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ANNEXURE-I

Medical Equipment Technical Areas

This voluntary scheme shall include various types of medical equipment which need maintenance for efficient working ranging from non-active to active devices which are used in the various department in hospitals such as critical care department, operation theatre department, radiology department, laboratory department, emergency department, sterilization department, dental department, ophthalmology department, cardiology department, nephrology department, neurology department, oncology department, ENT department, Obstetrics and Gynaecology department, respiratory department etc.

This voluntary scheme can be used across all the hospitals globally since it has followed the international norms used by the international accreditation Forum (IAF). The medical device classification used in this scheme is referred from the IAF MD 9 document. The main technical areas (categories) are taken into consideration are as follows:

1. Non-active Medical Devices
2. Active Medical Devices (Non-implantable)
3. In-vitro Diagnostic Medical devices (IVD)
4. Sterilization method for Medical devices



Table
Medical Equipment Technical Areas

	As per IAF Main Technical Areas (Category)	As per IAF Technical Areas (Sub-Category)	Identification code for Sub- Category	Identification code for Scheme Product Category	Product Categories Covered by the Technical Areas as per IAF (Scheme Product Category)	Indian MDR Category
A	Non-active medical devices	General non-active, non-implantable medical devices	A1	A1-1	Non-active devices for anesthesia, emergency, and intensive care	Anesthesiology, General Hospital / Orthopaedic Instruments, Respiratory
				A1-2	Non-active devices for injection, infusion, transfusion and dialysis	General Hospital / Orthopaedic Instruments, Nephrology and Renal Care
				A1-3	Non-active orthopedic and rehabilitation devices	General Hospital / Orthopaedic Instruments, Physical Support Rehabilitation
				A1-4	Non-active medical devices with measuring function	Anesthesiology, Cardiovascular, General Hospital / Orthopaedic Instruments, Operation Theatre, Respiratory,

						Obstetrical and Gynecological
				A1-5	Non-active ophthalmologic devices	Ophthalmic
				A1-6	Non-active instruments	Operation Theatre, Neurological
				A1-7	Contraceptive medical devices	Urology
				A1-8	Non-active medical devices for disinfecting, cleaning, rinsing	General Hospital / Orthopaedic Instruments
				A1-9	Non-active devices for in vitro fertilisation (IVF) and assisted reproductive technologies	Obstetrical and Gynecological devices, Urology
				A1-10	Non-active medical devices for ingestion	Gastroenterological
		Non-active dental devices	A2	A2	Non-active dental devices/equipment and instruments	Dental
		Non-active medical devices other than specified above	A3	A3		
B	Active Medical Devices (Non-Implantable)	General active medical devices	B1	B1-1	Devices for extra-corporal circulation, infusion and haemopheresis	Cardiovascular, General Hospital / Orthopaedic, Operation Theatre Nephrology and Renal Care, Pediatric and Neonatology
				B1-2	Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia	Anesthesiology, Respiratory, Pediatric and Neonatology
				B1-3	Devices for stimulation or inhibition	Neurology, Pain Management,

					Cardiovascular, Rehabilitation	
				B1-4	Active surgical devices	Operation Theatre, ENT, Gastroenterological, Urological, General Hospital / Orthopaedic Instruments, Operation Theatre, Neurological, Obstetrical and Gynecological, Dermatology and Plastic Surgery
				B1-5	Active ophthalmologic devices	Ophthalmic, Pediatric and Neonatology
				B1-6	Active dental devices	Dental
				B1-7	Active devices for disinfection and sterilization	General Hospital / Orthopaedic Instruments
				B1-8	Active rehabilitation devices and active prostheses	Rehabilitation, Physical Support, Neurological
				B1-9	Active devices for patient positioning and transport	General Hospital / Orthopaedic Instruments, Pain Management, Physical Support, ENT, Operation Theatre, Obstetrical and Gynecological



			B1-10	Active devices for in vitro fertilization (IVF) and assisted reproductive technologies	Obstetrical and Gynecological devices, Urology
			B1-11	Medical gas supply systems and parts thereof	Anesthesiology, Respiratory
	Devices for imaging	B2	B2-1	Devices utilizing ionizing radiation	Interventional Radiology, Oncology
			B2-2	Devices utilizing non-ionizing radiation	Interventional Radiology, Cardiovascular, Oncology, Neurological
	Monitoring devices	B3	B3-1	Monitoring devices of non-vital physiological parameters	ENT, Ophthalmic, Rehabilitation
			B3-2	Monitoring devices of vital physiological parameters	Anesthesiology, Cardiovascular, Operation Theatre, Respiratory, Neurological, Pediatric and Neonatology, Obstetrical and Gynecological
	Devices for radiation therapy and thermo therapy	B4	B4-1	Devices utilising ionizing radiation	Radiotherapy, Oncology
			B4-2	Devices utilising non-ionizing radiation	Oncology, Pediatric and Neonatology, Dermatology and Plastic Surgery
			B4-3	Devices for hyperthermia / hypothermia	Radiotherapy, Urology



