

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

NOTICE

File No. 29/Misc./03/2020-DC (187)

Date: 09 AUG 2021

Subject: Classification of medical device pertaining to Ophthalmology 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, clinical investigation, sale and distribution, 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 are to be commence 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 of the device, risk associated with the device and other parameters specified in the First Schedule.

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 who intend 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 and is subject to revision from time to time under the provisions of the Medical Devices Rules, 2017.

V. G. Somani

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

To,

1. CDSCO Website

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Classification of Medical Devices Pertaining to Ophthalmology

S. No.	Device Name	Intended Use	Risk Class
1	Adaptometer	An ophthalmic device intended to measure the time required for retinal adaptation and the minimum light threshold.	B
2	Amsler grid	An ophthalmic device intended to rapidly detect central and paracentral irregularities in the visual field.	A
3	Anomaloscope	A ophthalmic instrument used to test a patient for abnormal red/green colour vision by differentiating the red/green colour vision defects.	A
4	Aqueous/vitreous humour replacement medium kit	A collection of sterile devices, including a fluid or semifluid substance, used in combination to replace the fluid of the eye.	D
5	Automated lensmeter(Dioptometer)	An ophthalmic instrument designed to measure the focusing power (dioptric power) and other optical characteristics of a spectacle lens, contact lens, or prism.	A
6	Bagolini lens	An ophthalmic plane lens, intended to determine harmonious/anomalous retinal correspondence.	A
7	Binocular vision test unit	An ophthalmic device for binocular vision testing.	A
8	Blepharoplasty scissors	A hand-held, manual, ophthalmic surgical instrument intended to be used to cut eyelid tissue during plastic surgery of the eyelids (blepharoplasty).	A
9	Capsular bag anchor	A device intended to be permanently implanted in the posterior chamber of the eye for correction and fixation of a subluxated capsular bag, typically in association with in-the-bag intraocular lens (IOL) implantation.	C

10	Colour discrimination tester	An ophthalmic lamp, used to test a person's ability to differentiate between colours.	A
11	Colour-discrimination eye chart	Intended for testing colour vision.	A
12	Conjunctival scissors	A hand-held, manual, ophthalmic surgical instrument intended to be used to cut the conjunctiva and Tenon's capsule on the eye surface to access the sclera.	A
13	Contact Lens (Including Coloured Contact Lens)	Device intended to be worn directly against the cornea and adjacent limbal and scleral areas of the eye to correct vision conditions or act as a therapeutic bandage or/and to change the appearance of the eye for decorative purposes.	B
14	Contact lens agitation cleaning system	An assembly of devices used to clean and disinfect contact lenses through automated or manual mechanical agitation .	B
15	Contact lens disinfecting solution	An aqueous formulation containing appropriate agents for loosening debris from contact lenses, and that contains a disinfectant intended to act on contact lens.	B
16	Contact lens protein-removal solution	A formulation of proteolytic enzymes, used to remove debris and protein deposits from reusable contact lenses, or to remove protein deposits only.	B
17	Contact lens radius gauge	A measuring instrument used in ophthalmology to determine the radius of curvature of contact lenses.	A
18	Contact lens thermal cleaner	A unit intended to disinfect or sterilize reusable soft contact lenses by means of heat.	B
19	Corneal burr manual instrument	A hand-held, ophthalmic surgical instrument, used to excavate corneal tissue through manual rotation.	B
20	Corneal burr system	An assembly of devices designed for abrasion of the cornea and other eye tissues.	B
21	Corneal burr, abrasion	A device designed for abrasion of the cornea to polish corneal scratches and/or the pterygium bed after surgical removal, and/or for abrasion of lid margin lesions.	B
22	Corneal burr, rust ring removal	A device designed for gentle removal of rust stains (rust rings) from the cornea after the extraction of a ferrous foreign object.	B

