

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

NOTICE

File No. 29/Misc./03/2020-DC (145)

Date: 23 AUG 2021

Subject: Classification of medical device pertaining to Urology 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.



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

To,

1. CDSCO Website

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

Classification of Medical Devices Pertaining to Urology

S. No.	Device Name	Intended Use	Risk Class
1	Bare-metal urethral stent, short-term	A sterile non-bioabsorbable tubular device intended to be placed short-term (<= 30 days) in the urethra to facilitate urethral patency and an unimpeded flow of urine from the bladder; it is typically used to relieve lower urinary tract symptoms (LUTS) due to benign prostatic hyperplasia (BPH).	C
2	Biliary/urinary stone retrieval basket	A flexible manual instrument designed to remove biliary and/or urinary stones (gallbladder and/or renal calculi) from the body during an endoscopic procedure.	B
3	Bladder neck spreader	A manual gastroenterology-urology surgical instrument with specially designed moveable blades intended to be used to separate and spread the bladder neck. This is a reusable device.	A
4	Bladder-emptying vibratory stimulator	A battery-powered, hand-held device intended to be used in the home or healthcare facility by a patient to help initiate urination and facilitate complete bladder emptying through application of small mechanical vibrations to the lower abdomen to promote urethral sphincter relaxation.	B
5	Closed-ended wearable urine collection bag, non-sterile	A non-sterile flexible plastic pouch designed to connect to a urinary catheter and to be strapped to the leg of a patient to collect discharged urine; it is not designed with an opening for urine drainage.	A
6	Closed-ended wearable urine collection bag, sterile	A sterile flexible plastic pouch designed to connect to a urinary catheter and to be strapped to the leg of a patient to collect discharged urine; it is not designed with an opening for urine drainage.	A
7	Cystometer	A device used to examine the bladder, providing measurement data concerning pressure and volume. This data will be used for diagnostic evaluation of the neuromuscular mechanisms of the bladder.	B
8	Cystometer probe, ultrasonic	A device that emits ultrasound energy generated by a cystometer in order to study bladder function by measuring bladder capacity, sensation, pressure, and residual urine.	B
9	Cystoscopic electrode	A sterile electrical conductor intended to be placed in contact with the bladder to stimulate it and/or record its electrical activity for diagnostic examination.	B

10	Diaphragm wearable urinal	A non-sterile urine drainage device designed for men with incontinence consisting of a front piece with a scrotal support and a leak-proof, flexible diaphragm through which the penis passes into a closed cone-shaped tube connected to a leg bag into which the urine is collected.	A
11	Draping incontinence liner	A non-sterile padded sheet intended to cover and protect a device/piece of furniture (e.g., wheelchair, bed, sofa) occupied by an incontinent person by catching and retaining urine.	A
12	Drip wearable urinal	A non-sterile urine drainage device designed for men to contain a moderate leakage consisting of a front piece with an integrated tubular sheath that fits fully over the penis and into which dribbling urine is collected.	A
13	Electrohydraulic lithotripsy system	An assembly of devices that uses plasma-induced shock waves for the intracorporeal fragmentation of stones (calculi) found in the kidney, ureter, and bladder.	B
14	Electrohydraulic/pneumatic lithotripsy system probe, urinary, single-use	A sterile, slender, rod-like device intended to be used as part of an intracorporeal lithotripsy system to transmit shock waves from electrohydraulic or pneumatic sources directly to a calculus in the urinary tract (i.e., kidneys, ureters, and bladder), providing high-speed fragmentation of the calculus in situ.	B
15	Electromechanical lithotripsy system, extracorporeal	An assembly of devices that non-invasively disintegrates stones (i.e., calculi) by sending focused shock waves from outside the body produced by an electromechanical generator.	B
16	Electromechanical lithotripsy system, intracorporeal	An assembly of devices designed to create shock waves through electromechanical action for the intracorporeal fragmentation of calculi (stones) in the urinary tract (i.e., kidney, ureter and bladder); the resulting debris may be actively removed or passed out by natural means at a later date.	B
17	Female wearable urinal, reusable	A non-sterile, urine drainage device designed for women that typically consists of a flexible tube attached to a collector that is specially formed to securely fit around the female genitals to provide a route to channel urine, via a tube, into a collection bag.	A
18	Fibreoptic ureteral catheter, reusable	A flexible tube containing a fibreoptic bundle that emits light throughout its length, intended to be inserted into the ureter for illumination to enable the path of the ureter to be seen. It also includes a plug for connection to a fibreoptic light source and a port for irrigation at its proximal end.	B
19	Filiform urethral bougie	An extremely thin, wire-like, manual surgical instrument designed for traversing and exploring urethral strictures and/or dilating the urethra, introduced directly or through an appropriately-threaded urethral catheter.	B

