

Drugs Controller General (India)
Directorate General of Health Services
FDA Bhawan, Kotla Road, New Delhi

Notice

File No. 29/Misc./03/2020-DC (201)

Date: 27 SEP 2021

Subject: Classification of Medical Device pertaining to Neurological under the provisions of Medical Devices Rules, 2017- Reg.

Safety, quality and performance of medical devices are regulated under the provisions of the Drugs and Cosmetics Act, 1940 and rules made thereunder. For the regulation of medical devices with respect to the import, manufacture, sale and distribution, clinical investigation, the Central Government, after consultation with the Drugs Technical Advisory Board, has notified Medical Devices Rules, 2017 vide G.S.R. 78 (E) dated 31.01.2017 which is already implemented from 01.01.2018

In this connection, in exercise of the powers conferred under sub-rule (3) of rule 4 of Medical Devices Rules, 2017, the undersigned hereby classifies the medical devices, based on the intended use, risk associated with the device and other parameters specified in the First Schedule of the Medical Devices Rules-2017

List of medical devices placed at Appendix A subjected to the followings:

1. General intended use given against each of the devices is for guidance to the applicants intends to furnish application of import or manufacture of medical devices under the provisions of Medical Devices Rules, 2017. However, a device may have specific intended use as specified by its manufacturer.
2. This list is dynamic in nature and is subject to revision from time to time under the provisions of the Medical Devices Rules, 2017.



(Dr. V. G. Somani)
Drugs Controller General (India)

To,

1. CDSCO Website

File.No.29/Misc/03/2020-DC (201)
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
FDA, Bhawan, new Delhi-110002
Notice

Classification of Medical Devices Pertaining to Neurological

Sr. No.	Device Name	Intended Use	Risk Class
1	Analgesic PENS system	Intended to deliver controlled electrical impulses directly to the subcutaneous tissue (i.e., invasively) in the vicinity of a peripheral nerve as relief of chronic neuropathic pain.	B
2	Analgesic TENS system	Intended to treat pain by transcutaneous electrical stimulation on peripheral nerves.	B
3	Analytical non-scalp cutaneous electrode	Electrical conductor designed to be attached to the skin surface of a patient outside of the hair line (i.e., non-scalp) to conduct electrical signals to a parent device for electrophysiological recording/monitoring.	A
4	Analytical non-scalp cutaneous lead	Intended to conduct electrical signals between a skin electrode(s) or needle electrode(s) [electrode not included] and a device designed for electrophysiological recording/monitoring [e.g., electromyography (EMG), evoked potentials (EP), bioelectrical impedance].	A
5	Analytical scalp electrode	Intended to be attached to the scalp surface of a patient to transmit changes in the electrical potential of various areas of the brain for recording/monitoring by a connected parent device [i.e., an electroencephalograph (EEG), sleep, or evoked potential recording device].	B
6	Analytical scalp lead	Intended to connect an electroencephalographic electrode(s) to an electroencephalographic system to facilitate the transmission of the electrical signals during encephalography (EEG).	B
7	Aneurysm clip.	An aneurysm clip is a device used to occlude an intracranial aneurysm (a balloonlike sac formed on a blood vessel) to prevent it from bleeding or bursting	D
8	Antiseizure/psychiatric-therapy vagus nerve electrical stimulation system	Implantable device intended to apply periodic electrical stimuli to the vagus nerve to help control seizures and/or to help treat psychiatric disorder symptoms (e.g., depression).	D
9	Atrial cerebrospinal fluid catheter	Intended to be implanted as the distal component of a ventriculoatrial shunt to channel cerebrospinal fluid (CSF) to the right atrium where it can be absorbed into the body.	D
10	Autonomic neuropathy heart rate meter	Intended to diagnose autonomic nervous system dysfunction (autonomic neuropathy).	C

