

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

Notice

03 JUN 2022

File No. 29/Misc./03/2020-DC (181)

Date:

Subject: Classification of Medical Device pertaining to Obstetrical and Gynecological 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

Updated 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

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Classification of Medical Devices Pertaining to Obstetrical and Gynecological

Sr. No.	DEVICE NAME	INTENDED USE	Risk Class
1	Abdominal decompression chamber	Non- invasive medical device placed at abdomen to alleviate abdominal pain during pregnancy or delivery.	C
2	Abdominal decompression chamber pump	A dedicated pump used with hood-like device to control and reduce abdominal pressure of a pregnant women.	C
3	Abortion suction system manual aspirator	A non-sterile, manual, syringe-like device to aspirate fluid from the uterus for treatment of incomplete abortion, first trimester abortion, and/or for menstrual regulation. Also used for endometrial biopsy.	B
4	Birthing bed/table, powered	Bed used during labor and delivery.	A
5	Cardiotocograph	A device that records fetal heart rate and uterine contraction simultaneously.	C
6	Cardiotocograph transducer	A device that converts birthing contractions to electrical signals and is used together with cardiotocograph (CTG) which displays the signals.	C
7	Cardiotocography telemetric monitoring system	An assembly of devices intended to be used to continuously measure and wirelessly transmit foetal heart rate and uterine contraction signals from a patient to a monitor.	C
8	Cardiotocography telemetric monitoring system receiver	A part of wireless telemeter system. It receives signals from transmitter that senses fetal heart rate and uterine contraction during labor.	C
9	Cardiotocography telemetric monitoring system transmitter	It transmits signals related to fetal heart rate and uterine contractions to the receiver.	C
10	Cervical anaesthesia kit	For providing intercervical nerve block during gynaecological diagnostic tests such as dilation and curettage, small excisional procedures such as endometrial biopsy, or for pain management during labour and/or delivery. This is a single-use device.	B
11	Cervical anaesthesia needle, reusable or single use	A sharp bevel-edged, hollow tubular metal instrument intended to be used to administer anaesthetic agent to function as an intracervical nerve-block.	B
12	Colposcope	Special microscope for examination of female genital organs (e.g., vagina, cervix).	B

13	Contraceptive cervical cap, reusable or single use	Device inserted into the cervix to prevent semen from entering the uterus.	C
14	Contraceptive spermicide	A chemical substance (e.g., nonoxynol-9) intended to be introduced with an applicator or the finger into the vagina before sexual intercourse, to destroy sperm (spermatozoa) to prevent pregnancy.	C
15	Contraceptive sponge	Bubble like device works as a physical barrier to prevent spermatic invasion into uterus.	C
16	Diaphragm pessary	A circular device placed in the vagina prior to intercourse to mechanically prevent conception.	C
17	Endocervical aspirator	A collection of devices designed to remove superficial tissue from the mucous membrane lining the cervical canal (endometrium) through manually-powered suction.	B
18	Endocervical specimen collection kit, no additive	Sterile devices intended to be used for the collection, preservation, and transport of cellular and/or other material collected from the endocervix for culture, analysis, and/or other investigation	B
19	(a) Endometrial biopsy curette, reusable	Surgical instrument used for the removal of small amounts of endometrial secretions and/or tissue from the uterus for biopsy purposes.	B
	(b) Endometrial biopsy curette, single use/disposable		B
20	Endometrial biopsy kit	For the collection of a tissue sample taken from the lining of the uterus (endometrium).	B
21	Endometrial cytology brush	A brush used to collect mucosal cell for pathological diagnosis during endoscopic examination.	B
22	Fallopian tube biopsy everting-balloon catheter	A sterile device intended to be inserted through a hysteroscope to obtain biopsy samples from a fallopian tube for cytological examination.	B
23	Fallopian tube catheterization kit	A collection of sterile devices for the trans uterine catheterization of the fallopian tubes to inject dye or contrast medium for the evaluation of tubal patency.	B
24	Fallopian tube insufflator	Active invasive device designed to insufflate the Fallopian tubes with a gas [typically carbon dioxide (CO ₂)] to maintain tubal patency for a procedure.	B
25	Fallopian tube occlusion insert	Contraceptive implantable device implanted into the uterine end of the fallopian tubes to function as a contraceptive by obstructing the natural fallopian tube passage.	D
26	(a) Fixed-diameter cervical dilator, reusable	To dilate the cervical canal with balloon when uterine does not dilate enough due to inertia uteri.	B
	(b) Fixed-diameter cervical dilator, single use/disposable		B

