

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

Notice

File No. 29/Misc./03/2020-DC (143)

Date: 11 3 SEP 2021

**Subject: Classification of Medical Device pertaining to Nephrology and Renal Care
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.

V.G.S.

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

To,

1. CDSCO Website

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Classification of Medical devices pertaining to Nephrology and Renal Care

S. No.	Medical Device Name	Intended Use	Risk Class
1	Absorbable peritoneum catheter cuff	Intended to maintain stable contact between the skin and the peritoneal dialysis catheter, and prevents bacterial invasion from the outlet. It is embedded subcutaneously at the outlet of the peritoneal dialysis catheter.	D
2	Automated peritoneal dialysis system	An active medical devices intended to perform peritoneal dialysis.	C
3	Urinary stone retrieval basket	Intended to remove urinary stones (renal calculi) from the body during an endoscopic procedure.	B
4	Chair, Haemodialysis, Electrically powered/Manual.	Intended to support the patient in a seated or reclined posture during haemodialysis procedures.	A
5	Collagen-containing peritoneum absorbable catheter cuff	A cuff that consists of biodegradable porous material containing collagen, intended to be embedded subcutaneously at the outlet of the peritoneal dialysis catheter.	D
6	Crimp for plier, Haemodialysis	Intended to manipulate the arteriovenous shunt of patients required hemodialysis.	A
7	Dialyser connector	Intended to connect between a dialysis fluid circuit and dialyzer, etc.	B
8	Dialysis apheresis unit, Therapeutic	Intended to filtrates the blood and separates the plasma, and extracts specific substances in the plasma (e.g., LDL-cholesterol). Then, the plasma is passed through the filtration column in the device and the specific substances that are combined with various substrates are extracted.	C
9	Disposable Hemoperfusion Cartridge	Intended in hemoperfusion machine to thoroughly remove the endogenous and exogenous materials such as residual drugs, toxins and metabolic substances in patients by means of adsorption of synthetic resin and extracorporeal blood circulation.	C
10	Electrical conductivity measuring instrument for dialysis fluid	Intended to determine the concentration of dialysis fluid supplied to a dialyzer based on the measurement of electrical conductivity of dialysis fluid (usually it is electrically measured)	C
11	Flexible fiberoptic nephroscope	Intended for the visual examination of internal structures and treatment of the kidney (eg: renal calculus) by inserting percutaneously into the renal pelvis during nephroscopy.	B

12	Haemodialyzer reprocessing system	Intended to clean (incl. rinsing, cleaning, testing and record keeping of process) and disinfect haemodialysis dialyzers after each use so that they can be reused.	C
13	Haemofilters	A filter used in the process of haemofiltration, to allow for the removal of toxins and/or the replacement of electrolytes.	C
14	Hemodiafiltration system	A device used for blood purification with a hemodiafilter.	C
15	Hemodialysis blood tubing/Extracorporeal systems for blood purification	Sterilized blood tubing intended for hemodialysis (including hemofiltration and hemodiafiltration).	B
16	Hollow-fibre haemodialysis dialyser	Hollow fiber filter intended to remove impurities/fluid from the blood of a patient via haemodialysis machine.	C
17	Kidney donor-organ preservation/transport system	A dedicated system designed to support and maintain a donated kidney organ during transport from the donor to the receiver hospital where the organ will be transplanted into the recipient.	C
18	Kidney stone filter	A filter intended to be placed in the urinary duct to prevent a renal stone from moving from the kidney into the bladder.	C
19	Laser lithotripsy fibre/suction guide	Intended 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) in nephroscope, and for removal of debris (e.g., fluid, calculi fragments) when connected to a vacuum source.	B
20	Multi-patient dialysis fluid delivery system	Intended to prepares dialysis fluid for hemodialysis using an artificial kidney, capable of supplying dialysis fluid for two or more patients.	C
21	Peritoneal dialysis catheter adaptor	Intended to connect (devices of different makers and makes devices compatible with each other) a catheter for peritoneal lavage to an external device that manages dialysates.	B
22	Peritoneal dialysis catheter guidewire	A guidewire used temporarily for correction of the position of a peritoneal dialysis catheter.	B
23	Peritoneal dialysis dialysate warmer	Intended to heat the dialysate to within one degree, of kidney patient who is on continuous ambulatory peritoneal dialysis (CAPD), body temperature prior to infusion.	C
24	Peritoneal dialysis ultraviolet irradiation unit	intended for ultraviolet irradiation for disinfection of components of peritoneal dialysis transfer tube set.	B
25	Reverse Osmosis Unit (for dialysis)	Intended to be used with haemodialysis to produce water through reverse osmosis with quality suitable for use with haemodialysis equipment.	C

