

1 **S Table 1. Recalls of medical devices in Group B according to device category.**

Device category	Approved	Overall recall		Design recall				Design recall /
	N	N	(%)	N	(%)	Hardware, N	Software, N	Overall recall (%)
Contact lens	447	12	(2.7)	0	(0.0)	0	0	0.0
Tubes and catheters	319	8	(2.5)	1	(0.3)	1	0	12.5
Miscellaneous dental materials	154	4	(2.6)	0	(0.0)	0	0	0.0
Implantable devices and materials	93	3	(3.2)	0	(0.0)	0	0	0.0
Blood extracorporeal circulation device	65	9	(13.8)	7	(10.8)	4	6	77.8
Clinical chemical test devices	26	0	(0.0)	0	(0.0)	0	0	-
Surgical materials and orthopedic surgical materials	18	0	(0.0)	0	(0.0)	0	0	-
Devices for laser therapy and procedures	14	1	(7.1)	1	(7.1)	0	1	100
Therapeutic particle acceleration equipment	13	8	(61.5)	7	(53.8)	3	6	87.5
Instruments for blood drawing, transfusion, and infusion	12	3	(25.0)	0	(0.0)	0	0	0.0
Syringes and puncture devices	11	0	(0.0)	0	(0.0)	0	0	-
Endoscope	5	0	(0.0)	0	(0.0)	0	0	-
Electric surgical devices and related equipment	3	0	(0.0)	0	(0.0)	0	0	-

Equipment for radioisotope therapy and sealed radioactive source	3	0	(0.0)	0	(0.0)	0	0	-
Radiotherapy-related equipment	2	1	(50.0)	1	(50.0)	0	1	100
Instruments for ligature and suture	1	0	(0.0)	0	(0.0)	0	0	-
Peritoneal dialysis devices and related instruments	1	0	(0.0)	0	(0.0)	0	0	-
Overall	1,187	49	(4.1)	17	(1.4)	8	14	34.7

2 Group B: high-risk medical devices (Class III and IV) with approval standards

**S Table 2. Recalls of medical devices in Group C according to device category.**

Device category	Approved	Overall recall		Design recall				Design recall /
	N	N	(%)	N	(%)	Hardware, N	Software, N	Overall recall (%)
Implantable devices and materials	1,101	32	(2.9)	1	(0.1)	1	0	3.1
Tubes and catheters	200	9	(4.5)	0	(0.0)	0	0	0.0
Bio-function regulating equipment	146	20	(13.7)	16	(11.0)	10	8	80.0
Blood extracorporeal circulation device	67	10	(14.9)	2	(3.0)	2	1	20.0
Surgical materials and orthopedic surgical materials	59	3	(5.1)	0	(0.0)	0	0	0.0
Devices for laser therapy and procedures	46	4	(8.7)	1	(2.2)	0	1	25.0
Electric surgical devices and related equipment	45	5	(11.1)	2	(4.4)	1	1	40.0
Instruments for ligature and suture	37	2	(5.4)	0	(0.0)	0	0	0.0
Miscellaneous procedural devices	32	6	(18.8)	2	(6.3)	2	0	33.3
Miscellaneous bio-functional assist and alternating devices	26	2	(7.7)	0	(0.0)	0	0	0.0
Instruments for blood drawing, transfusion, and infusion	25	0	(0.0)	0	(0.0)	0	0	-
Peritoneal dialysis devices and related instruments	22	1	(4.5)	0	(0.0)	0	0	0.0

Equipment for radioisotope therapy and sealed radioactive source	17	2	(11.8)	0	(0.0)	0	0	0.0
Miscellaneous devices for treatment or operation	12	2	(16.7)	2	(16.7)	1	2	100
Testing equipment for bio-physical phenomena	8	2	(25.0)	1	(12.5)	1	1	50.0
Radiotherapy-related equipment	8	1	(12.5)	1	(12.5)	0	1	100
Equipment for disintegrating concretions	8	1	(12.5)	0	(0.0)	0	0	0.0
Diagnostic nuclear medicine equipment and related equipment	7	0	(0.0)	0	(0.0)	0	0	-
Therapeutic particle acceleration equipment	5	2	(40.0)	2	(40.0)	2	0	100
Dental bonding, filling, and temporary sealing materials	5	1	(20.0)	0	(0.0)	0	0	0.0
Miscellaneous dental materials	5	0	(0.0)	0	(0.0)	0	0	-
Syringes and puncture devices	4	0	(0.0)	0	(0.0)	0	0	-
Testing equipment for bio-electric phenomena	3	1	(33.3)	0	(0.0)	0	0	0.0
Miscellaneous equipment for laboratory testing	2	0	(0.0)	0	(0.0)	0	0	-
Bio-phenomena monitoring devices	1	0	(0.0)	0	(0.0)	0	0	-
Blood testing devices	1	0	(0.0)	0	(0.0)	0	0	-

Devices for dental consultation room	1	0	(0.0)	0	(0.0)	0	0	-
Miscellaneous imaging X-ray related equipment and materials	1	0	(0.0)	0	(0.0)	0	0	-
Overall	1,894	106	(5.6)	30	(1.6)	20	15	28.3

Group C: high-risk medical devices (Class III and IV) without either standard