27	Flexible fibreoptic culdoscope	Flexible endoscope for visual examination, diagnosis, and treatment of urinary bladder and urethra.	B
28	Flexible fibreoptic hysteroscope	For the visual examination and treatment of the canal of the cervix and the uterine cavity (uterus).	B
29	Flexible fibreoptic laparoscope	For the visual examination and treatment of the abdominal/retroperitoneal cavity and its organs	B
30	Flexible fibreoptic mammary ductoscope	For the visual examination and treatment of the mammary duct.	B
31	Flexible fibreoptic salpingoscope	For the visual examination and treatment of the fallopian tubes (oviducts).	B
32	Flexible ultrasound laparoscope	For the visual examination, treatment, and ultrasonic imaging of the abdominal/retroperitoneal cavity and its organs.	B
33	Flexible video culdoscope	For the visual examination and treatment of the female peritoneal cavity and organs.	B
34	Flexible video hysteroscope	For the visual examination and treatment of the canal of the cervix and the uterine cavity (uterus).	B
35	Flexible video laparoscope	For the visual examination and treatment of the abdominal/retroperitoneal cavity and its organs.	B
36	Flexible video mammary ductoscope	For the visual examination and treatment of the mammary duct.	B
37	Flexible video salpingoscope	For the visual examination and treatment of the fallopian tubes (oviducts).	B
38	Foetal acoustic stimulator	Uses sound stimuli to assess foetal well-being. This device is used to evaluate the status of the foetus as expressed by, e.g., foetal heart rate changes or foetal acid-base status, in antepartum tests and/or during intrapartum monitoring.	B
39	Foetal bladder shunt	A sterile non-bioabsorbable tubular device implanted in the bladder of a foetus with post-vesicular obstructive uropathy, to decompress the urinary tract for urine to pass from bladder into the amniotic sac, until the defect can be surgically repaired after birth	C
40	Foetal blood sampler	Invasive device to collect fetal blood through uterine cervix.	B
41	Foetal cardiac monitor	Active device designed to detect, measure, and display foetal heart activity during the perinatal period	C
42	Foetal pleuro-amniotic catheter	Sterile implantable device used to continuously drain fetal pleural effusion to maternal amniotic cavity.	C
43	Foetal scalp electrode, clip	Placed directly on the scalp of the fetus in the uterus to monitor fetal vital signs.	C
44	Foetal stethoscope	Mechanical hearing device used to listen to fetal heartbeat.	A
45	Foetal vacuum extraction cup, reusable or single use	A device used to extract the head of the fetus with a vacuum cup.	B

46	Foetal vacuum extraction system monitor	A battery-powered vacuum measuring device that is connected via tubing to the suction line of a foetal vacuum extracting cup, to measure and record data related to a vacuum-assisted delivery such as level of vacuum applied, the number and duration of pulls, and number of pop-offs.	B
47	Foetal vacuum extraction system, manual, reusable or single use	To facilitate the delivery of a foetus during vaginal childbirth or Caesarean.	B
48	Foetal vacuum extraction system, pneumatic	To facilitate the delivery of a foetus during vaginal childbirth or Caesarean.	B
49	Foetal/maternal multiple physiological parameter simulation kit	To imitate a variety of physiological parameters and conditions (both foetal and maternal) expressed during pregnancy in order to test and calibrate foetal and patient monitoring and recording equipment, check patient cable continuity, or train healthcare providers.	B
50	Foetal/maternal multiple physiological parameter simulator	To imitate a variety of physiological parameters and conditions (both foetal and maternal) expressed during pregnancy in order to test and calibrate foetal and patient monitoring and recording equipment, check patient cable continuity, or train healthcare providers.	B
51	Gynaecological bib	A piece of cloth worn by the patient.	A
52	Gynaecological examination/treatment table	To support a woman's body in the appropriate positions during gynaecological examinations.	A
53	Gynaecological operating table top	A component of a modular operating table designed as a detachable table top constructed for gynaecological surgical procedures.	A
54	Gynaecological operating table, electrohydraulic or electromechanical or hydraulic	Active device designed to support a patient during gynaecological surgical procedures	A
55	(a) Gynaecological scissors, reusable	To cut tissues during a gynaecological surgical procedure; it is not intended for obstetric use.	B
	(b) Gynaecological scissors, single use/disposable		B
56	Gynaecological surgical microscope	To improve visualization of anatomical structures via transmitted light during gynaecological surgery (e.g., on the fallopian tubes).	A
57	Heel stirrup	A device used during a medical/surgical procedure to steadily hold a patient's foot (feet) by cradling the heel or the whole foot.	A
58	Hysteroscopic insufflator	A device that sends the gas into the fallopian tube to maintain the patency of the tubes.	B
59	Hysteroscopic irrigation/insufflation system	Used during endoscopic procedures of the uterus to distend (expand by pressure) the uterus by filling the uterine cavity with a liquid to improve visualization and enlarge the surgical field. It also circulates the fluid to provide irrigation that will remove tissue/debris from the site.	B

