

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

Notice

File No. 29/Misc./03/2020-DC (182)

Date: 27 SEP 2021

Subject: Classification of Medical Device pertaining to Gastroenterology 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.



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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 Gastroenterology

Sr No.	Medical Device Name	Intended Use	Risk Class
1	Absorbent enteric stomal dressing	To be placed over a continent enteric stoma (surgically-created artificial opening between the intestines and the body surface through which bodily waste is drained from the intestines) to protect it from harmful external influences, which includes absorbent materials intended to protect the surrounding skin from enteric fluids.	B
2	Anal fistula circular cutter	To be intended for the circumferential resection of tissue to treat simple anal fistula	B
3	Anal fistula seton	A sterile implantable cord intended to be placed through an anal fistula tract and tied outside the fistula, forming a loop around the anus, to allow drainage through the fistula for tissue healing.	C
4	Anoscope, reusable	An endoscope with a rigid inserted portion intended for the visual examination and treatment of the anus and rectum.	B
5	Anoscope, single-use	A sterile endoscope with a rigid inserted portion intended for the visual examination and treatment of the anus and rectum.	B
6	Barium enema catheter	A flexible tube designed to administer barium, a contrast medium, into the lower gastrointestinal tract by way of the rectum, for radiographic visualization of the area.	B
7	Bile duct prosthesis	An implantable artificial substitute for the tube-like structure that carries bile from the gallbladder to the duodenum.	C
8	Biliary manometric catheter	A sterile, non-electrical flexible tube intended to be inserted into the biliary tree to measure pressures within the ducts, especially to evaluate sphincter of Oddi function.	B

9	Catheter-balloon inflator, reprocessed	A sterile device designed to manually inflate and regulate the pressure of a balloon catheter (e.g., by injecting and aspirating fluid or air within the balloon), and to deflate the balloon during a medical procedure. It is typically used during angiography, angioplasty, gastrointestinal (GI), or sinuplasty procedures.	B
10	Catheter-balloon inflator, reusable	A device designed to manually inflate and regulate the pressure of a balloon catheter (e.g., by injecting and aspirating fluid or air within the balloon), and to deflate the balloon during a medical procedure.	B
11	Catheter-balloon inflator, single-use	A sterile device designed to manually inflate and regulate the pressure of a balloon catheter (e.g., by injecting and aspirating fluid or air within the balloon), and to deflate the balloon during a medical procedure.	B
12	Cholangiopancreatography catheter, reusable	A flexible tube inserted through a flexible endoscope, after its placement in the duodenum via the oral cavity, for the endoscopic cannulation of the gastrointestinal ductal system (i.e., the pancreatic, hepatic, and/or common bile ducts) during endoscopic retrograde cholangiopancreatography (ERCP).	B
13	Cholangiopancreatography catheter, single-use	A flexible tube inserted through a flexible endoscope, after its placement in the duodenum via the oral cavity, intended for the endoscopic cannulation of the gastrointestinal ductal system (i.e., the pancreatic, hepatic, and/or common bile ducts) during endoscopic retrograde cholangiopancreatography (ERCP).	B
14	Closed-ended intestinal ostomy bag, multiple-piece	A non-sterile plastic pouch designed to be attached around a faecal stoma for use as a receptacle for faeces following a colostomy [the stool (faeces) being generally well formed].	A
15	Closed-ended intestinal ostomy bag, one-piece	A non-sterile plastic pouch designed to be attached with an adhesive to the skin around a faecal stoma and used as a receptacle for faeces following a colostomy [the stool (faeces) being generally well formed].	A
16	Colonic endoscopy cuff	A sterile distal attachment to a flexible endoscope intended to improve endoscopic control and bowel visualization during colonic endoscopy.	B
17	Colonic lavage kit, surgical	A collection of sterile devices intended to be used during open colorectal surgery (bowel resection) to irrigate the colon above (proximal to) the site of a lesion/blockage, prior to surgical anastomosis, when preoperative preparation of the colon has not been possible, normally due to obstruction.	B

