

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

Notice

File No. 29/Misc./03/2020-DC (196)

Date: **06 AUG 2021**

**Subject: Classification of Medical Device pertaining to ENT 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 is hereby classify 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.

V.G.

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

To,

1. CDSCO Website

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Classification of Medical Devices Pertaining to ENT

Sr. No.	Medical Device Name	Intended Use	Risk Class
1	Adenotome	Surgical instrument intended to dissect the adenoids.	A
2	Adenotome blade	Intended to mount on adenotome and perform dissection of adenoids.	B
3	Audiometer testing system	An assembly of electronic reference devices intended to calibrate an audiometer.	A
4	Audiometer	Intended for evaluation of hearing by generating tones throughout the audible range	B
5	Evoked response auditory stimulator	An evoked response auditory stimulator is a device that produces a sound stimulus for use in evoked response measurements or electroencephalogram activation.	B
6	Behind-the-ear air-conduction hearing aid	Intended to compensate for impaired hearing by transmitting amplified sound waves to the eardrum through air.	B
7	Behind-the-ear air-conduction tinnitus masker	Intended to provide noise of sufficient intensity and bandwidth to mask tinnitus.	B
8	Behind-the-ear bone-conduction tinnitus masker	Intended to provide ultrasonic broadband noise and/or sweep-frequency stimuli noise of sufficient intensity and bandwidth to mask tinnitus.	C
9	Cochlear implant assessment system	Intended to perform an integrity test on the implantable portion of a cochlear implant (CI) system in-situ.	C
10	Ear bowl	Constructed to fit the curvature of the head so that it will sit closely under the ear lobe and enable treatments of ear.	A
11	Ear canal impression tray	Intended to hold and confine the impression material in opposition to the surfaces to be recorded, and to control the impression material while it sets to form the impression of the ear canal.	A
12	Ear canal light	Intended to illuminate the ear canal.	A

13	Ear excavator	Designed for cutting, scraping, scooping and removing tissue during a surgical procedure in or around the ear.	A
14	Ear prosthesis	Intended to reconstruct the external ear by replacing damaged or missing tissue.	C
15	Ear wick	Intended to minimize bleeding during ear surgery.	A
16	Electroglottograph	Intended for recording the changes in electrical potential or impedance, resulting from movement of the vocal cords during respiration and phonation.	B
17	Endaural curette	Designed for scraping within the ear canal (e.g., removing wax), and for procedures during middle ear surgery (e.g., removal of the superior bony rim).	A
18	ENT chair, electric	Designed to support a patient in a seated position, electrically control position in a way to facilitate ear, nose, throat examination, treatment, and/or minor surgery.	A
19	ENT chair, mechanical	Designed to support a patient in a seated position, mechanically control position in a way to facilitate ear, nose, throat examination, treatment, and/or minor surgery.	A
20	ENT shaver system	Intended to resect/debride soft and osseous (bone) tissue in the nasal cavity or ear region during ear/nose/throat (ENT) or plastic surgery procedures; including functional endoscopic sinus surgery (FESS).	B
21	ENT surgical microscope	Intended to magnify minute structures (e.g., nerves, vessels) in the performance of ear, nose, and/or throat (ENT) surgery requiring high magnification and adjustable focusing.	A
22	ENT transilluminator	Intended to illuminate sinus tissue during an ear/nose/throat (ENT) procedure to render the tissue translucent for examination	A
23	Evoked-potential audiometer	Electroacoustic instrument designed to evaluate the activity of the auditory pathway of the brain in response to an acoustic signal [auditory brainstem response (ABR)] in patients.	B
24	Flexible fiberoptic nasopharyngo laryngoscope	Flexible endoscope intended for the visual examination and treatment of the nasal passages, including the sinus openings, the pharyngeal end of the auditory tube, the larynx, and the vocal cords.	B
25	Flexible fiberoptic nasopharyngoscope	Flexible endoscope intended for the visual examination and treatment of nasopharynx (the upper part of the throat behind the nose).	B

26	Flexible fibreoptic rhinoscope	Flexible endoscope intended for the visual examination and treatment of nasal cavity.	B
27	Flexible fibreoptic sinoscope	Flexible endoscope intended for the visual examination and treatment of the paranasal sinuses during an ear/nose/throat (ENT) intervention.	B
28	Flexible video antroscope	Flexible endoscope intended for the visual examination and treatment of a cavity, particularly the pathological changes in the area of the maxillary sinus.	B
29	Impedance audiometer	Intended to evaluate the functional condition of the middle ear by changing the air pressure in the external auditory canal to measure and graph the mobility characteristics of the tympanic membrane.	B
30	Nasal septum straightening forceps	Surgical instrument specifically designed to straighten the nasal septum through grasping and manipulation of the bone/cartilage of the septum during nasal reconstructive procedures.	A
31	Otoscope, endoscopic	Intended to be used in otology mainly for observation, diagnosis, and treatment of the outer and/or middle ear.	A
32	Tonsil knife	Intended for the removal of the tonsils during a surgical intervention.	A
33	Tracheal bistoury	Designed for opening abscesses or slitting up sinuses and/or fistulas in the trachea.	A
34	Middle ear mold	A middle ear mold is a preformed device that is intended to be implanted to reconstruct the middle ear cavity during repair of the tympanic membrane.	C
35	Fully-implantable middle ear implant system	An implanted assembly of sterile devices intended to compensate for impaired hearing by transmitting vibrations to the middle ear. It is powered by a battery that is recharged inductively, via an external device.	C
36	Larynx prosthesis	A device used for replacement and restoration of the laryngeal function, or for maintenance of patency of the larynx.	C
37	Epistaxis balloon	Device intended to control internal nasal bleeding by exerting pressure against the sphenopalatine artery.	B
38	Eustachian tube balloon dilation system	The system is intended for use in dilating the cartilaginous portion of the Eustachian tube for treating persistent Eustachian tube dysfunction.	B
39	Argon laser for otology, rhinology, and laryngology	Device is used for the purpose of coagulating and vaporizing soft and fibrous tissues, including osseous tissue while performing ENT surgical procedure.	C

