



APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. Country: *United States of America*

This public document

2. has been signed by CDR Cesar A. Perez, PhD.

3. acting in the capacity of Director, DRP2: Division of Establishment Support

4. bears the seal/stamp of U. S. Department of Health and Human Services

Certified

5. at Washington, D.C.

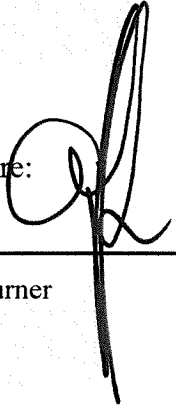
6. the seventeenth of July, 2023

7. by *Assistant Authentication Officer, United States Department of State*

8. No. 23043899-7

9. Seal/Stamp:

10. Signature:



Chana M Turner



**U.S. FOOD & DRUG
ADMINISTRATION**

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Certificate No. 8126-4-2023

CERTIFICATE TO FOREIGN GOVERNMENT

In order to allow the importation of United States products into foreign countries, the U.S. Food and Drug Administration (FDA) certifies the following information concerning the product(s) to be exported listed below:

Name of Product(s)

See Attached List

(Four Pages)

Name of Manufacturer/Distributor, Address

See Attached List

(One Page)

The product(s) described above (and the manufacturing/distribution site(s) which produces/distributes it) is subject to the jurisdiction of the FDA under the Federal Food, Drug, and Cosmetic Act.

It is certified that the above product(s) may be marketed in, and legally exported from, the United States of America at this time. The manufacturing plant(s) in which the product(s) is produced is subject to periodic inspections.

Sincerely,

CDR Cesar A. Perez, PhD, Director
DRP2: Division of Establishment Support
Office of Regulatory Programs
Office of Product Evaluation and Quality
Center for Devices and Radiological Health
U.S. Food and Drug Administration, DHHS

This certificate is valid from April 20, 2023 to April 19, 2025.



E04507673

FDA
CENTER FOR DRUGS
Certificate No. 8126-4-2023
Certificate to Foreign Govern
Name of Man
M.



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Certificate No. 8126-4-2023

Certificate to Foreign Government - Name of Manufacturer/Distributor Attachment Page 1 of 1

Name of Manufacturer

Manufacturer/Manufacturing Facility

BSN Medical S.A. de C.V.
Av. del Parque SN Villa Florida
Reynosa, Tamaulipas
MEXICO 88715

Name of Manufacturer/Distributor

Legal Manufacturer and Distributor

BSN MEDICAL, INC.
5825 CARNEGIE BLVD.
CHARLOTTE, NC
USA 28209

---END OF MANUFACTURER/DISTRIBUTOR LIST---



E04507674



CENTER FOR DEVICE

Certificate No. 8126-4-2023
Name of Manufacturer
Manufacturer/MS
BSN (Merit)



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Certificate No. 8126-4-2023

Certificate to Foreign Government - Name of Product(s) Attachment Page 1 of 4

Name of Manufacturer

Manufacturer/Manufacturing Facility

BSN Medical S.A. de C.V.
Av. del Parque SN Villa Florida
Reynosa, Tamaulipas
MEXICO 88715

Name of Manufacturer/Distributor

Legal Manufacturer and Distributor

BSN MEDICAL, INC.
5825 CARNEGIE BLVD.
CHARLOTTE, NC
USA 28209

Name of Product(s)