				B4-4	Devices for (extracorporeal) shock-wave therapy (lithotripsy)	Urology, Rehabilitation
		Active (non-implantable) medical devices other than specified above	B5	B5		
C	In Vitro Diagnostic Medical Devices (IVD)	IVD Instruments	C1	C1		In Vitro Diagnostics Medical Devices
D	Sterilization Method for Medical Devices	Ethylene oxide gas sterilization (EOG)	D1	D1		General Hospital / Orthopaedic Instruments
		Moist heat	D2	D2		General Hospital / Orthopaedic Instruments
		Thermic sterilization with dry heat	D3	D3		General Hospital / Orthopaedic Instruments
		Sterilization with hydrogen peroxide	D4	D4		General Hospital / Orthopaedic Instruments
		Radiation sterilization (e.g., gamma, x-ray, electron beam)	D5	D5		General Hospital / Orthopaedic Instruments



Annexure-II

Medical Equipment considered for Maintenance Scheme

S.No	Device Description	Identification code for Sub-Category
1	ACRYLIC CURING UNITS, DENTAL	B1
2	ACUPUNCTURE KITS	A3
3	AMALGAMATORS	B1
4	ANALGESIA UNITS	B1
5	ANALGESIA UNITS, INHALATION	B1
6	ANALYZERS, LABORATORY, BLOOD GAS	C1
7	ANALYZERS, LABORATORY, BLOOD GAS/PH	C1
8	ANALYZERS, LABORATORY, BLOOD GAS/PH/ELECTROLYTE	C1
9	ANALYZERS, LABORATORY, BLOOD GAS/PH/ELECTROLYTE/METABOLITE	C1
10	ANALYZERS, LABORATORY, BLOOD, BILIRUBIN	C1
11	ANALYZERS, LABORATORY, BLOOD, GLYCATED HEMOGLOBIN	C1
12	ANALYZERS, LABORATORY, BLOOD, IRON	C1
13	ANALYZERS, LABORATORY, BLOOD, UREA NITROGEN	C1
14	ANALYZERS, LABORATORY, BODY FLUIDS, AMINO ACID	C1
15	ANALYZERS, LABORATORY, BODY FLUIDS, CALCIUM	C1



16	ANALYZERS, LABORATORY, BODY FLUIDS, CHLORIDE	C1
17	ANALYZERS, LABORATORY, BODY FLUIDS, CREATININE	C1
18	ANALYZERS, LABORATORY, BODY FLUIDS, ELECTROLYTE, COULOMETRIC	C1
19	ANALYZERS, LABORATORY, BODY FLUIDS, ELECTROLYTE, FLAME PHOTOMETER	C1
20	ANALYZERS, LABORATORY, BODY FLUIDS, ELECTROLYTE, ION-SELECTIVE	C1
21	ANALYZERS, LABORATORY, BODY FLUIDS, ENZYME	C1
22	ANALYZERS, LABORATORY, BODY FLUIDS, GLUCOSE	C1
23	ANALYZERS, LABORATORY, BODY FLUIDS, LACTATE	C1
24	ANALYZERS, LABORATORY, BODY FLUIDS, LEAD	C1
25	ANALYZERS, LABORATORY, BODY FLUIDS, LITHIUM	C1
26	ANALYZERS, LABORATORY, BREATH, CARBON DIOXIDE	C1
27	ANALYZERS, LABORATORY, BREATH, CARBON MONOXIDE	C1
28	ANALYZERS, LABORATORY, BREATH, OXYGEN	C1
29	ANALYZERS, LABORATORY, CLINICAL CHEMISTRY	C1
30	ANALYZERS, LABORATORY, CLINICAL CHEMISTRY, AUTOMATED	C1
31	ANALYZERS, LABORATORY, CLINICAL CHEMISTRY, AUTOMATED, CONTINUOUS-FLOW	C1



32	ANALYZERS, LABORATORY, CLINICAL CHEMISTRY, AUTOMATED, DISCRETE	C1
33	ANALYZERS, LABORATORY, HEMATOLOGY	C1
34	ANALYZERS, LABORATORY, HEMATOLOGY, BLOOD GROUPING	C1
35	ANALYZERS, LABORATORY, HEMATOLOGY, BLOOD GROUPING, AUTOMATED	C1
36	ANALYZERS, LABORATORY, HEMATOLOGY, BLOOD GROUPING, SEMIAUTOMATED	C1
37	ANALYZERS, LABORATORY, HEMATOLOGY, CELL COUNTING, AUTOMATED	C1
38	ANALYZERS, LABORATORY, HEMATOLOGY, CELL COUNTING, MANUAL	C1
39	ANALYZERS, LABORATORY, HEMATOLOGY, CELL COUNTING, SEMIAUTOMATED	C1
40	ANALYZERS, LABORATORY, HEMATOLOGY, COAGULATION	C1
41	ANALYZERS, LABORATORY, HEMATOLOGY, COAGULATION, AUTOMATED	C1
42	ANALYZERS, LABORATORY, HEMATOLOGY, COAGULATION, MANUAL	C1
43	ANALYZERS, LABORATORY, HEMATOLOGY, COAGULATION, SEMIAUTOMATED	C1
44	ANALYZERS, LABORATORY, HEMATOLOGY, ERYTHROCYTE AGGREGATION	C1
45	ANALYZERS, LABORATORY, HEMATOLOGY, HEMOGLOBIN	C1
46	ANALYZERS, LABORATORY, HEMATOLOGY, PLATELET AGGREGATION	C1