40	Ear, nose, and throat microsurgical carbon dioxide laser	Device intended for the surgical excision of tissue from the ear, nose, and throat area while performing microsurgical procedures to excise lesions and tumors of the vocal cords and adjacent areas.	C
41	Esophagoscope (flexible or rigid)	Device intended to examine or treat esophageal malfunction symptoms, esophageal or mediastinal disease, or to remove foreign bodies from the esophagus.	B
42	Mediastinoscope and accessories	Device intended to examine or treat tissue in the area separating the lungs for diagnosis of tumors and lesions and to determine whether excision of certain organs or tissues is indicated.	B
43	Laryngostroboscope	A laryngostroboscope is a device that is intended to allow observation of glottic action during phonation.	B
44	Bone particle collector	A bone particle collector is a filtering device intended to be inserted into a suction tube during the early stages of otologic surgery to collect bone particles for future use.	A
45	Suction antichoke device	A suction antichoke device is a device intended to be used in an emergency situation to remove, by the application of suction, foreign objects that obstruct a patient's airway to prevent asphyxiation to the patient.	C
46	Tongs antichoke device	A tongs antichoke device is a device that is intended to be used in an emergency situation to grasp and remove foreign objects that obstruct a patient's airway to prevent asphyxiation of the patient.	C
47	Powered nasal irrigator	A powered nasal irrigator is an AC-powered device intended to wash the nasal cavity by means of a pressure-controlled pulsating stream of water.	B
48	External nasal splint	An external nasal splint is a rigid or partially rigid device intended for use externally for immobilization of parts of the nose.	A
49	Antistammering device	An antistammering device intended to minimize a user's involuntary hesitant or repetitive speech. It also prevent the user from hearing the sounds of his or her own voice	B
50	External upper esophageal sphincter compression device	An external upper esophageal sphincter compression device is intended to apply external pressure on the cricoid cartilage for the purpose of reducing the symptoms of laryngopharyngeal reflux disease.	C

51	Wireless air-conduction hearing aid	A wireless air-conduction hearing aid is intended to compensate for impaired hearing that incorporates wireless technology in its programming or use.	B
52	Hearing aid calibrator and analysis system	A hearing aid calibrator and analysis system is an electronic reference device intended to calibrate and assess the electroacoustic frequency and sound intensity characteristics emanating from a hearing aid, master hearing aid, group hearing aid or group auditory trainer.	B
53	Tympanic membrane contact hearing aid	A tympanic membrane contact hearing aid is a prescription device that compensates for impaired hearing by vibrating the tympanic membrane through a transducer that is in direct contact with the tympanic membrane.	B
54	Master hearing aid	A master hearing aid is an electronic device intended to simulate a hearing aid during audiometric testing.	B
55	Active implantable bone conduction hearing system	The active implantable bone conduction hearing system is intended to compensate for conductive or mixed hearing losses by conveying amplified acoustic signals to the cochlea via mechanical vibrations on the skull bone.	C
56	Battery-powered artificial larynx	A battery-powered artificial larynx is an externally applied device intended for use in the absence of the larynx to produce sound.	B
57	Nasal dilator	A nasal dilator is a device intended to provide temporary relief from transient causes of breathing difficulties resulting from structural abnormalities and/or transient causes of nasal congestion associated with reduced nasal airflow.	A
58	Transcutaneous air conduction hearing aid system	A transcutaneous air conduction hearing aid system is a wearable sound-amplifying device intended to compensate for impaired hearing without occluding the ear canal.	C
59	Acoustic chamber for audiometric testing	An acoustic chamber for audiometric testing is a room that is intended for use in conducting diagnostic hearing evaluations and that eliminates sound reflections and provides isolation from outside sounds.	A
60	Gustometer	A gustometer is a battery-powered device that consists of two electrodes that are intended to provide galvanic stimulus resulting in taste sensation.	B

61	ENT cupped forceps	A forcep with a spoon-(dish) like configuration at the distal end, and is used to treat the ear, nose, and throat (ENT), and remove tissue from the body.	A
62	Tongue depressor	A surgical instrument used to move the tongue to facilitate examination of surrounding organs and tissue.	A
63	Tonsillectome	A manually operated surgical device used to dissect the tonsils.	A
64	ENT Nasal snare	A hand-held manual surgical instrument intended to be inserted into the naris for the removal of tissue, typically polyps, tumours, and other abnormal tissue from the nasal cavity during ear/nose/throat (ENT) surgery	A
65	Otoscope, direct	A portable, battery-powered, hand-held device (non-endoscopic) primarily designed for examination of the outer ear canal and tympanic membrane (eardrum) by direct viewing through the ear opening.	A
66	Soft-tissue surgical forceps, alligator	A long, thin, hand-held manual surgical instrument designed to facilitate grasping and manipulation of soft-tissues/anatomical structures [typically during ear/nose/throat (ENT) surgery].	A
67	Ear, nose, and throat electric or pneumatic surgical drill	An ear, nose, and throat electric or pneumatic surgical drill is a rotating drilling device, including the handpiece, that is intended to drive various accessories, such as an ear, nose, and throat bur for the controlled incision or removal of bone in the ear, nose, and throat area.	B