

Către: Agenția Medicamentului  
și Dispozitivelor Medicale**NOTIFICARE**pentru înregistrarea dispozitivelor medicale în Registrul de stat al dispozitivelor medicale  
**nr. 73 din 11.10.2023**

Solicitantul **FPC "SOGNO" S.R.L.**, cu sediul MD-2028, un.Chișinău, str. Academiei, 2 tel.:  
(022)72-75-25 /069501992 , fax:(022)73-83-42, e-mail: [sognomd@gmail.com](mailto:sognomd@gmail.com), [pungaala@gmail.com](mailto:pungaala@gmail.com),  
solicit înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii și tipuri de  
dispozitive medicale pentru introducerea și punerea la dispoziție pe piață a:

**Conform Anexei nr. 3 "Lista dispozitivelor medicale BSS MEDICAL SUPPLY Co. Limited"****Se anexează următoarele acte:**

1. Declarație de Conformitate CE.
2. Scrisoarea autorizată a producătorului.
3. Declarație pe propria răspundere.
4. Lista dispozitivelor medicale.

Data: 11.10.2023

Semnătura

**Tabelul de recepționare a notificării**

(se completează de către Agenție în momentul depunerii notificării de către solicitant)

|                                                                                                    |  |
|----------------------------------------------------------------------------------------------------|--|
| Comentarii cu privire la acceptul/refuzul<br>recepționării notificării, inclusiv motivul refuzului |  |
| Data/nr. de ordine atribuit notificării de către<br>Agenție (în cazul acceptării recepționării)    |  |
| Numele, prenumele, funcția persoanei<br>responsabile de recepționarea dosarului                    |  |
| Semnătura persoanei responsabile                                                                   |  |

Către: Agenția Medicamentului  
și Dispozitive Medicale

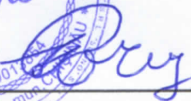
## DECLARAȚIE PE PROPRIE RĂSPUNDERE

Solicitant: **FPC "SOGNO" SRL**, cu sediul m. Chișinău, str. Academiei nr. 2, Republica Moldova, declar pe proprie răspundere, cunoscând prevederile art. 352<sup>1</sup>, Codul Penal al Republicii Moldova cu privire la falsul în declarații, că documentele și datele furnizate pentru notificarea dispozitivelor medicale:

**Conform Anexei nr. 3 "Lista dispozitivelor medicale BSS MEDICAL SUPPLY Co. Limited"**

Sunt autentice și corespund realității.

Data: 11.10.2023

Iarovoi Petru, Director  L.Ș.



## Lista dispozitivelor medicale BSS MEDICAL SUPPLY Co. Limited

| Numarul de catalog | Denumire                                     | Denumirea comerciala | Modelul               | Tip dispozitiv                        | Cod GMDN |
|--------------------|----------------------------------------------|----------------------|-----------------------|---------------------------------------|----------|
| B3030W             | ELECTROD ECG CU GEL LICIHD, SUPORT DIN SPUMĂ | BSS                  | Copii, rotund 30*30mm | Dispozitiv activ pentru diagnosticare | 35035    |
| B6060W             | ELECTROD ECG CU GEL LICIHD, SUPORT DIN SPUMĂ | BSS                  | Adult, rotund 60*60mm | Dispozitiv activ pentru diagnosticare | 35035    |

Iarovoi Petru, Director

Semnătura





## BSS MEDICAL SUPPLY CO., LIMITED

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We, BSS MEDICAL SUPPLY CO., LIMITED, based in No. 18, Shabian Road, Torch Hi-tech Industry Zone, Zhongshan, China 528437, assign FPC "SOGNO" SRL, based at No 2 Academiei str., Chisinau, Republic of Moldova, as authorized representative in correspondence with the conditions of the Regulation (EU)2017/745.

We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova.

Place: ZHONGSHAN

DATE: 11,10,2023

Signature: \_\_\_\_\_



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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**



## 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,<br>Zhongshan, China 528437                                                                                                                                                                                                                                 |
| European Representative                                          | CMC MEDICAL DEVICES& DRUGS, S.L.<br>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,<br>B3035,B2525,B2034,B2634,B5055,B2840,B4450,B3643,B3644,B3240,B3<br>244,B3236,B4748,B3238,B4040,B3535,B6060M,B5050M,B4748M,<br>B5050R,B4346R,B3030R,B2525N,B4748N,B4346W, B3030W, B5050W,<br>B6060W, B4045B, B4090B, BF22, BY22, FF22, FY22 |
| Purpose of usage (*)                                             | Application for ECG Monitoring or diagnosis with the connected<br>equipment as medical sensors.                                                                                                                                                                                                               |
| Basic UDI-DI (*)                                                 | 697408178                                                                                                                                                                                                                                                                                                     |
| Product Classification /<br>Classification Rule (*)              | (MDR, Annex VIII): Class I, Rule 1.                                                                                                                                                                                                                                                                           |
| GMDN Code (*)                                                    | 35035                                                                                                                                                                                                                                                                                                         |
| Conformity Assessment<br>(*)<br>(Marked in gifts on<br>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)

:11,10,2023

:31,12,2023

:WU YAN HUA

:Marketing Manager



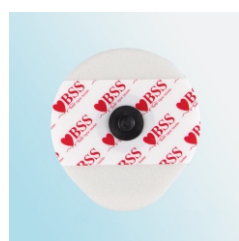
No.18,Shabian Road, Torch Hi-tech Industry Zone, Zhongshan, China  
+86 760 85280100 [www.bssmedical.com](http://www.bssmedical.com) [info@bssmedical.com](mailto:info@bssmedical.com)