18	Colonic mucosa barrier dressing	A non-sterile solution/suspension intended to be introduced into the sigmoid/descending colon as an enema for the treatment of inflammatory bowel disease (e.g., ulcerative colitis). It is intended to create an adhesive physical barrier on the colonic mucosa to protect the mucosa from potentially harmful substances in the distal colon lumen	C
19	Colonoscope positioning sleeve	A non-sterile endoscopic sheath with two inflatable balloons designed to be mounted on a colonoscope to position and stabilize the endoscope within the large intestine of a patient.	B
20	Colonoscope stiffener	A dedicated stiff wire that is inserted into a flexible colonoscope to allow the physician to increase the stiffness of the colonoscope when extra rigidity is required during a colonoscopy.	B
21	Colorectal sizer	A hand-held manual surgical instrument designed to assess colon and/or rectal lumen diameter to aid the selection of an appropriate size intraluminal stapler (i. e, the stapler head) for bowel anastomosis following transection.	B
22	Common bile duct dilator	A hand-held manual surgical instrument designed to dilate the common bile duct, i.e., the union of the cystic and hepatic ducts.	B
23	Duodenal bypass liner	A non-sterile stent-like device with a valve designed to be implanted in the duodenum where it is intended to reduce duodenal nutrient absorption from food to facilitate obese patient weight loss.	C
24	Duodenal-jejunal bypass liner	A sterile stent-like implant designed to function as an impermeable barrier in the duodenum and part of the jejunum for partially-digested food from the stomach (chyme) passing on its inside and bile/digestive enzymes passing on its outside, intended to treat type 2 diabetes mellitus and obesity.	C
25	Endoscope tissue removal cap	A sterile plastic tube designed to be placed onto the distal end of an endoscope (e.g., oesophagoscope) to facilitate the removal of coagulated blood/tissue during electrosurgical treatment (e.g., for the treatment of Barrett's oesophagus).	B
26	Endoscopic biopsy valve, non-sterile	A non-sterile device intended to be fitted to an endoscope biopsy port to enable access for/exchange of endoscopic devices while maintaining insufflation and minimizing leakage of biomaterial during an endoscopic procedure.	A
27	Endoscopic biopsy valve, sterile	A sterile device intended to be fitted to an endoscope biopsy port to enable access for/exchange of endoscopic devices while maintaining insufflation and minimizing leakage of biomaterial during an endoscopic procedure.	B

28	Endoscopic cutting stapler connector	A rod-like component of an endoscopic cutting stapler intended to enable connection between the stapler handpiece and the endpiece/loading unit.	B
29	Endoscopic electro-surgical biopsy/resection kit, full-thickness	A collection of sterile devices, which includes an implantable haemostatic ligation clip, intended to be used to obtain a full-thickness tissue biopsy and/or therapeutic resection of gastric, duodenal, colonic, and/or rectal tissue during an endoscopic procedure.	C
30	Endoscopic electro-surgical biopsy/resection kit, partial-thickness	A collection of devices designed to be inserted through a compatible endoscope to obtain a mucosal tissue biopsy and/or therapeutic resection of upper gastrointestinal (GI) tract tissue, typically during endoscopic retrograde cholangiopancreatography (ERCP) procedures.	C
31	Endoscopic electro-surgical electrode/submucosal lift needle	A sterile, invasive, endoscopic device intended to deliver both: 1) a submucosal lifting solution; and 2) an electro-surgical current in a monopolar configuration (i.e., with a return electrode) to tissues for cutting/coagulation.	B
32	Endoscopic gastrointestinal stenosis dilator	A sterile invasive device intended to be used to dilate or expand a narrowing lesion (e.g., oesophageal stricture, stenosis) in the lumen of the gastrointestinal [GI] tract, under endoscopic visualization.	B
33	Endoscopic motorized cutting stapler, reusable	A hand-held, battery-powered surgical instrument designed to be used during endoscopic surgical procedures for the expeditious transection and resection of tissues and the creation of anastomoses.	B
34	Endoscopic motorized cutting stapler, single-use	A sterile, hand-held, battery-powered surgical instrument designed to be used during endoscopic surgical procedures for the expeditious transection and resection of tissues and the creation of anastomoses.	B
35	Endoscopic needleless submucosal lift catheter	A sterile, flexible tube intended to non-invasively deliver a submucosal lifting solution into the submucosa of the gastrointestinal tract through a flexible endoscope during an endoscopic procedure (e.g., gastroscopy, colonoscopy) to lift a lesion, typically for subsequent excision.	B
36	Endoscopic overtube, reusable	A tubular device intended to be used in combination with a compatible flexible endoscope to aid in endoscopic insertions and to secure a pathway for multiple endoscopic intubations during diagnostic and therapeutic endoscopic procedures (e.g., upper and/or lower gastrointestinal (GI) tract endoscopy).	B
37	Endoscopic spray catheter	A sterile, flexible tube intended to be used with an endoscope (e.g., colonoscope) to administer fluids (e.g., dyes for mucosal coloration) in spray form.	B