11	Bare-metal intracranial vascular stent	Intended to be implanted into the base or parent artery of an intracranial aneurysm.	D
12	Behavioural therapy electrical stimulation system	Intended in the treatment of obsessive/compulsive behaviour and drug abuse, by applying electrical impulse(aversion therapy).	C
13	Bladder/bowel-evacuation implantable electrical stimulation system	Intended to empty the urinary bladder and/or the bowels by applying electrical stimuli typically to the cone-shaped end of the spinal cord (conus medularis).	D
14	Brain injury adjunctive interpretive electroencephalograph assessment aid.	A brain injury adjunctive interpretive electroencephalograph assessment aid is a prescription device that uses a patient's electroencephalograph (EEG) to provide an interpretation of the structural condition of the patient's brain in the setting of trauma. A brain injury adjunctive interpretive EEG assessment aid is for use as an adjunct to standard clinical practice only as an assessment aid for a medical condition for which there exists other valid methods of diagnosis	C
15	Brain-responsive electrical stimulation system	Intended to continuously monitor brain activity and deliver electrical stimuli to seizure foci in response to neurological disorders (e.g., epilepsy).	D
16	Cardiac-therapy vagus nerve electrical stimulation system	Intended to apply periodic stimuli to the vagus nerve as a treatment for cardiac failure.	D
17	Cerebral perfusion catheter	Intended for brain protection during profound hypothermic circulatory arrest during aortic surgery.	D
18	Cerebrospinal fluid manometer,	Intended to measure the cerebrospinal fluid (CSF) pressure/intracranial pressure via lumbar puncture.	C
19	Cerebrospinal fluid shunt valve programmer	Intended to noninvasively modify the operating pressure of a programmable, non-active, implanted cerebrospinal fluid (CSF) shunt valve that is part of a CSF shunt.	C
20	Coma-arousal vagus nerve electrical stimulation system	Intended to apply periodic stimuli to the vagus nerve for the purpose of exciting the patient to arousal from a vegetative state (i.e., a deep coma).	D
21	Cortical electrode.	A cortical electrode is an electrode which is temporarily placed on the surface of the brain for stimulating the brain or recording the brain's electrical activity	D

22	Cranial bur,	Intended to fit into an appropriate powered handpiece that provides the rotation allowing the user to excavate soft or hard skull tissue.	A
23	Cranial electrotherapy stimulator.	A cranial electrotherapy stimulator is a device that applies electrical current to a patient's head to treat insomnia, depression, or anxiety	D
24	Cranial perforator	Metallic rotary endpiece designed to cut a hole(s) or a circular section(s) of the skull vault (calvarium) by attaching to powered drill/handpiece.	B
25	Cranial trephine,	Intende as a neurosurgical blade used to cut/remove circular sections of the skull vault (calvarium) to provide access to the interior	A
26	Craniotomy power tool system handpiece	Intended to be used to rotate a cranial cutting tool (i.e., a drill bit, bur, trephine or perforator) in order to produce a hole or holes in the skull vault (calvarium).	C
27	Cryogenic surgical device.	A cryogenic surgical device is a device used to destroy nervous tissue or produce lesions in nervous tissue by the application of extreme cold to the selected site	D
28	Cutaneous electrode.	A cutaneous electrode is an electrode that is applied directly to a patient's skin either to record physiological signals (e.g., the electroencephalogram) or to apply electrical stimulation	B
29	Deep brain electrical stimulation system	Designed to apply electrical stimuli to specific areas of the deep brain for the treatment of movement disorders, psychiatric disorders and/or to treat chronic, severe, intractable pain.	D
30	Deep brain electrical stimulation system lead	Intended to be implanted in specific areas of the deep brain and used along with deep brain electrical simulation system.	C
31	Depth electrode.	A depth electrode is an electrode used for temporary stimulation of, or recording electrical signals at, subsurface levels of the brain	C
32	Diagnostic peripheral nerve electrical stimulation system	Intended to apply electrical stimuli in one peripheral region of the body while the response is monitored in another peripheral region.	C
33	Diagnostic somatosensory tactile stimulation system	Intended to be used to apply tactile stimuli to the body (e.g., pneumatic activation of a membrane to the fingers and lips) typically for evoked response procedures to investigate the function and potential disorders of the brain.	B
34	Diskectomy system, percutaneous, automatic	Intended for the percutaneous (through the skin) removal of the nucleus pulposus from the lumbar disc.	D
35	Dura mater sealant	Intended to be applied to sutured dura mater to prevent cerebrospinal fluid (CSF) leakage during healing.	C