Bandage, Cast

71985-00030	GYPSONA 6CM X 2M 480
71985-00031	GYPSONA 8CM X 2M 380
71985-00032	GYPSONA 10CM X 3M 192
71985-00033	GYPSONA 12CM X 3M 144
71985-00034	GYPSONA 15CM X 3M 120
71985-00035	GYPSONA 20CM X 4M 80
71985-00040	GYPSONA 5CM X 2.7M 12
71985-00041	GYPSONA 7.5CM X 2.7M 12
71985-00042	GYPSONA 10CM X 2.7M 12
71985-00043	GYPSONA 15CM X 2.7M 12
71985-00044	GYPSONA 20CM X 2.7M 12
71987-00012	GYPSS 10CM X 18M 1 EN LPL2
71987-00013	GYPSONA 10CM X 2.75M 12 LPL2
71987-00014	GYPSONA 10CM X 4.5M 72 LPL2
71987-00015	GYPSONA 15CM X 2.75M 12 LPL2
71987-00016	GYPSONA 15CM X 4.5M 48 LPL2
71987-00017	GYPSONA 20CM X 2.75M 48 LPL2
71987-00018	GYPSONA 20CM X 4.5M 48 GYPSO LPL2
71987-00019	GYPSONA 5CM X 2.75M 24 LPL2
71987-00020	GYPSONA 7.5CM X 2.7M 72 GYPSO LPL2
71987-00021	GYPSONA 10CM X 2.7M 72 LPL4 6CT/1
71987-00022	GYPSONA 10CM X 4.5M 72 GYPSO LPL4
71987-00023	GYPSONA 20CM X 4.5M 48 GYPSO LPL4
71987-00024	GYPSONA 7.5CM X 2.7M 72 GYPSO LPL4
71987-00025	GYPSONA 12.5CM X 75CM 300 GYPSON LPL
71987-00026	GYPSONA 15CM X 2.7M 72 GYPSON LPL4
71987-00027	GYPSONA 15CM X 4.5M 48 LPL4
71987-00037	GYPSONA 90CM X 5.4M 1
71987-00040	GYPSONA 10CM X 3.5M 48
71987-00045	GYPSONA 15CM X 3.5M 24
71987-00050	GYPSONA 20CM X 3.5M 24
71987-00051	GYPSONA 5CM X 2.75M 24
71987-00054	GYPSONA 7.5CM X 3.5M 48
71987-00055	GYPSONA EX 10X2.7
71987-00056	GYPSONA EX 15X2.7
71987-00065	GYPSONA 15CM X 18M 1 LPL2
71988-00001	GYPSONA GYP S/DISP 10CM DISP
71988-00002	GYPSONA GYP S/DISP 15CM DISP
71988-00003	GYPSONA GYP S/DISP 20CM DISP
71988-00004	GYPSONA GYP SG 5CMX2.75M ROLL
71988-00005	GYPSONA GYP SLABBOX 12.7X76CM N**
71988-00008	GYPSONA 10CM X 75CM 300 GYPSO LPL2



FDA U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
CENTER FOR DEVICES AND RESEARCH
Certificate No. 8126-4-2023
71988-00009
71988-00010
71988-00011
Certificate to Foreign Government
GYPSONA

E04507675



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Certificate to Foreign Government - Name of Product(s) Attachment Page 2 of 4