38	Enema tip, reusable	A non-sterile device made with Hevea natural rubber latex (NRL) intended to be connected to an enema tube to facilitate delivery of an enema solution into the rectum.	A
39	Enema tube	A non-sterile, length of tubing that is used as a conduit between the enema bag and the enema tip for the delivery of the enema solution into the rectum.	A
40	Enteral feeding tube clearing kit	A collection of non-sterile compounds and devices intended to be used to prevent and/or remove, through biochemical action, an enteral formula clog in an in situ enteral feeding tube to maintain luminal patency.	B
41	Enteral feeding/decompression tube clearing stem	A non-sterile, sheath-covered device intended to be used to mechanically clear a clog in an in situ nasogastric, nasoenteral, gastrostomy and/or jejunostomy tube, used for feeding and/or decompression, to maintain luminal patency.	A
42	Enteral tube extension, non-sterile	A non-sterile, thin, flexible tube intended for extracorporeal connection to an enteral feeding tube (e.g., nasogastric tube) to increase the length of tubing from the patient to an oral/enteral device (e.g., syringe) during enteral feeding/medication administration or aspiration.	B
43	Enteral tube extension, sterile	A sterile, thin, flexible tube intended for extracorporeal connection to an enteral feeding tube (e.g., nasogastric tube) to increase the length of tubing from the patient to an oral/enteral device (e.g., syringe) during enteral feeding/medication administration or aspiration.	B
44	Externally-propelled flexible video colonoscope	A non-sterile endoscope with a highly flexible sleeve and distal tip intended for the visual examination of the entire adult colon [lower gastrointestinal (GI) tract].	B
45	Fistula-repair biomatrix implant	A sterile, bioabsorbable, animal-derived substance intended to be injected into a fistula tract (e.g., anal or rectal fistula) to close it by adding volume and promoting the ingrowth and neovascularization of host tissue.	D
46	Flexible fibreoptic choledochoscope	An endoscope with a flexible inserted portion intended for the visual examination and treatment of the choledoc, better known as the common bile duct (CBD).	B
47	Flexible fibreoptic colonoscope	An endoscope with a flexible inserted portion intended for the visual examination and treatment of the entire colon [lower gastrointestinal (GI) tract].	B
48	Flexible fibreoptic duodenoscope	An endoscope with a flexible inserted portion intended for the visual examination and treatment of the duodenum (the first part of the small intestine).	B

49	Flexible fibreoptic enteroscope	An endoscope with a flexible inserted portion intended for the visual examination and treatment of the small intestine (the duodenum, jejunum, and ileum).	B
50	Flexible fibreoptic gastroduodenoscope	An endoscope with a flexible inserted portion intended for the visual examination and treatment of the upper gastrointestinal (GI) tract [oesophagus, stomach, and duodenum (the first part of the small intestine), including the pancreas and the bile duct].	B
51	Flexible fibreoptic gastroscope	An endoscope with a flexible inserted portion intended for the visual examination and treatment of the oesophagus and the stomach.	B
52	Flexible fibreoptic oesophagoscope	An endoscope with a flexible inserted portion intended the visual examination and treatment of the oesophagus.	B
53	Flexible fibreoptic pancreatoscope	An endoscope with a flexible inserted portion intended for the visual examination and treatment in the pancreas.	B
54	Flexible fibreoptic sigmoidoscope	An endoscope with a flexible inserted portion intended for the visual examination and treatment of the sigmoid colon (the distal S-shaped part of the large intestine leading to the rectum).	B
55	Flexible ultrasound colonoscope	An endoscope with a flexible inserted portion intended for the visual examination and treatment of the entire colon [lower gastrointestinal (GI) tract].	B
56	Flexible ultrasound duodenoscope	An endoscope with a flexible inserted portion, combined with an ultrasound probe, intended for the visual examination and treatment of the duodenum (the first part of the small intestine).	B
57	Flexible ultrasound gastroduodenoscope	An endoscope with a flexible inserted portion, combined with an ultrasound probe, intended for the visual examination and treatment of the upper gastrointestinal (GI) tract [oesophagus, stomach, and duodenum (the first part of the small intestine), including the pancreas and the bile duct].	B
58	Flexible video choledochoscope	An endoscope with a flexible inserted portion intended for the visual examination and treatment of the choledoc, better known as the common bile duct (CBD).	B
59	Flexible video choledochoscope, single-use	An endoscope with a flexible inserted portion intended for the visual examination and treatment of the biliary tract and related ducts [e.g., common bile duct (CBD), cystic duct, pancreatic duct], and for the removal of gallstones.	B
60	Flexible video colonoscope, reusable	An endoscope with a flexible inserted portion intended for the visual examination and treatment of the entire colon [lower gastrointestinal (GI) tract].	B

