



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,
Zhongshan, 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!



nqa.

This is to certify that the Quality Management System of

BSS MEDICAL SUPPLY CO., LIMITED

Unified Social Credit Code : 914420000946157180

Operation Address : Unit B, 3F, Building 3, 1 of No.18, Shabian Road, Torch Hi-Tech Industry Zone, Zhongshan City, Guangdong Province, China

Registered Address : Unit B, 3F, Building 3, 1 of No.18, Shabian Road, Torch Hi-Tech Industry Zone, Zhongshan City, Guangdong Province, China

applicable to

Production of disposable ECG electrode(within the scope of license qualification)

has been assessed and registered by NQA against the provisions of

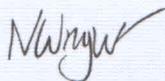
ISO 13485: 2016

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

Certified Clients shall accept regular surveillance assessments, the validity of certificates shall be maintained for the positive result of audit.

The information of this certificate can be checked on CNCA's website (www.cnca.gov.cn)

SNQA's website : www.snqa.com.cn



Managing Director



Certificate Number

46274

Date:

11 April 2019

Valid Until:

11 April 2022

EAC Code:

19





Newbest
Testing
Service

Certificate of Compliance

Certificate No. NB201811001

Issue Date: November.08,2018

Applicant : BSS MEDICAL SUPPLY CO., LIMITED
Address : No. 18 shabian road torch hi-tech indstry zone,
zhongshan, guangdong china
Sample Name : Disposable ECG Electrode
Sample Model NO. : -

This certificate of compliance is based on a test procedure or an evaluation of the above-mentioned product. This is to certify that the above-mentioned product is in compliance with the following standards:

European Council Directive 2011/65/EU on the Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment (RoHS)

It is only valid in connection with the test report (Report No.: NB20181105051).

RoHS



Signed for and on Behalf of NBTS



Gongdong Newbest Testing Services Co.,Ltd

No.1, 8/F, Guangyao Building, Shengfeng Road, Venture Industrial Park, Xinhe
Community, Wanjiang District, Dongguan City, China
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