47	ANALYZERS, LABORATORY, IMMUNOASSAY, CHEMILUMINESCENT	C1
48	ANALYZERS, LABORATORY, IMMUNOASSAY, FLUORIMETRIC	C1
49	ANALYZERS, LABORATORY, IMMUNOASSAY, NEPHELOMETRIC	C1
50	ANALYZERS, LABORATORY, IMMUNOASSAY, PHOTOMETRIC, ELISA	C1
51	ANALYZERS, LABORATORY, IMMUNOASSAY, PHOTOMETRIC, ENZYME (EIA)	C1
52	ANALYZERS, LABORATORY, IMMUNOASSAY, PHOTOMETRIC, MICROPLATE READING	C1
53	ANALYZERS, LABORATORY, MICROBIOLOGY, BLOOD CULTURE, AUTOMATED	C1
54	ANALYZERS, LABORATORY, MICROBIOLOGY, BLOOD CULTURE, MANUAL	C1
55	ANALYZERS, LABORATORY, MICROBIOLOGY, BLOOD CULTURE, MYCOBACTERIA	C1
56	ANALYZERS, LABORATORY, MICROBIOLOGY, SUSCEPTIBILITY	C1
57	ANALYZERS, LABORATORY, MICROBIOLOGY, SUSCEPTIBILITY, AUTOMATED	C1
58	ANALYZERS, LABORATORY, MICROBIOLOGY, SUSCEPTIBILITY, MANUAL	C1
59	ANALYZERS, LABORATORY, RADIOIMMUNOASSAY	C1
60	ANALYZERS, LABORATORY, RADIOIMMUNOASSAY, AUTOMATED	C1
61	ANALYZERS, LABORATORY, SEMEN	C1
62	ANALYZERS, LABORATORY, URINE, AUTOMATED	C1



63	ANALYZERS, LABORATORY, URINE, SEMIAUTOMATED	C1
64	ANALYZERS, PHYSIOLOGIC, DENTAL PULP	C1
65	ANALYZERS, PHYSIOLOGIC, MIDDLE EAR	C1
66	ANALYZERS, PHYSIOLOGIC, MIDDLE EAR, ACOUSTIC REFLECTOMETRY	C1
67	ANALYZERS, PHYSIOLOGIC, MIDDLE EAR, IMPEDANCE TYMPANOMETRY	C1
68	ANALYZERS, PHYSIOLOGIC, NEUROMUSCULAR FUNCTION, DYNAMOMETRIC	C1
69	ANALYZERS, PHYSIOLOGIC, PERISTALTIC MOTILITY, COLON/RECTUM	C1
70	ANALYZERS, PHYSIOLOGIC, PERISTALTIC MOTILITY, ESOPHAGEAL	C1
71	ANALYZERS, PHYSIOLOGIC, PERISTALTIC MOTILITY, GASTROINTESTINAL	C1
72	ANALYZERS, PHYSIOLOGIC, PULMONARY FUNCTION	C1
73	ANALYZERS, PHYSIOLOGIC, PULMONARY FUNCTION, ADULT	C1
74	ANALYZERS, PHYSIOLOGIC, PULMONARY FUNCTION, NEONATAL/PEDIATRIC	C1
75	ANALYZERS, PHYSIOLOGIC, SOMNOGRAPHY	C1
76	ANALYZERS, PHYSIOLOGIC, VISUAL FUNCTION	C1
77	ANALYZERS, PHYSIOLOGIC, VISUAL FUNCTION, EYE MOVEMENT	C1
78	ANALYZERS, POINT-OF-CARE, URINE	C1
79	ANALYZERS, POINT-OF-CARE, WHOLE BLOOD, COAGULATION	C1