23	Corneal epithelium perforator	Intended to create a number of small perforations in the epithelial layer of the cornea through which riboflavin can pass into the cornea during corneal collagen crosslinking, to treat corneal ectasia (typically keratoconus).	B
24	Corneal epithelium trephine	Intended to create a circular cut through the epithelial layer of the cornea to create an epithelial flap intended to be folded back during laser assisted epithelial keratomileusis (LASEK) surgery, after which the flap is replaced.	B
25	Corneal inlay, aperture reducing	A implantable device inserted into the natural cornea to treat presbyopia based on aperture reduction.	C
26	Corneal inlay, cornea-reshaping	A implantable device inserted into the natural cornea to treat refractive errors by reshaping the cornea.	C
27	Corneal light shield	A device, typically made of a non-abrasive fluid-absorbing material that is placed on the surface of the cornea to shield the retina from excessive illumination during an ophthalmic procedure.	B
28	Corneal marker	A manual instrument intended to be used to imprint, indent, and/or incise corneal tissue prior to an ophthalmic surgical procedure.	B
29	Corneal resection holder	A device designed to hold donated corneal tissue so that it can be resected in preparation for transplantation.	B
30	Corneal scissors	A hand-held, manual, ophthalmic surgical instrument intended to be used to cut corneal tissue.	B
31	Corneal shield	A mechanical eye shield made of collagen that is placed on the eye to protect the cornea.	B
32	Corneoscleral punch	A hand-held, manual ophthalmic surgical instrument designed to excise a segment of tissue from the sclera or cornea of a patient or from grafts taken from cadaver donors.	B
33	Diagnostic condensing lens	An ophthalmic lens used in binocular indirect ophthalmoscopy to focus reflected light from the fundus of the eye.	A
34	Donor cornea container	A receptacle intended to maintain, transport, and facilitate clinical examination of a donated cornea during the period between cornea collection and transplantation surgery.	C

35	Eikonometer	An ophthalmic instrument for diagnosing aniseikonia.	A
36	Electronic occlusion spectacles	An ophthalmic device designed to test and train vision for conditions where decreased visual acuity may be due to unequal vision in the eyes.	A
37	Endoscopic-imaging ophthalmic solid-state laser system	A device assembly intended to treat retinal and other eye disorders, such as glaucoma, during endoscopic cyclophotocoagulation (ECP) procedures.	C
38	Enucleation scissors	A hand-held, manual, ophthalmic surgical instrument used to cut tissue during eye surgery involving enucleation of the eye and/or its related structures.	A
39	Epiretinal/inner limiting membrane scraper	A hand-held manual surgical instrument intended to be used during posterior segment surgery to lift the inner limiting membrane (ILM) and/or an epiretinal membrane (ERM), and which may have additional posterior segment membrane manipulation uses.	B
40	Euthyscope	A modified ophthalmoscope that projects a bright light encompassing an arc of approximately 30 degrees on the fundus of the eye for the treatment of amblyopia.	A
41	Exophthalmometer	An ophthalmic instrument used to measure the degree of exophthalmos.	A
42	Eye cup	A receptacle designed to fit around the eye socket and which is filled with warm water or an eyewash solution and placed over the eye to allow the liquid to wash the affected eye.	A
43	Eye heat therapy pack	A device intended to be placed over closed eyes to apply heat for the treatment of meibomian gland dysfunction (MGD), dry eye syndromes, blepharitis and other related ocular conditions.	B
44	Eye irrigation shield	A device intended to be used with an eye irrigation kit/system to direct irrigation solution to the surface of the eye and allow the solution to gently lavage the surface of the eye.	A
45	Eye muscle clamp	An hand-held manual ophthalmic surgical instrument designed to atraumatically grasp and hold the extraocular muscles (EOM) during an ophthalmic surgical intervention.	B