60	(a) Intrauterine cannula, reusable	To aspirate fluid/material from the uterus for treatment of incomplete abortion, first trimester abortion, and/or for menstrual regulation; it may also be intended for endometrial biopsy.	B
	(b) Intrauterine cannula, single use/disposable		B
61	Intrauterine haemostatic balloon catheter	A sterile, flexible tube with an inflatable balloon inserted into the uterus and distended with a medium (e.g., sterile water, medical air or other appropriate gas) to reduce postpartum bleeding with pressure.	B
62	Intrauterine haemostatic suction catheter	Inserted into the uterus to reduce postpartum bleeding through aspiration of blood/debris and induction of uterine contractions.	B
63	Intrauterine imaging medium catheter	Intrauterine injection of an opaque tracer medium, to facilitate radiography of the fallopian tubes/uterus.	B
64	Intrauterine imaging medium catheterization kit	Sterile devices intended for the intrauterine injection of an opaque tracer medium, to facilitate radiography of the fallopian tubes/uterus.	B
65	(a) Laparoscope laser coupler	To connect the laparoscope to the laser or the laser arm for laparoscopic laser treatment.	B
	(b) Laparoscope laser adaptor		A
66	Laparoscope system	For the visual examination and treatment of the abdominal/retroperitoneal cavity and its organs (laparoscopy).	B
67	Laparoscope system, reusable or single use	For the visual examination and treatment of the abdominal/retroperitoneal cavity and its organs (laparoscopy).	B
68	Manual expandable cervical dilator	To dilate the cervical canal with balloon when uterine does not dilate enough due to inertia uteri.	B
69	Mechanical foetal heart simulator	To imitate a foetal heart (e.g., foetal heart ultrasound signals) when used in combination with a foetal/maternal multiple physiological parameter simulator in order to test foetal monitoring and recording equipment [e.g., cardiotocograph (CTG)], check patient cable continuity, or to train healthcare providers.	B
70	Motorized laparoscopic forceps	Active surgical instrument designed for grasping, mobilizing, and suturing tissues/vessels under direct or endoscopic visualization during a surgical procedure.	B
71	Papanicolaou smear kit or Endometrial sampling kit	Used to collect and prepare pap smears samples in a medical institute.	B
72	Pelvic examination kit	For performing pelvic examination	B
73	Pelvimeter	A measuring device used to determine the pelvic dimensions.	B
74	Pelviscope	An endoscope used for visual examination and diagnosis of pelvis.	B
75	Perineal warmer	it is useful for pain relief in the vulva after episiotomy.	B
76	Perineometer	To determine perineal muscle strength through resistance to spontaneous contraction of perineal muscle. Also used to diagnose and treat urinary incontinence and sexual dysfunction through movement.	B