80	ANALYZERS, POINT-OF-CARE, WHOLE BLOOD, GAS/PH/ELECTROLYTE	C1
81	ANALYZERS, POINT-OF-CARE, WHOLE BLOOD, GLUCOSE	C1
82	ANALYZERS, POINT-OF-CARE, WHOLE BLOOD, HEMATOLOGY	C1
83	ANESTHESIA UNIT ABSORBERS, CARBON DIOXIDE	A1
84	ANESTHESIA UNIT VAPORIZERS	B1
85	ANESTHESIA UNITS	B1
86	ANESTHESIA UNITS, DENTAL	B1
87	ANGIOPLASTY SYSTEMS	B1
88	ANGIOPLASTY SYSTEMS, ATHERECTOMY	B1
89	ANGIOSCOPIES	A1
90	ANGIOTOMES	A3
91	APHERESIS UNITS	B1
92	APPLANOMETERS	B1
93	APPLICATORS, POLYMER, DENTAL	A2
94	ARTHROSCOPES	B2
95	ARTHROSCOPIC SHAVER SYSTEMS	B1
96	ARTICULATORS, DENTAL	A2
97	ASPIRATORS	B1
98	ASPIRATORS, DENTAL	B1
99	ASPIRATORS, EMERGENCY	B1
100	ASPIRATORS, ENDOCERVICAL	B1
101	ASPIRATORS, ENDOSCOPIC IRRIGATION	B1
102	ASPIRATORS, INFANT	B1
103	ASPIRATORS, LIPOSUCTION	B1
104	ASPIRATORS, LOW-VOLUME	B1
105	ASPIRATORS, NASAL	B1



106	ASPIRATORS, SURGICAL	B1
107	ASPIRATORS, THORACIC	B1
108	ASPIRATORS, TRACHEAL	B1
109	ASPIRATORS, ULTRASONIC	B1
110	ASPIRATORS, UTERINE	B1
111	ASPIRATORS, WOUND	B1
112	AUDIOMETERS	B1
113	AUDIOMETRIC BOOTHS	B1
114	AUDITORY FUNCTION SCREENING DEVICES	B1
115	AUTOTRANSFUSION UNITS, BLOOD PROCESSING	B1
116	AUTOTRANSFUSION UNITS, WHOLE BLOOD RECOVERY	B1
117	BALANCES	B5
118	BALANCES, ELECTRONIC	B5
119	BALANCES, ELECTRONIC, PRECISION	B5
120	BALANCES, MECHANICAL	A3
121	BALANCES, MECHANICAL, PRECISION	A3
122	BATHS, DIALYSATE WARMING	B5
123	BATHS, FREEZING	B5
124	BATHS, PARAFFIN, DENTAL	B5
125	BATHS, PARAFFIN, PHYSICAL THERAPY	B5
126	BATHS, PORTABLE	B5
127	BATHS, STEAM	B5
128	BATHS, TISSUE FLOTATION	B5
129	BATHS, WATER	B5
130	BATHS, WATER, LABORATORY	B5
131	BATHS, WATER, MOLDED PLASTIC SPLINT	B5
132	BATHS, WATER, PLASMA-THAWING	B5
133	BATHS, WATER, SHAKER	B5



134	BATHS, WHIRLPOOL	B5
135	BATTERY CHARGERS	B5
136	BEDS, ELECTRIC, ALTERNATING PRESSURE	B1
137	BEDS, ELECTRIC, VERTICAL TILTING	B1
138	BILIRUBINOMETERS	B1
139	BILIRUBINOMETERS, CUTANEOUS	B1
140	BIOFEEDBACK SYSTEMS	B1
141	BLOOD CELL PROCESSORS	B1
142	BLOOD-FLOW DETECTORS, ULTRASONIC	B1
143	BONE MILLS	A3
144	BRACHYTHERAPY APPLICATORS, AFTERLOADING	B4
145	BRACHYTHERAPY SOURCES	B4
146	BRACHYTHERAPY SYSTEMS, REMOTE AFTERLOADING	B4
147	BRONCHOSCOPES	B2
148	BRONCHOSCOPES, FLEXIBLE	B2
149	BRONCHOSCOPES, FLEXIBLE, VIDEO	B2
150	BRONCHOSCOPES, RIGID	B2
151	CABINETS, STORAGE, FLAMMABLE LIQUID	B5
152	CALIBRATORS, RADIOPHARMACEUTICAL	B5
153	CALIPERS	A1
154	CALIPERS, OTHER	A1
155	CALIPERS, SKINFOLD, MANUAL	A1
156	CAMERAS, CINE	B2
157	CAMERAS, ENDOSCOPIC	B2
158	CAMERAS, FUNDUS	B2
159	CAMERAS, GAMMA	B2
160	CAMERAS, IDENTIFICATION	B2
161	CAMERAS, MICROSCOPE	B2



