



## **BSS MEDICAL SUPPLY CO., LIMITED**

Document Number : CE-DC-002

Version: A/0

### **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

**CMC MEDICAL DEVICES&  
DRUGS, S.L.**

C/Horacio Lengo N° 18 CP  
29006, Málaga-Spain

We, the manufacturer, herewith declare that the products

### **Surgical Pencil**

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



The product concerned has been manufactured under a quality management system according to Annex V of Directive 93/42/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.**



Issue Date: 18, Nov 2019

Expiry Date: 17, Nov 2024

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

**+86 760 85280100**

**www.bssmedical.com**

**info@bssmedical.com**

**BSS-----Better Signal Solution Partner**





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 and sales of disposable ECG electrode(within the scope of qualification license); sales of disposable neutral electrodes and high-frequency surgical electrodes (within the scope of qualification license)

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](http://www.cnca.gov.cn))

SNQA's website: [www.snqa.com.cn](http://www.snqa.com.cn)

Managing Director

Certificate Number: **46274**

Issue Date: 11 April 2019

Previous Certificate Expiry: 11 April 2022

The Latest Audit Date: 23 March 2022

Reissue Date: 18 April 2022

Valid Until: 11 April 2025



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