77	Pudendal anaesthesia kit	A collection of sterile devices designed to deliver anaesthetic agent to the external genitalia of humans.	B
78	Resectoscope	An endoscope used for visual examination, diagnosis and treatment, especially for resection of tissues.	B
79	Rigid culdoscope	An endoscope with a rigid inserted portion intended for the visual examination and treatment of the female peritoneal cavity and organs.	B
80	Rigid fibreoptic hysteroscope	An endoscope with a rigid inserted portion intended for the visual examination and treatment of the canal of the cervix and the uterine cavity (uterus).	B
81	Rigid mammary ductoscope	An endoscope with a rigid inserted portion intended for the visual examination and treatment of the mammary duct	B
82	Rigid optical laparoscope	An endoscope with a rigid inserted portion intended for the visual examination and treatment of the abdominal/retroperitoneal cavity and its organs.	B
83	Rigid salpingoscope	An endoscope with a rigid inserted portion intended for the visual examination and treatment of the fallopian tubes (oviducts)	B
84	Rigid ultrasound laparoscope	An endoscope with a rigid inserted portion, combined with an ultrasound probe, intended for the visual examination, treatment, and ultrasonic imaging of the abdominal/retroperitoneal cavity and its organs	B
85	Rigid video hysteroscope	Active device intended to allow visual examination and treatment of the canal of the cervix and the uterine cavity (uterus).	B
86	Rigid video laparoscope	An endoscope with a rigid inserted portion intended for the visual examination and treatment of the abdominal/retroperitoneal cavity and its organs	B
87	(a) Suprapubic needle, surgical, reusable	Percutaneously puncture the lower abdominal wall to provide suprapubic access for surgical repair.	B
	(b) Suprapubic needle, surgical, single use/disposable		B
88	Umbilical ligator	Surgical device used for umbilical cord ligation.	A
89	Uterine injector	Used to inject liquid, drug, or other substance into uterus. It is a reusable device.	B
90	Uterine manipulator cervical cup/transilluminator	Allow manipulation of the uterus under suction whilst preventing laparoscopic insufflation gas from escaping from the cervix (during hysterectomy).	B
91	(a) Uterine manipulator, reusable	Surgical instrument designed to mechanically manipulate the position of the uterus during a gynaecological intervention	B
	(b) Uterine manipulator, single use/disposable		B

92	Uterine packer	A hand-held, surgical instrument used to introduce dressings into the uterus or vagina. This is a reusable device.	A
93	(a) Uterine probe, reusable	For exploring the uterus during a surgical procedure. Used as a component of a uterine manipulator	B
	(b) Uterine probe, single use/disposable		B
94	Uterus-supporting pessary	Inserted into the vagina to hold the uterus in place.	B
95	Vaginal applicator, reusable or single use	A device designed to apply medication to the vagina.	A
96	(a) Vaginal dilator, reusable	Inserted into the vagina to dilate a narrow vaginal opening due to congenital defect. Can be used during examination, treatment or surgical procedure.	B
	(b) Vaginal dilator, single use/disposable		B
97	Vaginal douche, reusable or single use	To deliver a liquid (usually solution) directly into the vaginal cavity for hygienic purpose as a douche.	B
98	Vaginometer	A device that measures the length and diameter of vagina.	A
99	Vaginoscope	For paediatric vaginal examination. To search foreign matter or bleeding site.	B
100	Viscera retention paddle or Visceral retainer	Used to hold an organ at proper position (i.e., viscera) while the surgeon performs a suturing procedure (typically internal wound closure). It is also implanted into a surgical site temporarily.	B
101	Breast transilluminator	Active device transmitted through the female breast to visualize translucent tissue for the diagnosis of cancer, or other conditions, diseases or abnormalities.	C
102	Amniotic membrane perforator, reusable	A surgical instrument used to rupture the amniotic membrane to assist in childbirth, without causing injury to the mother or foetus	A
103	Amniotome, reusable	A surgical instrument used to rupture the amniotic membrane to assist in childbirth, without causing injury to the mother or foetus	B
104	Bladder-supporting pessary	inserted into the vagina to facilitate management of female urinary incontinence and/or to reduce bladder prolapse.	B
105	Catheter-tip transducer, pressure	A device intended to be incorporated into the distal end of a catheter (not included) to measure pressure.	B
106	Foetal Doppler system	Active non-invasive device to detect foetal heart beats using ultrasound/Doppler technology.	C
107	Foetal Doppler system probe	Placed on the surface of a pregnant woman's abdomen to detect foetal heart beats using ultrasonic/Doppler technology.	C
108	Preservation medium for human semen	It is intended for cryopreservation of human semen for later use in Assisted Reproductive procedure. It may include medicinal and biological components like glycerol, gentamicin, Test Yolk Buffer (TYB),etc.	C
109	Sperm cryopreservation medium	It is intended for use in Assisted Reproductive procedure involving the cryopreservation and storage of semen.	C