162	CAMERAS, MULTI-IMAGE	B2
163	CAMERAS, VIDEO	B2
164	CAMERAS, VIDEO, ENDOSCOPE	B2
165	CAPNOGRAPHS	B3
166	CARDIAC OUTPUT UNITS	B3
167	CARDIOGRAPHS	B3
168	CASEWORK, NURSING STATION	B4
169	CAST CUTTER VACUUMS	B1
170	CAST CUTTERS	B1
171	CAST CUTTERS, ELECTRIC	B1
172	CAST CUTTERS, PNEUMATIC	B1
173	CASTING FURNACES, DENTAL	B1
174	CASTING UNITS, DENTAL	B1
175	CATARACT EXTRACTION UNITS	B1
176	CATARACT EXTRACTION UNITS, PHACOEMULSIFICATION	B1
177	CELL DISRUPTERS, ULTRASONIC	B5
178	CENTRIFUGES, FLOOR	B5
179	CENTRIFUGES, FLOOR, HIGH-SPEED	B5
180	CENTRIFUGES, FLOOR, LOW-SPEED, NONREFRIGERATED	B5
181	CENTRIFUGES, FLOOR, LOW-SPEED, NONREFRIGERATED, BLOOD BANK	B5
182	CENTRIFUGES, FLOOR, LOW-SPEED, REFRIGERATED	B5
183	CENTRIFUGES, FLOOR, ULTRAHIGH-SPEED	B5
184	CENTRIFUGES, TABLETOP	B5
185	CENTRIFUGES, TABLETOP, HIGH-SPEED	B5



186	CENTRIFUGES, TABLETOP, HIGH-SPEED, MICROHEMATOCRIT	B5
187	CENTRIFUGES, TABLETOP, HIGH-SPEED, MICRO-SAMPLE	B5
188	CENTRIFUGES, TABLETOP, LOW-SPEED, NONREFRIGERATED	B5
189	CENTRIFUGES, TABLETOP, LOW-SPEED, NONREFRIGERATED, BLOOD BANK	B5
190	CENTRIFUGES, TABLETOP, LOW-SPEED, NONREFRIGERATED, CELL WASHING	B5
191	CENTRIFUGES, TABLETOP, LOW-SPEED, NONREFRIGERATED, CYTOLOGICAL	B5
192	CENTRIFUGES, TABLETOP, LOW-SPEED, NONREFRIGERATED, HAND-DRIVEN	B5
193	CENTRIFUGES, TABLETOP, LOW-SPEED, NONREFRIGERATED, MICRO-SAMPLE	B5
194	CENTRIFUGES, TABLETOP, LOW-SPEED, REFRIGERATED	B5
195	CENTRIFUGES, TABLETOP, ULTRAHIGH-SPEED	B5
196	CHAIRS, EXAMINATION/TREATMENT	B1
197	CHAIRS, EXAMINATION/TREATMENT, DENTISTRY	B1
198	CHAIRS, EXAMINATION/TREATMENT, OPHTHALMOLOGY	B1
199	CHAMBERS, ANAEROBIC	B5
200	CHAMBERS, FREEZING	B5
201	CHARTS, EYE, VISUAL ACUITY	B1
202	CHOLEDOCHOSCOPES	B2
203	CHROMATOGRAPHY SYSTEMS, GAS	C1



204	CHROMATOGRAPHY SYSTEMS, GAS, CAPILLARY COLUMN	C1
205	CHROMATOGRAPHY SYSTEMS, GAS, PACKED COLUMN	C1
206	CHROMATOGRAPHY SYSTEMS, LIQUID	C1
207	CHROMATOGRAPHY SYSTEMS, LIQUID, PACKED COLUMN	C1
208	CHROMATOGRAPHY SYSTEMS, LIQUID, PACKED COLUMN, HIGH-PRESSURE	C1
209	CHROMATOGRAPHY SYSTEMS, LIQUID, PACKED COLUMN, HIGH-PRESSURE, BONDED-PHASE	C1
210	CHROMATOGRAPHY SYSTEMS, LIQUID, PACKED COLUMN, HIGH-PRESSURE, ION-EXCHANGE	C1
211	CHROMATOGRAPHY SYSTEMS, LIQUID, PLANAR, THIN-LAYER	C1
212	CIRCULATORY ASSIST UNITS, CARDIAC	B1
213	CIRCULATORY ASSIST UNITS, CARDIAC, INTRA-AORTIC BALLOON	B1
214	CIRCULATORY ASSIST UNITS, CARDIAC, VENTRICULAR	B1
215	CLIPPERS	A1
216	COLD PACK CHILLING UNITS	A3
217	COLD PACKS	A3
218	COLLECTORS, FRACTION	B5
219	COLONOSCOPES	B2
220	COLONOSCOPES, VIDEO	B2
221	COLPOSCOPES	B2
222	COMPRESSORS, MEDICAL-AIR	B5
223	COMPUTERS, RADIOTHERAPY PLANNING SYSTEM	B4