71988-00009	GYPSONA 12.5CMX 75CM 300 GYPSO LPL2
71988-00010	GYPSONA 7.5CM X 75CM 300 GYPSO LPL2
71988-00011	GYPSONA 10CM X 75CM 300 GYPSO LPL4
71988-00012	GYPSONA 5CM X 2.7M 72 LPL4 3CT/24
71988-00013	GYPSONA 7.5CM X 75CM 300 GYPSO LPL4
71988-00021	GYPSONA 10CM X 20M 1
71988-00022	GYPSONA 15CM X 20M 1
71988-00023	GYPSONA 20CM X 20M 1
71988-00024	GYPSONA SLABS 10CMX20M-PACK OF 1
71988-00025	GYPSONA PST BA 1 U/W 20LB BULK BAND
71991-00000	GYPSONA ROLL 15 LAYERS 10CM 1
71991-00001	GYPSONA 10CM 1 GYPSO ROLL 10 LAYERS
71991-00002	GYPSONA 12.5CM 1 GYPSO ROLL 10 LAYERS
71991-00003	GYPSONA ROLL 10 LAYERS 15CM 1
71991-00004	GYPSONA 5CM 1 GYPSO ROLL 10 LAYERS
71991-00005	GYPSONA 7.5CM 1 GYPSO ROLL 10 LAYER
71991-00006	GYPSONA 12.5CM 1 GYPSO ROLL 15 LAYERS
71991-00007	GYPSONA 15CM 1 GYPSO ROLL 15 LAYERS
71991-00008	GYPSONA 4" X 3YDS 12 GYPSO S
71991-00009	GYPSONA 15CMX2.7MX12S
71991-00010	GYPSONA 7.5CMX2.7MX12S
71991-00025	GYPSONA 6" X 3 YDS W 12
71991-00026	GYPSONA 8" X 3 YDS W 12
71993-00002	GYPSONA 12 GYPSO S 6INCHX3V 1CT/12
71993-00031	GYPSONA 2" X 3YDS 12 X-FAST
71993-00032	GYPSONA 3" X 3YDS 12 X-FAST
71993-00033	GYPSONA 4" X 5YDS 12 X-FAST
71993-00034	GYPSONA 6" X 5YDS 12 X-FAST
71993-00035	GYPSONA 8" X 5YDS 12 X-FAST
71993-00038	GYPSONA S FAST 2" X 3YDS 12
71993-00039	GYPSONA S XTFAST 2" X 3YDS 12
71993-00053	GYPSONA S FAST 3" X 3YDS 12
71993-00054	GYPSONA S XTFAST 3" X 3YDS 12
71993-00060	GYPSONA S FAST 4" X 5YDS 12
71993-00061	GYPSONA S XTFAST 4" X 5YDS 12
71993-00065	GYPSONA S FAST 5" X 5YDS 12
71993-00066	GYPSONA S XTFAST 5" X 5YDS 12
71993-00067	GYPSONA S FAST 6" X 5YDS 12
71993-00068	GYPSONA S XTFAST 6" X 5YDS 12
71993-00069	GYPSONA S FAST 8" X 5 YDS 12
71993-00070	GYPSONA S XTFAST 8" X 5YDS 12
71993-00071	GYPSONA 4" X 4YDS 12 ELASTIC
71993-00072	GYPSONA 5" X 4YDS 12 ELASTIC
71993-00074	GYPSONA 3" X 15" 50 FAST
71993-00075	GYPSONA 3" X 15" 50 X-FAST
71993-00076	GYPSONA 4" X 15" 50 FAST
71993-00077	GYPSONA 4" X 15" 50 X-FAST
71993-00078	GYPSONA 5" X 30" 50 FAST
71993-00079	GYPSONA 5" X 30" 50 X-FAST
71993-00080	GYPSONA 5" X 45" 50 FAST
71993-00086	GYPSONA 3" X 15" 50 X-FAST
71993-00087	GYPSONA 4" X 15" 50 X-FAST
71993-00088	GYPSONA 5" X 30" 50 X-FAST
71993-00089	GYPSONA SPL OAR 6" X 20' 1
71993-00090	GYPSONA SPL OAR 5" X 20' 1
71993-00091	GYPSONA SPL OAR 4" X 20' 1
71993-00092	GYPSONA SPL OAR 3" X 20' 1
71993-00093	GYPSONA SPL OAR 2" X 20' 1



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FDA
CENTER FOR DEVICES
Certificate No. 8126-4-2023
Certificate to Foreign Government
72003-00028
72003-00029
72003-00030
GYPSOIA S 10



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Certificate to Foreign Government - Name of Product(s) Attachment Page 3 of 4