61	Flexible video colonoscope, single-use	A sterile endoscope with a flexible inserted portion intended for the visual examination and treatment of the entire colon [lower gastrointestinal (GI) tract].	B
62	Flexible video duodenoscope, reusable	An endoscope with a flexible inserted portion intended for the visual examination and treatment of the duodenum (the first part of the small intestine).	B
63	Flexible video duodenoscope, single-use	An endoscope with a flexible inserted portion intended for the visual examination and treatment of the duodenum (the first part of the small intestine).	B
64	Flexible video enteroscope	An endoscope with a flexible inserted portion intended for the visual examination and treatment of the small intestine (the duodenum, jejunum, and ileum).	B
65	Flexible video gastroduodenoscope	An endoscope with a flexible inserted portion intended for the visual examination and treatment of the upper gastrointestinal (GI) tract [oesophagus, stomach, and duodenum (the first part of the small intestine), including the pancreas and the bile duct].	B
66	Flexible video gastroscope	An endoscope with a flexible inserted portion intended for the visual examination and treatment of the oesophagus and the stomach.	B
67	Flexible video oesophagoscope, reusable	An endoscope with a flexible inserted portion intended for the visual examination and treatment of the oesophagus. It is inserted into the body through the mouth. Anatomical images are obtained via a camera incorporated at the distal end of the oesophagoscope and are shown on a monitor. This device is commonly used to examine abnormalities in the tissue structure and mucous lining of the oesophagus. This is a reusable device.	B
68	Flexible video oesophagoscope, single-use	An endoscope with a flexible inserted portion intended for the visual examination and treatment of the oesophagus.	B
69	Flexible video pancreatoscope	An endoscope with a flexible inserted portion intended for the visual examination and treatment in the pancreas.	B
70	Flexible video sigmoidoscope	An endoscope with a flexible inserted portion intended for the visual examination and treatment of the sigmoid colon (the distal S-shaped part of the large intestine leading to the rectum).	B
71	Gastric sleeve	A sterile implantable device intended to be wrapped around the proximal portion of the stomach to reduce stomach volume and facilitate weight loss in overweight/obese patients by attempting to restrict the quantity of food consumed through an increased sense of satiety (fullness).	C

72	Gastric tonometry catheter	A sterile flexible tube intended for orogastric, nasogastric, or rectal insertion to sample carbon dioxide (CO ₂) from the mucosal vasculature of the stomach or sigmoid colon for the measurement of partial pressure (i.e., tonometry) of CO ₂ (pCO ₂) during diagnosis of mesenteric ischemia.	B
73	Gastrointestinal anastomosis coupler, bioabsorbable	An implantable device intended to be used to join and transect excess tissue of gastrointestinal structures through the coupling of two ring-shaped components that are inserted into the ends of the segments to be attached.	D
74	Gastrointestinal anastomosis coupler, non-bioabsorbable	An implantable device intended to be used to join and transect excess tissue of gastrointestinal structures through the coupling of two ring-shaped components that are inserted into the ends of the segments to be attached.	C
75	Gastrointestinal catheter/endoscope tracking system	A multicomponent assembly of mains electricity (AC-powered) devices designed for real-time visualization/navigation of a catheter and/or endoscope during insertion in the gastrointestinal tract, by detecting its position/movement within an electromagnetic (EM) field and displaying three-dimensional (3-D) virtual images on a monitoring screen.	B
76	Gastrointestinal endoscopic clip applier	A device intended to be used in combination with a compatible flexible endoscope for the application of a gastrointestinal endoscopic clip(s) [not included] to the mucosal lining of the gastrointestinal (GI) tract for endoscopic marking, haemostasis, tissue approximation, closure of luminal perforations, and/or for treating mucosal/submucosal defects during an endoscopic procedure.	B
77	Gastrointestinal endoscopic clip cutter	A sterile device intended to be used in combination with a generator to remove a gastrointestinal endoscopic clip.	C
78	Gastrointestinal endoscopic clip cutter generator	A portable, mains electricity (AC-powered) device intended to be used in conjunction with a cutter for the endoscopic removal of a gastrointestinal endoscopic clip.	C
79	Gastrointestinal endoscopic clip, long-term	A sterile clip intended to be implanted long-term (>30 days) within the gastrointestinal (GI) tract during an endoscopic procedure for endoscopic marking, haemostasis, tissue approximation, closure of luminal perforations, and/or for treating mucosal/submucosal defects.	C