224	COMPUTERS, STEREOTACTIC SURGERY	B1
225	CONCENTRATORS, SPECIMEN	B5
226	CONDUCTIVITY METERS	B5
227	COOLING UNITS, PATIENT	B5
228	COUNTERS, COLONY	B5
229	COUNTERS, GAMMA	B5
230	COUNTERS, INTRAVENOUS DROP	B5
231	COUNTERS, NEEDLE	A3
232	COUNTERS, SCINTILLATION	B5
233	CRIMPERS	A1
234	CROWN/INLAY REMOVERS	A2
235	CRYOSURGICAL UNITS	B1
236	CRYOSURGICAL UNITS, GENERAL-PURPOSE	B1
237	CRYOSURGICAL UNITS, OPHTHALMIC	B1
238	CUTTERS	A1
239	CUTTERS, BONE	B1
240	CUTTERS, SYRINGE/NEEDLE	B5
241	CYSTOMETERS	B2
242	CYSTOSCOPES, FLEXIBLE	B2
243	CYSTOSCOPES, RIGID	B2
244	CYTOMETERS, AUTOMATED	C1
245	CYTOMETERS, AUTOMATED, FLOW	C1
246	CYTOMETERS, MANUAL	C1
247	CYTOMETERS, MANUAL, DIFFERENTIAL	C1
248	DEFIBRILLATOR/PACEMAKERS, EXTERNAL	B1
249	DEFIBRILLATORS	B1
250	DEFIBRILLATORS, EXTERNAL, AUTOMATED	B1
251	DEFIBRILLATORS, EXTERNAL, MANUAL	B1



252	DEFIBRILLATORS, EXTERNAL, MANUAL, LINE-POWERED-ONLY	B1
253	DENSITOMETERS	B2
254	DENSITOMETERS, BONE	B2
255	DENSITOMETERS, BONE, ISOTOPE, SINGLE-PHOTON ABSORPTIOMETRY	B2
256	DENSITOMETERS, BONE, ULTRASONIC	B2
257	DENSITOMETERS, BONE, X-RAY, DUAL-ENERGY ABSORPTIOMETRY	B2
258	DENSITOMETERS, LABORATORY, LIQUID, URINE	C1
259	DENSITOMETERS, LABORATORY, SCANNING LIGHT	C1
260	DENSITOMETERS, X-RAY FILM	B5
261	DENTAL AIR ABRASION UNITS	B1
262	DENTAL COLOR CODING RINGS	B1
263	DENTAL DELIVERY UNITS	B1
264	DENTAL ENGINES	B1
265	DENTAL HAND INSTRUMENTS, ENDODONTIC	B1
266	DENTAL HAND INSTRUMENTS, SURGICAL	B1
267	DENTAL PORCELAINS	A2
268	DENTAL WAX	A3
269	DERMABRASION UNITS	B5
270	DERMATOMES	B5
271	DERMATOSCOPES	B2
272	DESENSITIZERS	B5
273	DIALYSATE CONDUCTIVITY METERS	B5
274	DIALYSATE DELIVERY SYSTEMS, MULTIPATIENT	B1
275	DIALYSATE DELIVERY SYSTEMS, SINGLE-PATIENT	B1
276	DIALYZER REPROCESSING UNITS	B5



277	DIFFRACTOMETERS, X-RAY	B5
278	DIGITAL IMAGING SYSTEMS	B2
279	DIGITAL IMAGING SYSTEMS, ANGIOGRAPHIC/CARDIOVASCULAR	B2
280	DIGITAL IMAGING SYSTEMS, COMPUTED RADIOGRAPHY	B2
281	DILUTERS	B5
282	DILUTERS, BLOOD CELL	B5
283	DISINFECTORS	B1
284	DISPENSERS	B5
285	DISPENSERS, FLUID	B5
286	DISPENSERS, LIQUID, LABORATORY	B5
287	DISPENSERS, PARAFFIN	B5
288	DISRUPTERS, CELL	B5
289	DISSECTORS	A1
290	DISTILLING UNITS	B5
291	DOSIMETERS, RADIATION	B5
292	DRILLS, BIOPSY	B1
293	DRILLS, BONE	B1
294	DRILLS, FINGERNAIL	B1
295	DRILLS, MIDDLE EAR SURGERY	B1
296	DRYERS	B5
297	DRYERS, LABWARE	B5
298	DRYERS, SLIDE	B5
299	DUODENOSCOPES	B2
300	DUODENOSCOPES, VIDEO	B2
301	DYNAMOMETER EXERCISE SYSTEMS, COMPUTERIZED	B1
302	DYNAMOMETERS	A3