36	Echoencephalograph.	An echoencephalograph is an ultrasonic scanning device (including A-scan, B-scan, and doppler systems) that uses noninvasive transducers for measuring intracranial interfaces and blood flow velocity to and in the head	C
37	Ejaculation electrical stimulation system	Intended to apply electrical stimuli to the nerves that control ejaculation.	C
38	Electroconvulsive therapy system	Intended to apply strong electrical stimuli to a patient's brain to induce convulsions and loss of consciousness, typically to treat major depression, schizophrenia, or mania.	C
39	Electroencephalogram (EEG) signal spectrum analyzer.	An electroencephalogram (EEG) signal spectrum analyzer is a device used to display the frequency content or power spectral density of the electroencephalogram (EEG) signal	B
40	Electroencephalograph electrode/lead tester.	An electroencephalograph electrode/lead tester is a device used for testing the impedance (resistance to alternating current) of the electrode and lead system of an electroencephalograph to assure that an adequate contact is made between the electrode and the skin	B
41	Electroencephalograph test signal generator.	An electroencephalograph test signal generator is a device used to test or calibrate an electroencephalograph	B
42	Electroencephalograph tester	Intended to perform quality control procedures on an electroencephalograph (EEG) machine and/or a sleep recording machine.	A
43	Electroencephalograph.	An electroencephalograph is a device used to measure and record the electrical activity of the patient's brain obtained by placing two or more electrodes on the head	C
44	Electroencephalographic electrode cap	Analytical scalp electrodes preconfigured within a head-worn device to use with electroencephalography (EEG).	B
45	Electroencephalographic long-term ambulatory recorder	Intended to continuously record electroencephalographic signals in ambulatory patients for periods usually from 24 to 72 hours to assess a variety of neurological conditions (e.g., epilepsy) and psychiatric disorders.	B
46	Electroencephalographic monitoring system	Intended to continuously measure the electrical signals produced by a patient's brain and display/record them as an electroencephalogram (EEG) to evaluate brain function. Alongwith which measuring of other physiological parameters such as electromyogram (EMG), respiration wave forms, blood pressure, ocular motility, and/or haemoglobin oxygen saturation (SpO2) and carbon dioxide (CO2) in relation to EEG.	C
47	Electromyograph	Intended in clinical diagnosis of muscular disorders to evaluate muscle weakness and to determine if the weakness is related to the muscles themselves or a problem with the nerves that supply the muscles.	B
48	Electronystagmograph	Intended for detecting the electrical potential caused by eye movements.	B

49	Epicranial brain electrical stimulation system	Intended to apply weak, pulsed (not continuous) electrical stimuli from beneath the scalp to specific areas of the brain for the treatment of focal epilepsy.	C
50	Esthesiometer.	An esthesiometer is a mechanical device which usually consists of a single rod or fiber which is held in the fingers of the physician or other examiner and which is used to determine whether a patient has tactile sensitivity	A
51	Extramuscular diaphragm/phrenic nerve electrical stimulation system	Intended to provide ventilatory support to a patient with diaphragm dysfunction of neuromuscular origin through electrical stimulation of the phrenic nerve, to contract the diaphragm rhythmically (using extramuscular electrodes) and cause the patient to draw breath in a manner similar to natural breathing.	D
52	Facial nerve locating system	Intended to locate a facial nerve by applying an electrical stimulus.	B
53	Gait-enhancement electrical stimulation system, external	Intended to improve the gait in a patient suffering from partial paralysis of the lower extremities or other neuromuscular disorders by applying external electrical simulation.	B
54	Gait-enhancement electrical stimulation system, implantable	Intended to improve the gait in a patient suffering from partial paralysis of the lower extremities or other neuromuscular disorders by applying internal electrical simulation.	D
55	Home seizure monitoring system	Intended to detect and record a seizure by continuous measurement of one or more physical/physiological parameters (e.g., body motion, electrical activity of the heart or skeletal muscles) in a patient with epilepsy during daily activities and/or sleep in the home; some types may also be used in clinical settings.	C
56	Human dura mater.	Human dura mater is human pachymeninx tissue intended to repair defects in human dura mater	D
57	Implantable pulse generator mesh bag, bioabsorbable	Intended to envelop an implantable pulse generator (IPG) (e.g., cardiac pacemaker/defibrillator, neurostimulator) to stabilize the implant in the subcutaneous pocket in which it is implanted.	D
58	Implantable spinal cord electrical stimulation system programmer	Device designed to change, telemetrically, one or more of the operating parameters (the programs) of an implanted spinal cord electrical stimulation system pulse generator (EPG).	C
59	Implanted cerebellar stimulator.	An implanted cerebellar stimulator is a device used to stimulate electrically a patient's cerebellar cortex for the treatment of intractable epilepsy, spasticity, and some movement disorders. The stimulator consists of an implanted receiver with electrodes that are placed on the patient's cerebellum and an external transmitter for transmitting the stimulating pulses across the patient's skin to the implanted receiver	D