20	Flexible endoscopic stone-retrieval forceps, reusable	A flexible manual device intended to be inserted through the working channel of a compatible flexible endoscope to grasp and remove stones (e.g., calculi from the urinary tract) or foreign bodies during an endoscopic procedure.	B
21	Flexible fibreoptic cystonephroscope	An endoscope with a flexible inserted portion intended for the visual examination/treatment of the bladder, the urethra (including the prostate region), and the kidneys.	B
22	Flexible fibreoptic cystoscope	An endoscope with a flexible inserted portion intended for the visual examination and treatment of the bladder and the urinary tract.	B
23	Flexible fibreoptic cystourethroscope	An endoscope with a flexible inserted portion intended for the visual examination and treatment of the bladder and the urethra, including the prostate region.	B
24	Flexible fibreoptic nephroscope	An endoscope with a flexible inserted portion intended for the visual examination and treatment of the kidney. It is inserted percutaneously into the renal pelvis during nephroscopy.	B
25	Flexible fibreoptic ureterorenoscope	An endoscope with a flexible inserted portion intended for the visual examination and treatment of the ureter and the renal pelvis.	B
26	Flexible fibreoptic ureteroscope	An endoscope with a flexible inserted portion intended for the visual examination and treatment of the ureter (the upper urinary tract that connects the kidney to the bladder).	B
27	Flexible fibreoptic urethroscope	An endoscope with a flexible inserted portion intended for the visual examination and treatment of the urethra (the muscular tube that leaves the urinary bladder for the excretion of urine).	B
28	Flexible ureteral sheath/fibreoptic telescope	A sterile device assembly intended to function as a flexible endoscope for the visual examination and treatment of body cavities/organs that can be accessed via the ureter for cystoscopic, nephroscopic, laparoscopic, and ureteroscopic procedures.	B
29	Flexible video cystonephroscope	An endoscope with a flexible inserted portion intended for the visual examination/treatment of the bladder, urethra (including prostate region), and kidneys.	B
30	Flexible video cystoscope, reusable	An endoscope with a flexible inserted portion intended for the visual examination and treatment of the bladder and the urinary tract by introduction through the urethra.	B
31	Flexible video cystourethroscope	An endoscope with a flexible inserted portion intended for the visual examination and treatment of the bladder and the urethra, including the prostate region.	B
32	Flexible video nephroscope	An endoscope with a flexible inserted portion intended for the visual examination and treatment of the kidney.	B