72003-00028	GYPSONA S 10CM X 2.74M 12
72003-00029	GYPSONA S 15CM X 2.74M 12
72003-00030	GYPSONA S 20CM X 2.74M 12
72003-00031	GYPSONA S 5CM X 2.74M 12
72003-00055	GYPSONA S 10CM X 2.75M 12
72003-00056	GYPSONA S 15CM X 2.75M 12
72003-00057	GYPSONA S 20CM X 2.75M 12
72003-00058	GYPSONA S 5CM X 2.75M 12
72003-00059	GYPSONA S 7.6CM X 2.75M 12
72003-00060	GYPSONA S 10CM X 4.5M 8
72003-00061	GYPSONA S 15CM X 4.5M 8
72003-00062	GYPSONA S 20CM X 4.5M 8
72945-00000	YSO GYPSONA S 5CM X 2.75M W 12
72945-00001	YSO GYPSONA S 7.5CM X 2.75M W 12
72945-00002	YSO GYPSONA S 10CM X 2.75M W 12
72945-00003	YSO GYPSONA S 15CM X 2.75M W 12
72945-00004	YSO GYPSONA S 20CM X 2.75M W 12
73461-00053	GYPSONA 12.5CM X 3M 20
73461-00054	GYPSONA 15CM X 3M 20
73461-00090	GYPSONA 10CM X 3M 12
73461-00091	GYPSONA 12.5CM X 3M 12
73461-00092	GYPSONA 15CM X 3M 12
73461-00093	GYPSONA 20CM X 3M 12
73461-00094	GYPSONA 20CM X 4M 12
73461-00095	GYPSONA 5CM X 3M 12
73461-00097	GYPSONA 10CM X 3M 12
73461-00098	GYPSONA 12.5CM X 3M 12
73461-00099	GYPSONA 15CM X 3M 12
73462-00000	GYPSONA POFP 2" X 3YD W 12
73462-00001	GYPSONA POFP 3" X 3YD W 12
73462-00002	GYPSONA POFP 4" X 5YD W 12
73462-00003	GYPSONA POFP 5" X 5YD W 12
73462-00004	GYPSONA POFP 6" X 5YD W 12
73462-00005	GYPSONA POFP 8" X 5YD W 12
73471-00000	GYPSONA 3" X 5YDS 24
73471-00001	GYPSONA 4" X 5YDS 12
73471-00002	GYPSONA 5" X 5YDS 12
73471-00003	GYPSONA 6" X 5YDS 12
73471-00004	GYPSONA 8" X 5YDS 12
73471-00010	GYPSONA 2" X 3YDS 24
73471-00011	GYPSONA 3" X 3YDS 12
73471-00012	GYPSONA 4" X 3YDS 12
73471-00013	GYPSONA 5" X 3YDS 12
73471-00014	GYPSONA 6" X 3YDS 12
73471-00015	GYPSONA 8" X 3YDS 12
73471-00016	GYPSONA 3" X 5YDS 12
73471-00017	GYPSONA 4" X 5YDS 12
73471-00018	GYPSONA 5" X 5YDS 12
73471-00019	GYPSONA 6" X 5YDS 12
73471-00020	GYPSONA 8" X 5YDS 12
73473-00000	GYPSONA 2" X 3YD W 12 ES
73473-00001	GYPSONA 3" X 3YD W 12 ES
73473-00002	GYPSONA 3" X 5YD W 12 ES
73473-00003	GYPSONA 4" X 3YDS W 12 ES
73473-00004	GYPSONA 4" X 5YD W 12 ES
73473-00005	GYPSONA 5" X 5YD W 12 ES
73473-00006	GYPSONA 6" X 5YD W 12 ES
73473-00007	GYPSONA 8" X 5YD W 12 ES





Center for Devices
Certificate No. 8126-4-2023
Certificate to Foreign Gover
73473-00008 GYPSONA 6" V
73473-00009 GYPSONA 6" V
74480-00000 GYPSONA 6" V

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73473-00008	GYPSONA 6" X 3YD W 12 ES
73473-00009	GYPSONA 8" X 3YD W 12 ES
74480-00050	BANDAGE, 4"X5 YD, W/CORE, FAST
END OF PRODUCT LIST	





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