110	Vitrification freezing kit	It is intended for use in Assisted Reproductive procedure for vitrification and storage of human oocytes (MII), Pronuclear (PN) zygotes through day 3 cleavage stage embryos and blastocyst stage embryos. It may include medicinal and protein supplements like Gentamicin, Dextran Serum Supplement (DSS), etc.	C
111	Vitrification Thawing/Warming kit	Intended for use in the thawing of vitrified oocytes (MII), pronuclear (PN) zygotes through day 3 cleavage stage embryos and blastocyst stage embryos that have been vitrified using vitrification freeze kit. It may include medicinal and protein supplements like Gentamicin, Dextran Serum Supplement (DSS), etc.	C
112	Handling medium	Intended for use in Assisted reproductive procedure which involves manipulation of gametes or embryos. Specially, it is indicated for use as an oocyte retrieval medium during ovarian follicle aspiration procedure, washing sperm prior to IVF and ICSI (Intra Cytoplasmic sperm injection) fertilization procedures, and for transport of the embryo to the uterus during embryo transfer procedure. It may include medicinal and protein supplements like Gentamicin, Human Serum Albumin (HSA), etc.	C
113	Gamete and embryo retrieval, storage and transfer medium	Used in Assisted reproductive procedure which includes retrieval, culture, transport, storage, handling, and transfer of human gametes and embryos by creating a physiological environment. It may include buffer solution and medicinal substance like Gentamicin, etc.	C
114	Hyaluronidase solution	Intended for use in removing cumulus cells surrounding oocytes (denudation) in preparation for ICSI (Intra cytoplasmic sperm injection) or other Assisted reproductive procedures. It is an enzymatic solution containing bovine derived hyaluronidase in a HEPES (4-(2-hydroxyethyl)-1-piperazineethanesulfonic acid) buffered HTF (Human Tubal Fluid) medium supplemented with therapeutic grade human serum albumin and gentamicin sulfate.	C
115	Polyvinylpyrrolidone (PVP) Solution	Used in Assisted reproductive procedure which include human gamete and embryo manipulation. It uses PVP solution for immobilizing sperm for ICSI (Intra cytoplasmic sperm injection) procedures. This solution may include protein supplement like Human Serum Albumin (HSA), etc.	C
116	Sperm Separation Medium	It is intended for separation of the motile fraction of sperm from seminal fluid. It works on the principle of isopycnic separation.	B
117	Sperm processing media	Designed to maintain sperm quality on the table top without CO2 incubation. This procedure includes use of this medium for sperm washing by supporting all steps of sperm preparation prior to fertilization. It may contain protein supplements like human serum albumin (HSA), bovine serum albumin, etc.	C
118	Water for Assisted Reproductive Technologies	Intended for use in ART Laboratories procedure requiring a non-pyrogenic high quality pure grade of water.	B
119	In Vitro embryo Culture medium, through day 5/6 of development	It is intended for use in assisted reproductive procedures which include gamete and embryo manipulation. It is used as a culture medium for human gametes and embryos from fertilization through day 5/6 of development. It may include medicinal substance like Gentamicin and protein supplement like Human serum Albumin (HSA), etc.	C

120	In Vitro embryo culture medium, through day 3 of development	This medium is intended for use in assisted reproductive procedures which include human gamete and embryo manipulation. It is used as a culture medium through day 3 of development. It may be used as a stand-alone medium, or as the first stage of a sequential medium protocol. It may include medicinal substance like Gentamicin, etc.	C
121	Protein supplement for in vitro embryo culture	For use in assisted reproductive procedures which include gamete and embryo manipulation, as a supplement for culture media. It may include protein supplement like Human Serum Albumin (HSA), Synthetic Serum Substitute (SSS), Dextran Serum Supplement (DSS), etc. Not for use as an injectable product.	B
122	Oil for embryo culture	It is used as an overlay to cover small volumes of culture media during human embryo and gamete manipulation to prevent evaporation of culture media.	B
123	Menstrual Cup	Placed in the vagina to collect blood and cellular debris discharges during menstruation and discharges outside of the monthly menses.	B