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

## Radiolucent Electrodes for ECG Monitoring

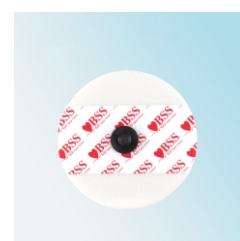
Recommended for: Radiology · Emergency · Cath Lab · Surgery

**B4346R**



43\*46mm  
Foam Backing/ Solid Gel  
50 pcs/ bag 40 bags/ ctn  
(2000 pcs/ ctn)

**B5050R**



50\*50mm  
Foam Backing/ Solid Gel  
50 pcs/ bag 40 bags/ ctn  
(2000 pcs/ ctn)

**B5050NR**

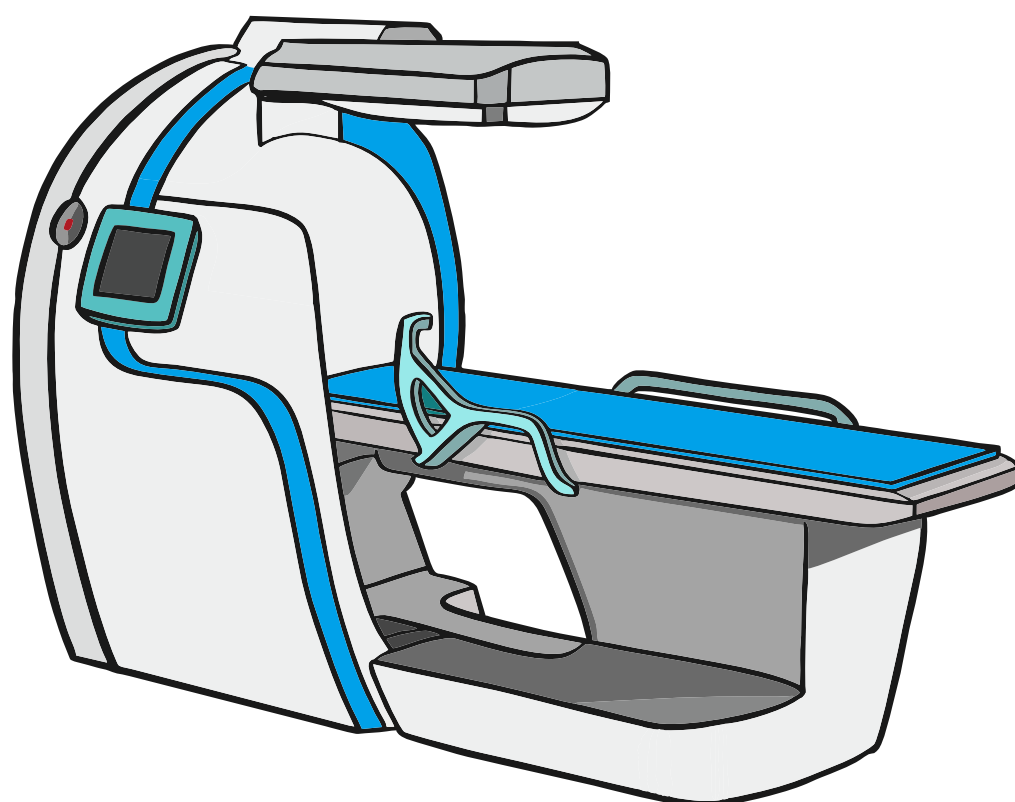


50\*50mm  
Cloth Backing/ Solid Gel  
50 pcs/ bag 40 bags/ ctn  
(2000 pcs/ ctn)

**B3030R**



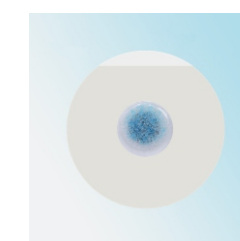
30\*30mm  
Foam Backing/ Solid Gel  
50 pcs/ bag 80 bags/ ctn  
(4000 pcs/ ctn)



## Other Electrodes

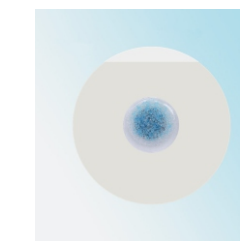
Wet Gel Electrodes

**B3030W**



30\*30mm  
Foam Backing/ Liquid Gel  
50 pcs/ bag 20 bags/ ctn  
(1000 pcs/ ctn)

**B6060W**



60\*60mm  
Foam Backing/ Liquid Gel  
50 pcs/ bag 20 bags/ ctn  
(1000 pcs/ ctn)

Electrodes Allergic Constitution

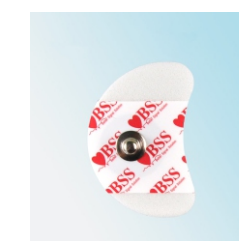
**B3643**



36\*43mm  
Foam Backing/ Solid Gel  
50 pcs/ bag 40 bags/ ctn  
(2000 pcs/ ctn)

EEG / ABR Electrodes

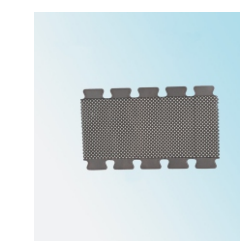
**B2840**



28\*40mm  
Foam Backing/ Solid Gel  
50 pcs/ bag 40 bags/ ctn  
(2000 pcs/ ctn)

Resting Tab

**B2334**



23\*34mm  
100pcs/ bag 10bags/box  
10boxes/ctn (10000pcs)