33	Flexible video ureterorenoscope, reusable	An endoscope with a flexible inserted portion intended for the visual examination and treatment of the ureter and the renal pelvis.	B
34	Flexible video ureteroscope, reusable	An endoscope with a flexible inserted portion intended for the visual examination and treatment of the ureter (the upper urinary tract that connects the kidney to the bladder).	B
35	Flexible video urethroscope	An endoscope with a flexible inserted portion intended for the visual examination and treatment of the urethra (the muscular tube that leaves the urinary bladder for the excretion of urine).	B
36	General-purpose ureteral catheter	A flexible tube designed for introduction into the ureters through a cystoscope or nephroscope.	B
37	Hand pneumatic lithotripsy system, urinary	An assembly of devices, held by the operator, that uses pneumatically-created ballistic shock waves for the intracorporeal fragmentation of stones (calculi) in the urinary tract (i.e., kidneys, ureters, and bladder) for their removal.	B
38	Hand-held urinal, female	A portable, hand-held container/set, typically made of plastic, intended to be directly urinated into by a female (typically bed-bound) patient for excretory purposes.	A
39	Hand-held urinal, male, reusable	A portable, hand-held container intended to be directly urinated into by a male (typically bed-bound) patient for excretory purposes.	A
40	Hepatic function analysis system	An assembly of mains electricity (AC-powered) devices intended to aid in the quantitative assessment of liver function by the in vivo measurement of the plasma concentration and clearance of a tracer substance [e.g., indocyanine green (ICG)] in the peripheral vasculature following intravenous injection.	B
41	Home faecal specimen collection kit	A collection of non-sterile devices and materials intended to be used by a layperson to collect and mail a faecal (stool) sample to a clinical laboratory for diagnostic testing or screening purposes (e.g., occult blood, cytology).	A
42	Hydraulic male urinary incontinence treatment system	An assembly of implantable devices intended to treat male urinary incontinence by applying pressure to partially/fully occlude the bladder neck and/or urethra, typically after radical prostatectomy or transurethral resection of the prostate.	C
43	Hydraulic male urinary incontinence treatment system port	An implantable component of a hydraulic male urinary incontinence treatment system intended to provide access to the system's inflatable pad (e.g., cushion, balloon), for the intra- and/or postoperative introduction/removal of fluid (e.g., saline).	C

44	Hydraulic male urinary incontinence treatment system tubing	An implantable length of tube that functions as a component of a hydraulic male urinary incontinence treatment system and intended to provide connection between the system's inflatable pad (e.g., cushion, balloon) and the system's port, for the intra- and/or postoperative introduction/removal of fluid (e.g., saline); it is typically made of silicone and metal.	C
45	Hydraulic male urinary incontinence treatment system tubing plug	An implantable component of a hydraulic male urinary incontinence treatment system intended to seal the system's tubing to prevent spillage/leakage of its contents when introduction/removal of fluid to/from the system's pad (e.g., cushion, balloon) is not needed; it is typically made of metal.	C
46	Incontinence device suspender	A device used by a person with a disability to secure a body-worn incontinence device [e.g., a nappy (diaper) or a pad] in a stable and safe position.	A
47	Incontinence penis clamp, reusable	A male urinary incontinence device designed to gently compress the penis, either the proximal shaft or the glans penis, to occlude the urethra and prevent involuntary urination/dribbling for men who are incontinent of the bladder.	A
48	Incontinence sensor/alarm	A electrically-powered electronic device intended to provide an audible, visible and/or tactile signal to alert the patient or a caregiver when a small quantity of urine and/or faeces incontinently released is detected by a sensing mechanism (e.g., a sensor pad or detector).	B
49	Inflatable penile prosthesis	An inflatable/deflatable sterile device designed of several interconnected components intended to be surgically implanted in a patient with erectile dysfunction (ED) [commonly known as impotence] in order to achieve selective penile tumescence and rigidity adequate for vaginal intercourse	C
50	Intermittent urethral catheterization kit, non-sterile	A collection of non-sterile devices that includes a urological catheter (with or without a urine drainage bag), a cap, and other related accessories intended for self-urinary catheterization.	B
51	Intermittent urethral catheterization kit, sterile	A collection of sterile devices that includes a urological catheter (with or without a urine drainage bag), a cap, and other related accessories intended for self-urinary catheterization.	B
52	Intermittent urethral drainage catheter, antimicrobial	A sterile, flexible or rigid, tube designed to be repeatedly inserted through the urethra, typically by the user (i.e., self-applied), to the urinary bladder to provide short-term, episodic urine drainage (removed after each void), typically for an individual who is physiologically incapable of voiding.	B

