

Certificate of Registration



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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## BSS MEDICAL SUPPLY CO., LIMITED

### EU Medical Device Regulation 2017/745 Declaration of Conformity

<b>Manufacturer Name (*)</b>	BSS MEDICAL SUPPLY CO., LIMITED
<b>Manufacturer Address (*)</b>	No. 18, Shabian Road, Torch Hi-tech Industry Zone, Zhongshan, China 528437
<b>European Representative</b>	<b>CMC MEDICAL DEVICES&amp; DRUGS, S.L.</b> C/Horacio Lengo N°18 CP 29006, Malaga- Spain
<b>Name of the product (*)</b>	ECG Electrode
<b>Catalog/Reference Number (*)</b>	B1,B2,B4,B6, <b>B7</b> ,B8,B9, B10,B15.B18, <b>B5055</b> ,B4346,B4545,B2334,B3050, B3035,B2525,B2034,B2634,B5055,B2840,B4450,B3643, <b>B3644</b> ,B3240,B3 244,B3236,B4748,B3238,B4040,B3535,B6060M,B5050M,B4748M, B5050R,B4346R,B3030R,B2525N,B4748N,B4346W, <b>B5050W</b> ,B4045B, B4090B, BF22, BY22, FF22, FY22
<b>Purpose of usage (*)</b>	Application for ECG Monitoring or diagnosis with the connected equipment as medical sensors.
<b>Basic UDI-DI (*)</b>	697408178
<b>Product Classification / Classification Rule (*)</b>	(MDR, Annex VIII): Class I, Rule 1.
<b>GMDN Code (*)</b>	35035
<b>Conformity Assessment (*)</b> (Marked in gifts on products)	<input checked="" type="checkbox"/> ANNEX-IV (ANNEX II & III) Declaration of Conformity

(\*) Sections beginning with are required

BSS MEDICAL SUPPLY CO., LIMITED, As we declare under our responsibility that the devices covered by this declaration comply with the Regulation (EU) 2017/745 of the European Parliament and of the Council on Medical Devices and that the requirements specified in the Regulation are fulfilled for these devices.

**Signature Date and Place**

: 09, June 2022 ZHONGSHAN

**Valid Date and Place (if any)**

:31,12,2023 ZHONGSHAN

**Signed by**

: WU YAN HUA

**Mission**

:Marketing Manager

**(Signature and stamp)**



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

+86 760 85280100

www.bssmedical.com

info@bssmedical.com

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