60	Implanted diaphragmatic/phrenic nerve stimulator.	An implanted diaphragmatic/phrenic nerve stimulator is a device that provides electrical stimulation of a patient's phrenic nerve to contract the diaphragm rhythmically and produce breathing in patients who have hypoventilation (a state in which an abnormally low amount of air enters the lungs) caused by brain stem disease, high cervical spinal cord injury, or chronic lung disease. The stimulator consists of an implanted receiver with electrodes that are placed around the patient's phrenic nerve and an external transmitter for transmitting the stimulating pulses across the patient's skin to the implanted receiver	D
61	Implanted intracerebral/subcortical stimulator for pain relief.	An implanted intracerebral/subcortical stimulator for pain relief is a device that applies electrical current to subsurface areas of a patient's brain to treat severe intractable pain. The stimulator consists of an implanted receiver with electrodes that are placed within a patient's brain and an external transmitter for transmitting the stimulating pulses across the patient's skin to the implanted receiver	D
62	Implanted neuromuscular stimulator.	An implanted neuromuscular stimulator is a device that provides electrical stimulation to a patient's peroneal or femoral nerve to cause muscles in the leg to contract, thus improving the gait in a patient with a paralyzed leg. The stimulator consists of an implanted receiver with electrodes that are placed around a patient's nerve and an external transmitter for transmitting the stimulating pulses across the patient's skin to the implanted receiver. The external transmitter is activated by a switch in the heel in the patient's shoe	D
63	Implanted spinal cord stimulator for bladder evacuation.	An implanted spinal cord stimulator for bladder evacuation is an electrical stimulator used to empty the bladder of a paraplegic patient who has a complete transection of the spinal cord and who is unable to empty his or her bladder by reflex means or by the intermittent use of catheters. The stimulator consists of an implanted receiver with electrodes that are placed on the conus medullaris portion of the patient's spinal cord and an external transmitter for transmitting the stimulating pulses across the patient's skin to the implanted receiver	D
64	Intracranial pressure monitor device	Intended for intermittent or continuous measurement and display of intracranial pressure (ICP). It is used in conjunction with an invasive intracranial device.	D
65	Intramuscular diaphragm/phrenic nerve electrical stimulation system	Intended to provide ventilatory support to a patient with diaphragm dysfunction of neuromuscular origin through electrical stimulation of the phrenic nerve to contract the diaphragm rhythmically (using intramuscular electrodes) and cause the patient to draw breath in a manner similar to natural breathing.	D