80	Gastrointestinal endoscopic clip, short-term	A sterile clip intended to be placed short-term (≤ 30 days) within the gastrointestinal (GI) tract during an endoscopic procedure for endoscopic marking, haemostasis, tissue approximation, closure of luminal perforations, and/or for treating mucosal/submucosal defects.	B
81	Gastrointestinal manometric catheter, electronic	A non-sterile flexible tube with electronic sensors at the distal end intended to be inserted through the nose or rectum into the gastrointestinal (GI) tract to evaluate peristaltic motility anywhere in the GI tract (pharynx, oesophagus, stomach, duodenum, small bowel, colon, and anorectal area) by measuring pressure; it may additionally be intended to measure pH and electrical impedance and contain a lumen.	B
82	Gastrointestinal manometric catheter, non-electronic	A non-sterile, non-electrical flexible tube intended to be inserted through the nose or rectum into the gastrointestinal (GI) tract for measuring pressure to assess peristaltic motility in the GI tract (e.g., oesophagus, stomach) or rectal musculature and anal sphincter functions, typically in the evaluation of GI disorders [e.g., gastro-oesophageal reflux disease (GERD), faecal incontinence].	B
83	Gastrointestinal ostomy tube pocket	A non-sterile, noninvasive pouch designed to be wrapped around the protruding end of a gastrointestinal ostomy tube (e.g., gastrostomy or jejunostomy tube) to hold and support it in order to ensure its stabilization on the patient.	A
84	Gastrojejunostomy tube	A sterile, thin, flexible, hollow cylinder percutaneously inserted into the stomach, typically through puncture of the abdominal wall and stomach after distention of the stomach by endoscopic methods, with an extended portion inserted through the pylorus into the jejunum. It is used to feed a patient who has a physical disability that prevents oral feeding (e.g., a birth defect of the mouth, oesophagus, or stomach, or a neuromuscular condition that affects chewing and swallowing), and to provide drainage/decompression for the stomach when it is necessary to bypass a longstanding obstruction of the stomach outlet into the small intestine.	C
85	Gastro-oesophageal antireflux prosthesis	An implantable device introduced into the gastro-oesophageal sphincter to reduce a sliding hiatal hernia, preventing the reflux of gastric contents into the oesophagus.	C

86	Gastro-oesophageal pH/impedance catheter, non-sterile	A non-sterile flexible tube with electronic sensors at its distal end intended to be inserted through the nose into the oesophagus and stomach to measure pH and/or electrical impedance, typically for the evaluation of gastro-oesophageal reflux disease (GERD), gastric ulcers, or other gastrointestinal conditions.	B
87	Gastro-oesophageal pH/impedance catheter, sterile	A sterile flexible tube with an with an electrical conductor at its distal end intended to be inserted through the nose into the oesophagus and stomach to measure pH and/or electrical impedance, typically for the evaluation of gastro-oesophageal reflux disease (GERD), gastric ulcers, or other gastrointestinal conditions.	B
88	Gastrostomy aspiration system gravity set	A collection of non-sterile devices designed as the external portion of a gastrostomy aspiration system intended to be used post-surgery by the patient after implantation of the stomach tube for the removal of a portion of stomach contents after meals, by aspiration, to achieve portion control and subsequently weight loss in a morbidly obese (bariatric) patient (≥ 18 years).	C
89	Gastrostomy aspiration system stomach tube	A sterile, thin, flexible, hollow cylinder intended to be percutaneously implanted by endoscopic methods into the stomach of a morbidly obese (bariatric) patient (≥ 18 years) for the removal of a portion of stomach contents after meals by aspiration when used with a dedicated gravity kit that is the external portion of a gastrostomy aspiration system.	C
90	Gastrostomy button	A sterile, short, tube that is inserted into the stomach percutaneously to permit long-term enteral feeding.	C
91	Gastrostomy T fastener	A device intended to be inserted into the stomach percutaneously to appose the anterior gastric wall to the anterior abdominal wall, typically to facilitate the insertion of a percutaneous gastrostomy tube or for procedures requiring stabilization/fixation of hollow gastrointestinal (GI) structures.	C
92	Gastrostomy tube Y-piece connector	A sterile connecting device shaped in the form of a "Y" intended for connection to the proximal end of a gastrostomy tube to enable administration of nutrient liquids and/or medication through the gastrostomy tube.	B
93	Gastro-urological director	A slender, rod-like surgical instrument made of metal, typically with groove running along the centre of it distal shaft and/or continuing with an elongated malleable wire loop, that is used to guide other devices or instruments into a selected intracorporeal location during a gastroenterological/urological (GU) procedure.	B

