: Oct. 18 2018  
Cert. No.: 2006US698518  
Expiration Date: Dec. 31 2019