

MEDICAL DEVICE REGISTRATION AND LISTING STATS, FY2010; As of 1/7/10

The hierarchy for all tables is based on the ranking in the left-most column. For example, if an establishment is both a manufacturer and a contract manufacturer, it will be counted only as a manufacturer.

RANK	ESTABLISHMENT_TYPE	DOMESTIC	FOREIGN	TOTAL
1	Manufacturer	4,085	5,356	9,441
2	Contract Manufacturer	246	514	760
3	Contract Sterilizer	16	29	45
4	Specification Developer	1,018	228	1,246
5	Reprocessor of Single Use Devices	14	0	14
6	U.S. Manufacturer of Export Only	66	0	66
7	Repackager/Relabeler	947	236	1,183
8	Remanufacturer	39	42	81
9	Foreign Exporter	0	684	684
10	Initial Distributor/Importer	2,994	0	2,994
	Unknown	105	47	152
	Total:	9,530	7,136	16,666

RANK	ESTABLISHMENTS ESTABLISHMENT_TYPE	DOMESTIC				FOREIGN				GRAND TOTAL
		CLASS 1	CLASS 2*	CLASS 3*	TOTAL	CLASS 1	CLASS 2*	CLASS 3*	TOTAL	
1	Manufacturer	1,401	2,360	324	4,085	2,737	2,416	203	5,356	9,441
2	Contract Manufacturer	106	115	25	246	225	266	23	514	760
3	Contract Sterilizer	9	7	0	16	23	5	1	29	45
4	Specification Developer	394	566	58	1,018	86	135	7	228	1,246
5	Reprocessor of Single Use Devices	3	11	0	14	0	0	0	0	14
6	U.S. Manufacturer of Export Only	7	26	33	66	0	0	0	0	66
7	Repackager/Relabeler	527	393	27	947	171	62	3	236	1,183
8	Remanufacturer	16	23	0	39	37	5	0	42	81
9	Foreign Exporter				0	528	146	10	684	684
	Unknown				105				47	152
	Total:	2,463	3,501	467	6,536	3,807	3,035	247	7,136	13,672

Class 2 includes "Unclassified," Class 3 includes "Not Classified"

RANK	LISTINGS ESTABLISHMENT_TYPE	DOMESTIC				FOREIGN				GRAND TOTAL
		CLASS 1	CLASS 2*	CLASS 3*	TOTAL	CLASS 1	CLASS 2*	CLASS 3*	TOTAL	
1	Manufacturer	12,980	21,793	1,041	35,814	23,694	15,604	585	39,883	75,697
2	Contract Manufacturer	377	641	73	1,091	1,512	1,696	71	3,279	4,370
3	Contract Sterilizer	41	367	25	433	31	15	1	47	480
4	Specification Developer	4,459	6,199	328	10,986	747	1,362	15	2,124	13,110
5	Reprocessor of Single Use Devices	115	125	1	241	1	19	0	20	261
6	U.S. Manufacturer of Export Only	71	319	95	485	0	0	0	0	485
7	Repackager/Relabeler	6,174	4,013	194	10,381	2,824	740	22	3,586	13,967
8	Remanufacturer	51	184	0	235	85	15	0	100	335
9	Foreign Exporter	0	0	0	0	2,932	593	39	3,564	3,564
	Total:	24,268	33,641	1,757	59,666	31,826	20,044	733	52,603	112,269

Class 2 includes "Unclassified," Class 3 includes "Not Classified"

Each listing is counted only for the highest ranked establishment type