46	Eye muscle sleeve	An implantable device made from synthetic materials that is used to encase or isolate an ocular muscle.	C
47	Eye pad	A sterile, cushion-like device intended to protect the eye or to absorb eye secretions.	A
48	Eye spud	A hand-held, manual, ophthalmic surgical instrument intended to be used to remove a foreign body/object embedded in or adhering to the surface of the eye globe.	A
49	Eye valve	An implantable device designed to regulate the flow of fluid between the anterior chamber and the space around the conjunctiva of the eye by allowing flow when the pressure in the chamber is above a pre-set value.	C
50	Eyelid clamp	A hand-held manual surgical instrument designed to atraumatically grasp and hold the eyelid during an ophthalmic surgical intervention.	A
51	Eyelid weight, external	An ophthalmic device that is applied to the outside of the upper eyelid to "lidload" the eyelid to restore upper eyelid muscle function.	A
52	Eyelid weight, implantable	An ophthalmic device that is implanted subcutaneously within the upper eyelid to "lidload" the eyelid to restore upper eyelid muscle function.	C
53	Felt tangent screen	A black tangent screen intended for assessing the extent of the patient's peripheral visual field by mapping the visual response to a test object moved from the periphery towards the centre of the screen.	A
54	Femtosecond ophthalmic solid-state laser system	A device assembly in which input energy is used to excite a glass/crystal rod to emit a high-power laser beam intended for ocular resections and incisions.	C
55	Fibreoptic general-purpose ophthalmic hook	A hand-held manual surgical instrument inserted into the eye during surgical intervention to manipulate anatomical structures or foreign bodies within the eye and simultaneously conduct a field of cold light to illuminate the surgical site.	A
56	Flieringa ophthalmic ring	A circular band, sutured to the sclera to prevent collapse of the globe during difficult intraocular operations.	A
57	Fornixscope	A manually-operated, ophthalmic device intended to provide indirect access and viewing of the upper conjunctival fornix and inner surface of	A

		the eyelid as an alternative to eyelid eversion.	
58	Fresnel lens	A very thin and flexible ophthalmic lens intended to be applied to the back of spectacle lenses to focus light to a focal point to help manage various vision conditions.	A
59	Fresnel prism	A device intended to be applied to spectacle lenses to give a prismatic effect typically to manage strabismus or other eye muscle dysfunction.	A
60	Fundus-imaging ophthalmic diode laser system	Intended for: ocular laser treatment procedures, including coagulation of abnormal retinal vasculature; and capturing real-time digital images of the anterior/posterior eye segments created using colour, fluorescein angiography and infrared imaging, for diagnosis/treatment planning.	C
61	Fundus-imaging ophthalmic solid-state laser system	Intended to coagulate abnormal vascular tissue in the retina and for other ocular photocoagulation procedures.	C
62	Glaucoma supraciliary implant	A non-bioabsorbable synthetic polymer device designed to be implanted in the supraciliary space (between the ciliary muscle/body and the sclera) for the restoration of aqueous humour outflow and subsequent reduction of intraocular pressure as part of treatment for open angle glaucoma.	C
63	Glaucoma therapy ultrasound system	A system designed to transduce radio-frequency (RF) electrical energy from a generator into ultrasound energy, for the extracorporeal application of high intensity focused ultrasound (HIFU) to the eye, to decrease aqueous humour production and reduce intraocular pressure (IOP)	C
64	Haidinger brush imager	An ophthalmic device designed to produce an image which facilitates his/her visual function evaluation, particularly the macular integrity.	A
65	Hand-held campimeter	A portable, hand-held device intended for assessing the central 30° visual field.	A
66	Hand-held telescope	A device that consists of an arrangement of ophthalmic lenses or mirrors with a handle intended to enlarge images for a visually impaired patient/person.	A