66	Intramuscular diaphragm/phrenic nerve electrical stimulation system programmer	Intended to change, telemetrically, one or more of the operating parameters (the programs) of an intramuscular diaphragm/phrenic nerve electrical stimulation system external pulse generator (EPG).	C
67	Intranasal cooling system	Intended for rapid cooling induction in patients where temperature reduction is clinically indicated (e.g., following a cerebral ischemic event, during cardiac arrest) to help minimize damage to the brain and heart.	C
68	Invasive-detection physiological monitor	Intended for continuous or intermittent measurement, display and/or recording of several invasively-detected physiological parameters [e.g., intracranial pressure (ICP), compartmental pressure].	C
69	Leukotome	Intended to cut brain tissue (i.e., cutting white matter, leukotomy).	B
70	Magnetoencephalography system	Intended to non-invasively detect, measure, and display bio-magnetic signals produced by electrically-active cortical brain tissue, and that provide diagnostic information about the location of the active tissue responsible for cognitive brain functions relative to the surrounding brain anatomy	B
71	Manual surgical saw, flexible	Intended for cutting bone through a sawing action during neurological or orthopaedic surgery.	B
72	Meningeal prosthesis	Intended to repair the meningeal membrane (meninges).	D
73	Nasopharyngeal electrode.	A nasopharyngeal electrode is an electrode which is temporarily placed in the nasopharyngeal region for the purpose of recording electrical activity	C
74	Needle electrode.	A needle electrode is a device which is placed subcutaneously to stimulate or to record electrical signals	C
75	Nerve conduction velocity measurement device.	A nerve conduction velocity measurement device is a device which measures nerve conduction time by applying a stimulus, usually to a patient's peripheral nerve. This device includes the stimulator and the electronic processing equipment for measuring and displaying the nerve conduction time	C
76	Nerve guide, bioabsorbable, animal-derived	Collagen matrix material intended to be used to create a tunnel through which a discontinuous peripheral nerve can regenerate to bridge the proximal and distal nerve stumps.	D
77	Nerve guide, bioabsorbable, synthetic	Synthetic material intended to be used to create a tunnel through which a discontinuous peripheral nerve can regenerate to bridge the proximal and distal nerve stumps.	D
78	Nerve guide, non-bioabsorbable	Non-bioabsorbable material intended to be used to create a tunnel through which a discontinuous peripheral nerve can regenerate to bridge the proximal and distal nerve stumps.	D
79	Neurological endoscope.	A neurological endoscope is an instrument with a light source used to view the inside of the ventricles of the brain	C

80	Neurological stereotactic surgery system	Intended to store diagnostic images used for image-guided neurosurgery.	C
81	Neuromuscular transmission electrical skin sensor	Intended to detect electrical neuromuscular transmission (NMT) signals, for assessing the degree of neuromuscular block in a patient.	C
82	Neuromuscular transmission motion sensor	Intended to be placed on the thumb and index finger of a patient to detect movements and convert them into electrical neuromuscular transmission (NMT) signals during nerve stimulation.	B
83	Neuropsychiatric interpretive electroencephalograph assessment aid.	The neuropsychiatric interpretive electroencephalograph assessment aid is a prescription device that uses a patient's electroencephalograph (EEG) to provide an interpretation of the patient's neuropsychiatric condition. The neuropsychiatric interpretive EEG assessment aid is used only as an assessment aid for a medical condition for which there exists other valid methods of diagnosis	C
84	Neurosurgical chair	Intended to support and position a patient in a sitting or reclined position during neurosurgery.	A
85	Neurosurgical head holder (skull clamp).	A neurosurgical head holder (skull clamp) is a device used to clamp the patient's skull to hold head and neck in a particular position during surgical procedures	B
86	Neurosurgical headrests.	A neurosurgical headrest is a device used to support the patient's head during a surgical procedure	A
87	Neurosurgical microscope	Designed to magnify minute structures within the neurological fields for surgery, typically the brain or spine or surroundings in the performance of neurological surgical procedures which require high magnification by transmitted light.	B
88	Neurosurgical ultrasound navigation system	Intended for intraoperative imaging of the brain for precise navigation during brain surgery (e.g., resection of malignant brain tumours, treatment of vascular malformations).	B
89	Non-electroencephalogram (EEG) physiological signal based seizure monitoring system.	A non-electroencephalogram (non-EEG) physiological signal based seizure monitoring system is a noninvasive prescription device that collects physiological signals other than EEG to identify physiological signals that may be associated with a seizure	C
90	Nonpowered neurosurgical instrument.	A nonpowered neurosurgical instrument is a hand instrument or an accessory to a hand instrument used during neurosurgical procedures to cut, hold, or manipulate tissue. It includes specialized chisels, osteotomes, curettes, dissectors, elevators, forceps, gouges, hooks, surgical knives, rasps, scissors, separators, spatulas, spoons, blades, blade holders, blade breakers, probes, etc	A
91	Olfactometry system	Intended to determine the response of humans to odours delivered through the nose, including irritants.	C