53	Intermittent urethral drainage catheter, non-sterile	A non-sterile, flexible or rigid, tube designed to be repeatedly inserted through the urethra, typically by the user (i.e., self-applied), to the urinary bladder to provide short-term, episodic urine drainage (removed after each void), typically for an individual who is physiologically incapable of voiding.	B
54	Intermittent urethral drainage catheter, sterile	A sterile, flexible or rigid, tube designed to be repeatedly inserted through the urethra, typically by the user (i.e., self-applied), to the urinary bladder to provide short-term, episodic urine drainage (removed after each void), typically for an individual who is physiologically incapable of voiding.	B
55	Intracorporeal lithotripsy suction system	An assembly of devices designed for use with an intracorporeal lithotripsy system to evacuate, by suction, the irrigation fluid-containing fragments of urinary calculi from the kidneys, ureters, and bladder during lithotripsy.	B
56	Intraurethral valve/pump	A sterile, non-powered device intended to be inserted into the female urethra to facilitate urine voiding in patients with incomplete bladder emptying due to impaired detrusor contractility (IDC) of neurologic origin.	B
57	Laser lithotripsy fibre/suction guide	A sterile device intended to be inserted through the working channel of a rigid nephroscope during laser lithotripsy to function as a channel for insertion of the laser fibre of a laser beam guide (e.g., of a general/multiple surgical laser system), and for removal of debris (e.g., fluid, calculi fragments) when connected to a vacuum source.	C
58	Laser lithotripsy system	An assembly of devices consisting of a specialized ureteroscope, a laser resistant catheter, and a dedicated laser designed for the intracorporeal disintegration of ureteral stones (calculi).	C
59	Lithotrite	A hand-held manual surgical instrument designed for the mechanical crushing of renal stones (calculi) in the urinary tract and/or bladder	B
60	Male urinary outflow analysis system	A mains electricity (AC-powered) assembly of devices intended to be used to measure urine flow rate and to estimate iso-volumetric bladder pressure in men with the use of an inflatable penile cuff. It typically consists of a dedicated computer and application software, an automatic cuff inflation/deflation unit, a single-use penile cuff, and a load-measuring cell/stand.	B
61	Male urinary outflow analysis system cuff	A non-sterile inflatable cuff that is a component of a male urinary outflow analysis system.	B
62	Manometric catheter sheath	A non-sterile, synthetic polymer sleeve intended to cover/protect and prevent contamination of a manometric catheter (including barostat catheter).	B

63	Microwave hyperthermia system catheter, prostatic-ablation, reusable	A thin rod intended to be used as part of a hyperthermia system to treat disorders of the prostate [e.g., cancer, benign prostatic hyperplasia (BPH), prostatitis] through the local application of heat from microwaves.	C
64	Penile extracorporeal shock wave therapy system	A mobile assembly of devices designed to provide spark-gap-generated, low-intensity, extracorporeal shock wave therapy to treat erectile dysfunction (ED) [impotence] to rehabilitate penile erection and rigidity adequate for intercourse.	B
65	Penile extracorporeal shock wave therapy system applicator	A hand-held device designed to transmit spark-gap-generated (electrohydraulic), low-intensity, shock waves from a penile extracorporeal shock wave therapy system generator to the skin of the penile shaft and the penile crura to treat erectile dysfunction (ED) [impotence] to rehabilitate penile erection and rigidity adequate for intercourse.	B
66	Penis wearable urinal	A non-sterile, externally-worn, urine drainage device intended to be worn over the penis of an incontinent male patient to channel urine, via a tube, into a collection bag. It consists of a urinary incontinence penis attachment (e.g., sheath or adhesive port), tubing, and a wearable urine collection bag.	B
67	Penis/scrotum wearable urinal	A non-sterile urine drainage device designed for men with incontinence and a retracted penis that includes a front piece (a shaped cone) intended to contain both the penis and the scrotum to form a leak-proof seal around the male genitals.	B
68	Perineal orifice incontinence-control electrical stimulation system, remote control	An assembly of battery-powered, remote-controlled devices designed for intravaginal pelvic floor exercise to treat urinary incontinence and other pelvic problems in women (e.g., pelvic pain and sexual dysfunction) through the application of electrical stimuli to the muscles of the pelvic floor.	C
69	Piezoelectric lithotripsy system	An assembly of devices that non-invasively disintegrates stones (i.e., calculi) by sending focused shock waves from outside the body produced by a piezoelectric generator.	C
70	Pyeloscope	An endoscope with a rigid inserted portion intended for the visual examination and treatment of the renal pelvis and major or minor calyces.	B
71	Rigid cystoscope	An endoscope with a rigid inserted portion intended for the visual examination and treatment of the bladder and the urinary tract.	B
72	Rigid cystourethroscope	An endoscope with a rigid inserted portion intended for the visual examination and treatment of the bladder and the urethra, including the prostate region.	B
73	Rigid nephroscope	An endoscope with a rigid inserted portion intended for the visual examination and treatment of the kidney.	B

