



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)
SNQA's website: 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

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

Valid Date and Place (if any)

Signed by

Mission

(Signature and stamp)

: 09, June 2022 ZHONGSHAN

:31,12,2022 ZHONGSHAN

: WU YAN HU 吴彦虎

:Marketing Manager



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