303	EAR/NOSE/THROAT TREATMENT UNITS	B1
304	ECHOCARDIOGRAPHS	B2
305	ELECTROCARDIOGRAPHS, MULTICHANNEL, INTERPRETATIVE	B3
306	ELECTROCARDIOGRAPHS, MULTICHANNEL, NON-INTERPRETATIVE	B3
307	ELECTROCARDIOGRAPHS, MULTICHANNEL, NON-INTERPRETATIVE, SIGNAL-AVERAGING	B3
308	ELECTROCARDIOGRAPHS, SINGLE-CHANNEL	B3
309	ELECTROCARDIOGRAPHY	B3
310	ELECTROCAUTERY UNITS, BATTERY-POWERED	B3
311	ELECTROCAUTERY UNITS, LINE-POWERED	B3
312	ELECTROENCEPHALOGRAPHS	B3
313	ELECTROGLOTTOGRAPHS	B3
314	ELECTROMYOGRAPHS	B3
315	ELECTROPHORESIS SYSTEMS	B5
316	ELECTROPHORESIS SYSTEMS, CAPILLARY	B5
317	ELECTRORETINOGRAPHS	B3
318	ELECTROSTATIC VOLTAGE DETECTORS	B5
319	ELECTROSURGICAL UNITS	B1
320	ELECTROSURGICAL UNITS, BIPOLAR	B1
321	ELECTROSURGICAL UNITS, MONOPOLAR	B1
322	ELECTROSURGICAL UNITS, MONOPOLAR, ARGON-ENHANCED COAGULATION	B1
323	ELECTROSURGICAL UNITS, MONOPOLAR/BIPOLAR	B1
324	ENDOSCOPES, OTHERS	B2
325	ENDOSCOPES, RIGID	B2



326	VIDEO IMAGE PROCESSORS, OPERATING MICROSCOPE	B1
327	ENTEROSCOPES	B2
328	EPILATORS	B5
329	ERGOMETERS	A3
330	ERGOMETERS, BICYCLE	B1
331	ESOPHAGOSCOPES	B2
332	EVAPORATORS	B5
333	EXERCISERS	A3
334	EXERCISERS, CONTINUOUS PASSIVE MOTION	B1
335	EXERCISERS, CONTINUOUS PASSIVE MOTION, LOWER LIMB	B1
336	EXERCISERS, CONTINUOUS PASSIVE MOTION, UPPER LIMB	B1
337	EXTRACTORS, PLASMA	B5
338	FETAL HEART DETECTORS	B3
339	FETAL HEART DETECTORS, PHONO	B3
340	FETAL HEART DETECTORS, ULTRASONIC	B3
341	FIBRILLATORS	B1
342	FITTINGS/ADAPTERS	B5
343	FLOWMETERS	A3
344	FLOWMETERS, BLOOD	B5
345	FLOWMETERS, BLOOD, ULTRASONIC	B5
346	FLOWMETERS, GAS	B5
347	FLUOROMETERS	B5
348	FORCEPS, BIOPSY	A1
349	FORCEPS, DENTAL	A1
350	FORCEPS, DISSECTING	A1
351	FORCEPS, LAPAROSCOPIC	A1



352	FORCEPS, OTHER	A1
353	FREEZERS, BLOOD PLASMA	B5
354	FREEZERS, LABORATORY	B5
355	FUME EVACUATORS	B5
356	GAS SAMPLING UNITS	B5
357	GASOMETERS	B5
358	GASTROSCOPES	B2
359	GASTROSCOPES, FLEXIBLE	B2
360	GASTROSCOPES, FLEXIBLE, VIDEO	B2
361	GASTROSCOPES, RIGID	B2
362	GONIOSCOPES	B5
363	HAND DRILLS, SURGICAL	B1
364	HANDPIECES, DENTAL	B1
365	HANDPIECES, SURGICAL	B1
366	HEADLIGHTS	B5
367	HEARING AIDS	B5
368	HEART-LUNG BYPASS UNITS	B1
369	HEATING BLOCKS	B1
370	HEATING PADS	B1
371	HEATING UNITS	B1
372	HEATING UNITS, HOT-PACK	B1
373	HEATING UNITS, THERMAL PROBE	B1
374	HEMODIALYSIS UNIT BLOOD PUMPS	B1
375	HEMODIALYSIS UNITS	B1
376	HEMOFILTRATION UNITS	B1
377	HOMOGENIZERS, TISSUE	B5
378	HOMOGENIZERS, ULTRASONIC	B5
379	HOODS, MICROBIOLOGICAL	B1
380	HOT PACKS	B5



381	HOT PLATES	B5
382	HUMIDIFIERS	A1
383	HUMIDIFIERS, HEATED	B1
384	HUMIDIFIERS, NONHEATED	B5
385	HYSTEROSCOPIES	B2
386	IMAGE STORAGE DEVICES, FLUOROSCOPIC	B5
387	INCINERATORS, PATHOLOGY	B5
388	INCUBATORS, AEROBIC	B5
389	INCUBATORS, INFANT	B1
390	INCUBATORS, INFANT, MOBILE	B1
391	INCUBATORS, INFANT, TRANSPORT	B1
392	INCUBATORS, LABORATORY, THERMOCYCLING	B5
393	INCUBATORS, TEST TUBE	B5
394	INCUBATORS, TEST TUBE, PORTABLE	B5
395	INFORMATION SYSTEMS, DATA MANAGEMENT, CARDIOLOGY	B5
396	INFORMATION SYSTEMS, DATA MANAGEMENT, RADIOLOGY	B5
397	INFORMATION SYSTEMS, PICTURE ARCHIVING AND COMMUNICATION, RADIOLOGY	B5
398	INFUSION PUMPS	B1
399	INFUSION PUMPS, AMBULATORY	B1
400	INFUSION PUMPS, GENERAL PURPOSE	B1
401	INFUSION PUMPS, MULTICHANNEL	B1
402	INFUSION PUMPS, PATIENT-CONTROLLED ANALGESIC	B1
403	INFUSION PUMPS, SYRINGE	B1
404	INJECTORS, CONTRAST MEDIA	B1
405	INJECTORS, CONTRAST MEDIA, ANGIOGRAPHY	B1