26	Rigid nephroscope	Intended for visual examination, diagnosis, and treatment of the kidney, renal pelvis, major calyces, and minor calyces by percutaneously inserting scope into the renal pelvis.	B
27	Shunt thrombus suction set	A set used to suction a thrombus developing inside an arteriovenous shunt (external shunt) during procedures including hemodialysis.	B
28	Portable continuous peritoneal perfusate thermal conditioner	A device that heats the peritoneal perfusate before injection into the peritoneal cavity. The perfusate is usually heated through direct contact of the dialysis fluid bag with the radiant heat source.	B
29	Citric acid haemodialysis system cleaning cartridge	Intended for the in-line preparation of a citric acid solution to clean/disinfect the fluid pathways of the system (remove calcium and magnesium deposits) in combination with a heat disinfection program.	B
30	Extracorporeal circuit waste bag	Intended to be used for the collection of waste fluids during preparation and processing of an extracorporeal circuit (e.g., haemodialysis, haemofiltration, apheresis, adsorption treatment), including the collection and rinsing of ultrafiltrate fluid which may contain blood components.	B
31	Haemodialysis Concentrate	Intended to remove metabolic waste from the blood to help maintain physiological blood electrolyte and pH levels while haemodialysis is performed	C
32	Haemodialysis conductivity standard solution	Intended to calibrate conductivity meters used to test the conductivity of dialysate, dialysate concentrate, and water treatment systems used with haemodialysis delivery systems.	C
33	Haemodialysis dialysate water chlorine test kit/strip	Intended to be used to rapidly indicate, through colour change, the concentration of total chlorine in water used to prepare dialysate solution for haemodialysis.	B
34	Haemodialysis system air/foam detector	Intended to identify air bubbles and/or foam in blood returned to the body [usually through an arteriovenous fistula (AVF)] by the extracorporeal blood circuit of a haemodialysis system.	C
35	Hemodialysis system bicarbonate mixer	Intended to mixes two concentrates, A and B, plus water, to the dialysis solution (dialysate) and monitors the mixture.	C
36	Haemodialysis system central monitor	Device intended to connect with multiple haemodialysis systems in order to aid monitoring several dialysis treatments simultaneously.	C
37	Haemodialysis system plasma filtration unit	An electrically-powered integral unit of a haemodialysis system that allows for the removal of plasma from the blood and the infusion of an equal amount of plasma replacement solution to the blood.	C
38	Peritoneal dialysis system dialysate filter	A microporous device used to capture contamination particles of the dialysate before its instillation into the peritoneal cavity.	C

39	Sodium carbonate haemodialysis system cleaning cartridge	Intended to be connected to the fluid circuit of an institutional haemodialysis system for the in-line preparation of a sodium carbonate solution to clean the fluid pathways of the system (remove organic deposits, fats, proteins) in combination with a heat disinfection program.	C
40	Peritoneal Dialysis Transfer Set	A transfer set is tubing that you use to connect your catheter to the bag of dialysis solution. It consists of tubing, connectors etc.	B
41	Peritoneal Dialysis Catheter	That allows dialysis fluid to enter the abdominal cavity, dwell inside for a while, and then drain back out again	B
42	Hemodialysis Catheter (Long Term)	A dialysis catheter is a catheter used for exchanging blood to and from the hemodialysis machine from the patient. The dialysis catheter contains two lumens: Venous. Arterial	C
43	Hemodialysis Catheter	A catheter used for exchanging blood to and from the haemodialysis machine from the patient.	B
44	Single Needle Hemodialysis Catheter/ Blood lines	The single-needle dialysis, in which case only one cannula or a single lumen catheter is used to access the blood.	B