67	Hruby fundus lens	A 55 dioptre non-contact diagnostic ophthalmic lens intended for use in the examination of the vitreous body and the fundus of the eye under slitlamp illumination and magnification.	A
68	Implantable intraocular pressure monitoring system	An assembly of portable devices intended to continuously or regularly collect and display intraocular pressure (IOP) data for the diagnosis/monitoring of glaucoma.	C
69	Implantable iris prosthesis	An optical device intended to be implanted into the posterior chamber of the eye for the reconstruction of partial or total iris defects.	C
70	Indirect binocular ophthalmoscope	An ophthalmic instrument designed to examine the interior of the eye allowing the examiner to clearly see a wide angle, stereoscopic impression of the details of the fundus (retina) and other structures.	A
71	Intracorneal ring	An implantable, open-ended circular band designed to flatten the anterior corneal curvature, without disturbing the visual axis, to correct mild and moderate myopia.	C
72	Intranasal lacrimal neurostimulator	A hand-held device intended to be used in the home to provide electrical stimulation to sensory neurons of the nasal cavities to acutely increase tear production as treatment for aqueous deficient dry eye.	C
73	Intraocular pressure-reducing system	An assembly of manually-operated devices designed to reduce the intraocular pressure (IOP) by applying a controlled, external, mechanical compression to the surface of the eye in preparation for ophthalmic surgery.	C
74	Keratome	An ophthalmic surgical instrument intended to shave tissue from sections of the cornea for a lamellar (partial thickness) transplant.	B
75	Lacrimal tube	A implantable, single-lumen tube intended to provide tear drainage from the front surface of the eye, and also to facilitate saline solution irrigation to a paranasal sinus to manage chronic rhinosinusitis.	C
76	Lens spoon	A hand-held ophthalmic surgical instrument used in ophthalmic surgery to manipulate/remove the lens of the eye.	A

77	Maddox trial lens	A special ophthalmic trial lens in the form of a rod or series of rods (grooves/cylinders) that changes the size, shape, and colour of an image to dissociate the eyes in the evaluation of eye muscle dysfunction.	A
78	Mirror-prism spectacles	An optical device intended to enable the patient to see over the top of their head enabling them to look forward in the direction their head is pointing.	A
79	Nystagmus inducing optokinetic drum	An ophthalmic device intended to elicit nystagmus.	A
80	Nystagmus inducing tape	An ophthalmic device intended to be moved across a patient's field of vision to elicit optokinetic nystagmus and to test for blindness.	A
81	Ophthalmic calliper	A hand-held manual ophthalmic measuring instrument consisting of two legs hinged at one end and designed to measure the diameter, length, angles, and thicknesses of the eye.	A
82	Ophthalmic clip	A device typically made of a malleable metal (e.g., tantalum), intended to be implanted permanently or temporarily to bring together the edges of a wound, to aid in healing or to prevent bleeding from small blood vessels in the eye.	C
83	Ophthalmic cryosurgical system	An assembly of devices designed to apply cold from a gaseous or liquid refrigerant (cryogen) to a target tissue for its destruction and removal during an ophthalmic surgical procedure.	C
84	Ophthalmic distometer	An ophthalmic instrument designed to measure the distance between the cornea and a spectacle or trial lens (vertex distance).	A
85	Ophthalmic dye laser system	A laser device assembly intended to coagulate abnormal vascular tissue in the retina, and for other photocoagulation procedures in the eye.	C
86	Ophthalmic excimer laser system	A laser device assembly intended for corneal ablation and other ophthalmologic procedures.	C
87	Ophthalmic head reflector	A head-worn ophthalmic device intended to reflect light onto the eye of a patient to allow examination of the eye and its associated structures.	A