94	Gastro-urological probe	A slender, rod-like, hand-held manual surgical instrument, typically made of flexible metal with a blunt bulbous tip, designed for exploring gastroenterological/urological (GU) structures during a GU procedure.	B
95	Gastro-urological scoop	A heavy, hand-held, manual surgical instrument with a spoon-like, sharp-edged distal end on a long thin shaft that is used to access and scrape tissue from the common hepatic/bile duct system during a gastroenterological/urological (GU) procedure.	B
96	Gravity enema set	A collection of devices intended to be used to deliver an injection of fluid (e.g., saline solution) into the rectum to facilitate evacuation of the large intestine.	A
97	Implantable gastric clamp	A sterile implantable device designed to isolate the lesser curvature segment of the stomach (magenstrasse) to reduce stomach volume and facilitate weight loss in overweight/obese patients through a reduction in food consumption based on an increased sense of satiety (fullness).	C
98	Implantable incontinence-control electrical stimulation system	An assembly of battery-powered devices intended to treat chronic disorders of the pelvis and lower urinary or intestinal tract, typically related to urinary and/or faecal incontinence, through the application of electrical stimuli to the muscles and/or neural tissue of the pelvic floor/bladder.	C
99	Implantable peritoneal catheter holder	A small, sterile, implantable device designed to secure a peritoneal or lumboperitoneal catheter in situ by suturing it to the abdominal fascia at the point of entry/exit.	C
100	Intestinal ostomy bag anti-adhesion device	A non-sterile, noninvasive device intended to be applied to the inner surface of an intestinal ostomy bag to prevent opposing inner walls of the bag from sticking together (anti-pancaking).	A
101	Intestinal ostomy kit	A collection of non-sterile devices intended to be used for attachment/replacement of an intestinal ostomy bag (for collecting intestinal output such as faeces following a colostomy or ileostomy procedure).	A
102	Intestinal splint	A sterile rigid or flexible device intended to be implanted within the abdomen to stabilize a portion of the intestine, or to stabilize and protect an injured portion of the intestine.	C
103	Intestinal stoma shield/support belt, reusable	A non-sterile plate, typically with a waist belt for attachment, intended to be placed over an enteric stoma (surgically-created artificial opening between the intestines and the body surface through which bodily waste is drained) to protect it from harmful external influences (e.g., knocks, friction), to reduce the risk of stomal herniation, or to help maintain	A

		adhesion of the base plate to the skin.	
104	Intestinal stoma shield/support belt, single-use	A non-sterile plate, typically with a waist belt for attachment, intended to be placed over an enteric stoma (surgically-created artificial opening between the intestines and the body surface through which bodily waste is drained) to protect it from harmful external influences (e.g., knocks, friction), to reduce the risk of stomal herniation, or to help maintain adhesion of the base plate to the skin.	A
105	Intraluminal oesophageal retractor	A sterile, hand-held manual surgical instrument intended to be inserted through an orogastric (or nasogastric) tube to mechanically divert the oesophagus away from the site of surgery during electrical treatments of the heart (e.g., cardiac ablation), to facilitate surgical site access and to help prevent injury to the oesophagus.	B
106	Invasive silicone sheet dressing	A sterile, flat stretch of silicone elastomer intended for use as a short-term intra-abdominal dressing following abdominal surgery, when a re-exploration of the wound/abdomen is planned within a thirty day period. It is used to achieve temporary abdominal closure to avoid the complications of an open abdomen.	B
107	Laparoscopic cholangiography catheter/needle	A sterile, flexible, single-lumen tube with a distal needle intended to puncture the neck of the gallbladder (Hartmann's pouch) during laparoscopic cholangiography to allow injection of contrast media.	B
108	Laparoscopic grasping forceps, Non sterile	A sterile, rigid surgical instrument designed to be introduced through a laparoscope primarily for grasping and manipulating tissues during a laparoscopic surgical procedure.	A
109	Laparoscopic grasping forceps, sterile	A rigid surgical instrument designed to be introduced through a laparoscope primarily for grasping and manipulating tissues during a laparoscopic surgical procedure.	B
110	Laparoscopic swab forceps	An instrument designed to grasp a pledget swab at the distal end to obtain cytological specimens and/or to perform blunt dissection during gynaecologic and/or other (e.g., cholecystectomy) laparoscopic procedures.	B