74	Rigid ureterorenoscope	An endoscope with a rigid or semi-rigid inserted portion intended for the visual examination and treatment of the ureter and the renal pelvis; some types may have a flexible tip at the distal end of the inserted portion.	B
75	Rigid ureteroscope	An endoscope with a rigid inserted portion intended for the visual examination and treatment of the ureter, (the upper urinary tract that connects the kidney to the bladder).	B
76	Rigid urethroscope	An endoscope with a rigid inserted portion intended for the visual examination and treatment of the urethra (the muscular tube that leaves the urinary bladder for the excretion of urine).	B
77	Rigid video ureterorenoscope	A sterile endoscope with a rigid or semi-rigid inserted portion intended for the visual examination and treatment of the ureter and the renal pelvis; some types may have a flexible tip at the distal end of the inserted portion.	B
78	Spark-gap lithotripsy system	An assembly of devices that non-invasively disintegrates stones (i.e., calculi) by sending focused shock waves from outside the body produced by a spark-gap generator.	B
79	Suprapubic needle, surgical, reusable	A hand-held manual surgical instrument designed with a sharp pyramidal or conical point at the distal end to percutaneously puncture the lower abdominal wall to provide suprapubic access for surgical repair, typically to position a sling used in the treatment of female stress urinary incontinence (SUI) associated with bladder prolapse.	B
80	Temperature-monitoring indwelling urethral drainage catheter	A sterile, flexible tube with an inflatable balloon on its distal tip for retention in the urinary bladder, after its insertion through the urethra, where it functions as a long-term indwelling device for continuous urinary drainage and simultaneous monitoring of core body temperature through its integral temperature sensor, typically during or after surgery or in the presence of obstruction or paralysis.	B
81	Transobturator needle, reusable	A hand-held manual surgical instrument with a sharp pyramidal or conical point used to create a percutaneous puncture using the transobturator approach (i.e., the insertion points overlie the obturator space in the genitofemoral crease lateral to the vagina), for the surgical positioning of a sling used in the treatment of stress urinary incontinence (SUI), which may be associated with a prolapse.	B
82	Transvaginal needle, surgical	A hand-held manual surgical instrument with a sharp pyramidal or conical point designed to create a puncture in the vaginal wall for the surgical positioning of a sling typically used in the treatment of stress urinary incontinence (SUI) associated with bladder prolapse.	B

83	Ultrasonic lithotripsy system	An assembly of devices designed to use ultrasonic (US) shock waves for the intracorporeal fragmentation of stones (calculi) found in the kidney, ureter, and bladder.	B
84	Ureteral patency kit	A collection of devices intended to assist treatment of a blocked ureter and to help maintain ureteral patency through natural orifice or percutaneous access.	B
85	Urethral drainage catheter punch	A hand-held manual instrument designed for cutting a small hole (e.g., 0.3 mm diameter) into the distal end of a closed Foley catheter (usually 14.0 French or larger) to form a "Council tip Foley catheter", allowing it to be placed over a guidewire or ureteral catheter.	B
86	Urethral/suprapubic catheter valve-connector	A small, sterile valve intended to be connected to a urethral and/or suprapubic catheter to allow intermittent bladder drainage/filling (as an alternative to continuous drainage).	A
87	Urinary-incontinence vaginal insert, reusable	A non-sterile, device intended to be inserted into the vagina in order to relieve mixed or stress urinary incontinence in an adult female by providing urethral support when pressure is transferred from the abdomen to the pelvic floor area (e.g. upon coughing, laughing, sneezing, exertion).	A
88	Urodynamic measurement system	An assembly of devices used for advanced diagnosis/study of the bladder. It is used to identify the cause of abnormal voiding, including incontinence and is useful for the diagnosis of, e.g., neurogenic bladder diseases, stress incontinence, urinary path obstruction or spastic sphincters.	B