88	Ophthalmic Irrigation Solution (Balanced Salt Solution)	Intended for the irrigation of the anterior chamber during cataract surgery and other intraocular or extraocular procedures or for the irrigation of the conjunctiva following application of fluoresceine or for moistening the corneal and conjunctival surface during laser treatment.	B
89	Ophthalmic noble gas laser system	A laser device assembly intended to coagulate abnormal vascular tissue in the retina and for other photocoagulation procedures in the eye.	C
90	Ophthalmic operating table top	A component of a modular operating table intended to provide support for and stabilization of the head of the patient (typically includes a headrest) and to help provide optimal access for the surgeon(s) during the intervention (e.g., by having a small-width table top and therefore a shorter stretch distance for the surgeon).	A
91	Ophthalmic soft-tissue surgical forceps	A hand-held manual instrument designed to grasp and manipulate intraocular tissues during ophthalmic surgery (e.g., anterior segment surgery, vitreo-retinal procedures, iridectomy, capsulorhexis).	B
92	Ophthalmic surgical device handling forceps	A hand-held manual surgical instrument with blades designed to grasp and manipulate a nonimplantable invasive ophthalmic surgical device (e.g., ophthalmic cannula, handless iris retractor) and/or for ophthalmic suturing.	A
93	Ophthalmic suture scissors	A hand-held, manual, ophthalmic surgical instrument intended to be used to cut suture during eye surgery.	A
94	Ophthalmic tonometer	An ophthalmic, measuring instrument designed for determining the intraocular pressure (IOP).	B
95	Ophthalmic ultrasound imaging system	An assembly of devices designed for ophthalmic ultrasound imaging procedures.	B
96	Ophthalmodiastimeter	An ophthalmic instrument for determining the proper distance at which to place prescription lenses for the two eyes.	A
97	Ophthalmoleukoscope	An ophthalmic device intended to be used for testing colour perception by means of colours produced by polarized light.	A

98	Ophthalmoscope	An ophthalmic instrument designed to examine the interior of the eye allowing the examiner to clearly see the details of the retina and other structures/media.	B
99	Optical pachymeter	An ophthalmic, device that uses optics to measure the thickness of the cornea.	A
100	Orbital depressor	A hand-held ophthalmic surgical instrument used to displace tissue to facilitate examination of the surrounding area in the orbital cavity during eye surgery.	A
101	Orbital rim prosthesis	An implantable ocular device used to reconstruct the floor of the bony cavity that contains the eyeball and its associated muscles, vessels, and nerves and is intended to house an artificial eye.	C
102	Perimeter	A diagnostic, ophthalmic instrument intended for assessing the extent of the patient's peripheral visual field.	A
103	Periocular/lacrimal retractor	A hand-held, non-self-retaining, ophthalmic surgical instrument intended to be used to separate periocular tissues and/or draw aside the margins of a periocular surgical wound during an ophthalmic intervention.	A
104	Phacoemulsification system	An assembly of ophthalmic devices intended to deliver energy through a dedicated handpiece tip, which is introduced through an incision made in the lens capsule, to perform phacoemulsification.	C
105	Phorometer	An ophthalmic instrument intended to be used to test ocular balance.	A
106	Phoropter	A mechanical ophthalmic device that is used during an ophthalmic examination; typically to determine a patient's prescription for glasses.	A
107	Pleoptophor	An ophthalmic instrument used for the treatment of eccentric eye fixation (casts in the eye) by dazzling the perimacular retina, thereby relatively enhancing the visual capabilities of the fovea.	A
108	Polatest	An ophthalmic device used for evaluating hidden (latent) squinting, i.e., when the patient is not aware of the condition, and also when it cannot be seen.	A
109	Ptosis sling	A sterile implantable device intended for the surgical correction of ptosis.	C