92	Percussion hammer, manual	Intended to be used by an examining physician to gently tap near a patient's joints to test reflexes.	A
93	Percussor.	A percussor is a small hammerlike device used by a physician to provide light blows to a body part. A percussor is used as a diagnostic aid during physical examinations	A
94	Photodiode subretinal prosthesis system	Designed to provide visual function to a patient with vision loss due to retinal degeneration by detecting light, converting it into electrical signals, and relaying them to the retina for neural stimulation.	C
95	Physical therapy ultrasound/neuro muscular stimulation system	Designed to produce a rhythmic contraction/release of injured muscles to promote the removal of metabolic by-products while applying ultrasound treatments.	B
96	Pinwheel.	A pinwheel is a device with sharp points on a rotating wheel used for testing pain sensation	A
97	Rheoencephalograph.	A rheoencephalograph is a device used to estimate a patient's cerebral circulation (blood flow in the brain) by electrical impedance methods with direct electrical connections to the scalp or neck area	D
98	Scalp clip.	A scalp clip is a plastic or metal clip used to stop bleeding during surgery on the scalp	C
99	Scoliosis-treatment electrical stimulation system	Intended to apply electrical stimuli to the spinal musculature to produce a force that stabilizes or limits the progression of the spinal lateral curvature (i.e., scoliosis).	D
100	Skull plate anvil.	A skull plate anvil is a device used to form alterable skull plates in the proper shape to fit the curvature of a patient's skull	A
101	Skull punch.	A skull punch is a device used to punch holes through a patient's skull to allow fixation of cranioplasty plates or bone flaps by wire or other means	A
102	Skullplate screwdriver.	A skullplate screwdriver is a tool used by the surgeon to fasten cranioplasty plates or skullplates to a patient's skull by screws	A
103	Stereotactic neuronavigation/planning system	Intended to receive and analyse patient magnetic resonance imaging (MRI) images and position landmarks on these images, then register the images by the mean of a three-dimensional (3-D) optical positioning system (frameless stereotactic neuronavigation) to provide real-time relative positioning for the treatment probes and instruments.	B
104	Stereotactic radiosurgical system	Intended to deliver a therapeutic radiation dose to an anatomical region from external beams produced from multiple radionuclide sources arranged in a fixed focal point collimated array; typically used to treat brain, neck, breast and spinal tumours.	D

105	Tibial nerve percutaneous incontinence-control electrical stimulation system	Intended to treat urinary and/or faecal incontinence with electrical stimuli applied to the sacral nerve via percutaneous tibial nerve stimulation (PTNS).	D
106	Transcranial electrical stimulation system, continuous-current and pulsed-current	Intended for one or more psychiatric\neurological therapy types [e.g., transcranial direct current stimulation (tDCS), transcranial alternating current stimulation (tACS)]. And to induce a state resembling that of chemically-induced anaesthesia for treating one or more psychiatric disorders which may include anxiety, depression, insomnia, and/or addiction.	B
107	Transvenous phrenic nerve electrical stimulation control unit	Intended to configure/deliver stimulation of the phrenic nerve, via a transvenous electrode, to cause contraction of the diaphragm in conjunction with mechanical ventilation to assist earlier ventilation weaning.	D
108	Tuning fork	Intended to test the hearing acuity of a patient, to diagnose hearing disorders, and to test for vibratory sense.	A
109	Ultrasonic scanner calibration test block.	An ultrasonic scanner calibration test block is a block of material with known properties used to calibrate ultrasonic scanning devices (e.g., the echoencephalograph)	A
110	Vagus nerve electrical stimulation system programmer	The strength and duration of the electrical impulses are programmed	C