



Government of Pakistan
Ministry of National Health Services
Regulation & Coordination

Sr. No. 2348

Drug Regulatory Authority of Pakistan



FORM-8A

[see rule 15(5)]

**CERTIFICATE OF ENLISTMENT OR REGISTRATION OF A
MEDICAL DEVICE OR ACCESSORY OR COMPONENT FOR IMPORT**

Licence No. ELI-00604

Date of issue: 03/08/2021

F.No: 12-182/2020-MD

M/s IBS Pharmaceuticals

Office No.634, 6thFloor, Pak Medical Center, Khyber Bazar, Peshawar

The medical device as per details given below has been registered or enlisted under the DRAP Act, 2012 and the rules made there-under subject to the conditions appearing hereinafter:

Enlistment/ Registration No.	Name of medical device or accessory or component	Brief description	Class	Shelf life
(1)	(2)	(3)	(4)	(5)
MDIR-0002698	Bionen Needle Electrodes for EMG Needle (Needle Electrodes for EMG)	The Disposable Concentric Needle Electrode is used for electromyography (EMG) recording for examination of the peripheral neuromuscular system, by registration of the electrical activity from the muscles The BOTOX Injection Needle Electrode is intended to be inserted in the muscle while recording electromyography activity and proximally connected to electromyography recording equipment. [Codes & Sizes at Annex-A]	B	05 Years

Name and complete address of manufacturer:

M/s Bionen S.A.S


di Barbara Nencioni & Co., Via P. Petrocchi, 42/1- 50127, Florence, Italy

Dr. Ghazafar Ali Khan
Additional Director (MD&MC) Secretary MDB
Drug Regulatory Authority of Pakistan
M/o National Health Service,
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Government of Pakistan
Islamabad



2. This enlistment/registration shall be valid for a period of five years from the date mentioned above unless earlier suspended or cancelled.
3. The name shall be changed in case it has resemblance with already enlisted/registered medical device.
4. This enlistment/registration is subject to the conditions specified in the DRAP Act, 2012 and the rules made there-under.

Renewal Date: 02/08/2026

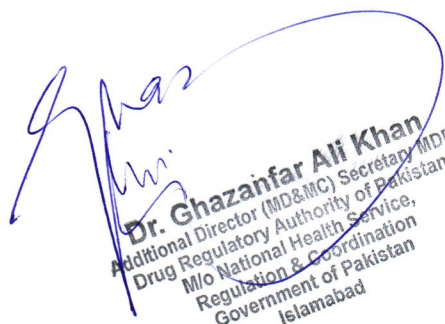

Dr. Ghaziantar Ali Khan
Additional Director (Medical) Secretary MDB
Drug Regulatory Authority of Pakistan
Ministry of National Health Service,
Regulation & Coordination
Government of Pakistan
Secretary
Medical Device Board
Seal:



ANNEXURE - (A)

Bionen Needle Electrodes for EMG Needle (Needle Electrodes for EMG)

0028.011, 0028.012, 0028.013, 0028.014, 0028.015, 0028.016, 0028.017, 0028.018, 0028.111, 0028.112, 0028.113, 0028.211, 0028.212, 0028.213, 0028.214, 0028.215, 0028.312, 0028.314, 0028.318, 0028.612, 0028.614, 0028.618, 0028.712, 0028.714, 0028.718


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