110	Pupillograph	A graphic recorder used for recording the response of the pupil to reflected light. It is used for ophthalmic diagnostic purposes.	A
111	Pupillometer	An ophthalmic instrument used for measuring the width or diameter of the pupil.	A
112	Retinal tack	A non-bioabsorbable, implantable device designed to permanently fix a detached retina to the underlying retinal pigment epithelium (RPE) during ophthalmic surgery.	C
113	Scleral buckling device	A device intended to be implanted on the sclera to compress the eye (scleral buckling) for the surgical treatment of retinal detachment.	C
114	Scleral expansion implant	A device designed for implantation in the sclera to produce expansion by altering the position of the underlying ciliary muscle.	C
115	Scleral marker	A manual instrument used to indent or imprint the surface of the sclera during an ophthalmic surgical or perioperative procedure.	B
116	Sclerotome	A hand-held manual ophthalmic surgical instrument that is knife-like in design and intended to be used to incise the sclera during a sclerotomy.	A
117	Scotometer	An instrument used for the recording and measuring of the areas of field of vision that is reduced, i.e., relative scotoma, or loss of sensitivity to light (absolute scotoma or blind spots).	A
118	Surgical binoculars	A pair of lenses intended to be mounted onto a surgeon's spectacles to function as small telescope and provide a magnified image of the visual field during patient examination or surgical intervention.	A
119	Symblepharon ring	An implantable device formed as a circular band used to help prevent the eyelid from adhering to the eyeball.	C
120	Synoptophor	A ophthalmic device used for the evaluation and training of a patient's binocular function.	A
121	Tachistoscope	An ophthalmic device designed to flash words or images at different speeds, for the purposes of ophthalmic diagnostic testing.	A
122	Ultrasound pachymeter	An ophthalmic device designed to use ultrasound to measure the thickness of the cornea, and may in addition be designed to measure axial length and anterior chamber depth.	B

123	Visual chart	An ophthalmic chart (Snellen chart) used in testing visual .	A
124	Visual light box	A light viewing box that uses a translucent version of the ophthalmic chart (Snellen chart) used for testing visual acuity.	A
125	Visual projector	An ophthalmic device intended to project an image on a screen to test visual acuity .	A
126	Visual evoked-potential electrode	An electrical conductor intended to record changes in the electrical potential for the purpose of measuring visual evoked responses.	A
127	Vitrectomy system	An assembly of ophthalmic devices intended to deliver energy through a dedicated hand-held instrument, typically used to treat diabetic vitreous haemorrhage, retinal detachment, epiretinal membrane, and macular hole.	C
128	Vitreous body prosthesis	A sterile bag/capsule intended to be implanted in the eye and filled with a fluid (not included) to replace the vitreous body and provide omnidirectional support of the retina for the treatment of severe retinal detachment.	C
129	Intraocular fluid	An intraocular fluid is a device consisting of a nongaseous fluid intended to be introduced into the eye to aid performance of surgery, such as to maintain anterior chamber depth, preserve tissue integrity, protect tissue from surgical trauma, or function as a tamponade during retinal reattachment.	C
130	Intraocular gas	An intraocular gas is a device consisting of a gaseous fluid intended to be introduced into the eye to place pressure on a detached retina.	C
131	Intraocular lens guide	An intraocular lens guide is a device intended to be inserted into the eye during surgery to direct the insertion of an intraocular lens and be removed after insertion is completed.	B
132	Ophthalmic refractometer	An ophthalmic refractometer is an automatic AC-powered device that consists of a fixation system, a measurement and recording system, and an alignment system intended to measure the refractive power of the eye by measuring light reflexes from the retina.	B

133	Keratoscope	A keratoscope is an AC-powered or battery-powered device intended to measure and evaluate the corneal curvature of the eye. Lines and circles within the keratoscope are used to observe the corneal reflex. This generic type of device includes the photokeratoscope and videokeratoscope which records corneal curvature by taking photographs or videos of the cornea.	B
134	Contact Lens Inserter/Remover	A device designed to insert and remove contact lenses from the eye.	A
135	Ophthalmic working-channel cannula	A rigid tube designed to create a channel through the sclera for internal ocular access during posterior segment ophthalmic surgery. It is typically made of plastic materials or high-grade stainless steel and enables the introduction of ophthalmic surgical instruments; it may also be used for irrigation (i.e., the infusion of fluids to maintain the interior pressure of the eye during surgery). This is a reusable device.	B