111	Manual enema device	A non-sterile device intended to be used to manually administer fluid (e.g., saline solution) into the rectum to facilitate evacuation of the large intestine through expansion of the lower intestinal tract and physical stimulation of peristalsis.	B
112	Manual enema device, reusable	A device intended to be used to manually administer fluid (e.g., saline solution) into the rectum to facilitate evacuation of the large intestine through expansion of the lower intestinal tract and physical stimulation of peristalsis.	B
113	Manual rectal irrigation system	A portable assembly of manually-operated devices designed to be used by or on a patient to irrigate the rectum with water, typically to provoke the defecation reflex for the evacuation of the bowels to treat/prevent constipation and reduce the risk of faecal incontinence.	B
114	Motorized laparoscopic forceps	A mains electricity (AC-powered) motorized surgical instrument designed for grasping, mobilizing, and suturing tissues/vessels under direct or endoscopic visualization during a surgical procedure.	B
115	Nasoenteral tube	A sterile, thin, flexible, hollow cylinder designed to access the small intestines (duodenum or jejunum) through the nose and nasopharynx for examination (e.g., of intestinal contents), treatment (e.g., decompression, short-term feeding), or other purposes.	B
116	Nasogastric tube holder, intranasal	A non-sterile, non-surgically invasive device intended to be used to secure a nasogastric tube to the nose of a patient to prevent displacement or removal of the tube.	B
117	Nasogastric tube holder, noninvasive, non-sterile	A small, non-sterile, noninvasive device intended to be used to secure a nasogastric tube to prevent displacement or removal of the tube from the patient.	A
118	Nasogastric tube holder, noninvasive, sterile	A small, sterile, noninvasive device intended to be used to secure a nasogastric tube to prevent displacement or removal of the tube from the patient.	A
119	Non-vascular catheter introduction set	A collection of sterile, invasive devices intended to enable percutaneous Seldinger-type introduction of a non-vascular catheter (e.g., drainage catheter) into a body cavity or lumen (e.g., biliary tract, ureter).	B
120	Oesophageal temperature monitor	An electronic device used to monitor the temperature of the oesophagus during surgical ablation of the wall of the left atrium. It typically measures the oesophageal temperature at several adjacent levels, and displays these temperature values simultaneously to help the surgeon avoid the application of heat high enough to form atrial-	B

		oesophageal fistulas.	
121	Paediatric-temperature nasogastric/orogastric tube	A sterile, thin, flexible, hollow cylinder designed as a paediatric or neonatal enteral feeding tube with an integrated temperature sensor that continuously measures oesophageal temperature.	C
122	Partially-implantable abdominal port/catheter	A sterile partially-implantable device intended to provide access to the peritoneal cavity for infusion (e.g., insulin, chemotherapeutic agents).	C
123	Percutaneous biliary biopsy procedure kit	A collection of sterile devices intended to be used to obtain a tissue specimen from within the biliary duct system for histological analysis by a percutaneous endoscopic approach, typically under fluoroscopic visualization.	B
124	Pharyngeal electrical stimulation catheter	A sterile, flexible tubular device intended to deliver pharyngeal electrical stimulation for the treatment of neurogenic dysphagia.	C
125	Powered rectal/colostomy irrigation system	A portable assembly of battery-powered devices intended to be used by, or on a patient, for the controlled introduction of a non-medicated solution (typically water) into the rectum to treat faecal incontinence or constipation (rectal irrigation), and/or for colostomy site irrigation.	B
126	Probiotic oropharyngeal mucosa dressing	A non-sterile substance intended to be applied to the mucosa of the mouth and/or pharynx to facilitate saprophytic microflora colonization within the oral cavity/pharynx, typically following antibiotic therapy, bacterial infection, or injury. It includes probiotic bacteria (e.g., <i>Streptococcus salivarius</i> , <i>Streptococcus oralis</i>) and compounds that create a barrier to facilitate growth of the probiotic bacteria.	C
127	Proctoscope, reusable	An endoscope with a rigid inserted portion intended for the visual examination and treatment of the rectum and anus.	B
128	Proctoscope, single-use	A sterile endoscope with a rigid inserted portion intended for the visual examination and treatment of the rectum and anus.	B
129	Rectal speculum	A hand-held manual surgical instrument intended to be used to expand or stretch the rectal orifice/canal after it is inserted and opened.	B
130	Rectal suction biopsy system	An assembly of disposable and reusable devices designed to obtain a submucosal tissue specimen from the rectum using suction [rectal suction biopsy (RSB)], typically for histopathological analysis [e.g., to help diagnose Hirschsprung's disease (HD)].	B

131	Rectal/colonic lavage support kit	A collection of non-sterile, noninvasive devices intended to be used in conjunction with a rectal and/or colonic irrigation system to support the introduction of an irrigation solution into the rectum/colon.	A
132	Rectoscope, reusable	An endoscope with a rigid inserted portion intended for the visual examination and treatment of the rectum and anus.	B
133	Rectoscope, single-use	A sterile endoscope with a rigid inserted portion intended for the visual examination and treatment of the rectum and anus.	B
134	Rectoscope/proctoscope handle	A manual device intended to be used as a handle to hold a rectoscope or proctoscope during an examination procedure.	A
135	Rectoscope/proctoscope handle end-cap	A small cap intended to be fitted to the proximal end of the handle of a rectoscope or proctoscope during an examination procedure to provide an airtight seal so that air can be pumped through the scope to inflate the bowel.	A
136	Rigid oesophagoscope	An endoscope with a rigid inserted portion intended for the visual examination and treatment of the oesophagus.	B
137	Rigid sigmoidoscope	An endoscope with a rigid inserted portion intended for the visual examination and treatment of the sigmoid colon (the distal S-shaped part of the large intestine leading to the rectum).	B
138	Robotic electro-surgical instrument, bipolar, single-use	A sterile electro-surgical device intended to be connected directly to the arm of a robotic surgical system to deliver electro-surgical current in a bipolar configuration (i.e., without a return electrode) from a generator directly to tissues for cutting/coagulation/ablation during robotic endoscopic (e.g., laparoscopic, arthroscopic) surgery.	C
139	Robotic surgical retractor	A surgical device intended to be used in conjunction with a robotic surgical system to enable retraction of tissues during a robotic endoscopic procedure.	B
140	Self-propelled flexible video colonoscope	A sterile endoscope with a highly-flexible, self-propelled, inserted portion intended for the visual examination of the entire colon.	B
141	Spring-loaded pneumoperitoneum needle, reusable	A slender, sharply-pointed metal tube designed to introduce or remove gas from the peritoneal cavity as a therapeutic or surgical/radiological procedural method. It is often inserted into the peritoneal cavity for the purpose of insufflation [e.g., with carbon dioxide (CO ₂)] to establish pneumoperitoneum prior to abdominal endoscopy.	B

142	Spring-loaded pneumoperitoneum needle, single-use	A slender, sharply-pointed metal tube designed to introduce or remove gas from the peritoneal cavity as a therapeutic or surgical/radiological procedural method. It is often inserted into the peritoneal cavity for the purpose of insufflation [e.g., with carbon dioxide (CO ₂)] to establish pneumoperitoneum prior to abdominal endoscopy.	B
143	Static magnetic anal plug	A non-sterile magnetic device designed to be inserted into the rectum by the user and retained there for a specified period of time (e.g., 1 to 2 hours per day for 10 to 20 days) to help reduce anal haemorrhoids with magnetism.	B
144	Stoma drainage catheter	A sterile flexible tube that is inserted into a stoma (an artificial opening in the body, especially in the abdominal wall, made during a surgical procedure) to drain bodily waste from an internal stoma container; normally directly into the toilet.	B
145	Stoma support implant	A sterile, non-bioabsorbable device intended to be implanted into the abdominal wall during a gastro-urological ostomy procedure to reduce the risk of parastomal hernia by supporting the abdominal wall surrounding the stoma.	C
146	TEM/TEO rectoscope, optical	An endoscope with a rigid inserted portion intended for surgical treatment of the lower part of the bowel during transanal endoscopic microsurgery (TEM) or transanal endoscopic operations (TEO).	B
147	TEM/TEO rectoscope, video	An endoscope with a rigid inserted portion intended for surgical treatment of the lower part of the bowel during transanal endoscopic microsurgery (TEM) or transanal endoscopic operations (TEO).	B
148	Thermal-regulation orogastric tube	A non-sterile, multi-lumen, multi-purpose tube intended for oral introduction into the gastrointestinal (GI) tract for both: 1) enteral feeding/gastric decompression; and 2) thermal regulation of the whole body via thermal transfer across the oesophagus (to lower and alternatively elevate core body temperature).	C
149	Transenteric drainage tube	A sterile non-bioabsorbable tube intended to be endoscopically implanted transmurally between the gastrointestinal (GI) tract and a pancreatic pseudocyst or the biliary tract for drainage.	C
150	Video capsule endoscopy system	An assembly of electronic devices designed for the internal visualization and examination of sections of the gastrointestinal (GI) tract using a non-digestible video capsule after it has been swallowed by a patient.	B

151	Video capsule endoscopy system application software	An individual software application program or group of programs, routines or algorithms that add specific computer assisted display, processing and analysis capabilities to a video capsule endoscopy system.	B
152	Video capsule endoscopy system capsule	A non-sterile, battery-powered, electronic component device of a video capsule endoscopy system designed to be swallowed by a patient for the internal visualization and examination of the gastrointestinal (GI) tract.	B
153	Pancreatic stent	Pancreatic duct stents are often placed in patients who have chronic pancreatitis.	C