406	INJECTORS, CONTRAST MEDIA, COMPUTED TOMOGRAPHY	B1
407	INJECTORS, CONTRAST MEDIA, MAGNETIC RESONANCE IMAGING	B1
408	INJECTORS, MEDICATION/VACCINE, NEEDLELESS	B1
409	INSUFFLATORS	B1
410	INSUFFLATORS, ARTHROSCOPIC	B1
411	INSUFFLATORS, HYSTEROSCOPIC	B1
412	INSUFFLATORS, LAPAROSCOPIC	B1
413	INSUFFLATORS, OPHTHALMIC	B1
414	INTRAVENOUS LINE CONNECTORS, NEEDLELESS	A3
415	IONTOPHORESIS UNIT	B1
416	IONTOPHORESIS UNITS, SWEAT TEST	B1
417	IRRIGATION/DISTENTION SYSTEMS, ARTHROSCOPIC	B1
418	KERATOMES	B1
419	LAMINAR AIR FLOW UNITS	B5
420	LAMINAR AIR FLOW UNITS, MOBILE	B5
421	LAPAROSCOPES	B2
422	LARYNGOSCOPE	B2
423	LARYNGOSCOPES, FLEXIBLE	B2
424	LARYNGOSCOPES, FLEXIBLE, INTUBATION	B2
425	LARYNGOSCOPES, RIGID	B2
426	LARYNGOSTROBOSCOPES	B2
427	LASER IMAGERS	B5
428	LASER,HE:NE	B5
429	LASERS	B5
430	LASERS, ALEXANDRITE, DERMATOLOGIC	B5
431	LASERS, ARGON, DENTAL	B1



432	LASERS, ARGON, OPHTHALMIC	B1
433	LASERS, ARGON, SURGICAL	B1
434	LASERS, ARGON/KRYPTON, OPHTHALMIC	B1
435	LASERS, CARBON DIOXIDE, DENTAL	B1
436	LASERS, CARBON DIOXIDE, SURGICAL/DERMATOLOGIC	B1
437	LASERS, DIODE	B5
438	LASERS, DIODE, BIOSTIMULATION	B5
439	LASERS, DIODE, DENTAL	B1
440	LASERS, DIODE, INTERSTITIAL THERMOTHERAPY	B4
441	LASERS, DIODE, OPHTHALMIC	B1
442	LASERS, DIODE, SURGICAL	B1
443	LASERS, DYE, PHOTODYNAMIC THERAPY	B4
444	LASERS, ER:YAG, DENTAL	B1
445	LASERS, ER:YAG, DERMATOLOGIC	B5
446	LASERS, ER:YAG, OPHTHALMIC	B1
447	LASERS, ER:YAG, SURGICAL	B1
448	LASERS, ER:YSGG	B1
449	LASERS, ERCR:YSGG, DENTAL	B1
450	LASERS, ERCR:YSGG, DERMATOLOGIC	B5
451	LASERS, EXCIMER, ANGIOPLASTY	B5
452	LASERS, EXCIMER, DENTAL	B1
453	LASERS, EXCIMER, OPHTHALMIC	B1
454	LASERS, EXCIMER, SURGICAL	B1
455	LASERS, EXCIMER/HO:YAG, OPHTHALMIC	B1
456	LASERS, HO:YAG, ANGIOPLASTY	B1
457	LASERS, HO:YAG, DENTAL	B1
458	LASERS, HO:YAG, OPHTHALMIC	B1
459	LASERS, HO:YAG, SURGICAL	B1



460	LASERS, KRYPTON, DERMATOLOGIC	B5
461	LASERS, KRYPTON, OPHTHALMIC	B1
462	LASERS, ND:YAG, ANGIOPLASTY	B5
463	LASERS, ND:YAG, DENTAL	B1
464	LASERS, ND:YAG, DERMATOLOGIC	B5
465	LASERS, ND:YAG, FREQUENCY-DOUBLED	B1
466	LASERS, ND:YAG, FREQUENCY-DOUBLED, OPHTHALMIC	B1
467	LASERS, ND:YAG, OPHTHALMIC	B1
468	LASERS, ND:YAG, SURGICAL	B1
469	LASERS, ND:YAG/ ND:YAG FREQUENCY-DOUBLED, SURGICAL	B1
470	LENSOMETERS	B1
471	LIGHT SOURCES	B1
472	LIGHT SOURCES, FIBEROPTIC	B1
473	LIGHT SOURCES, FIBEROPTIC, FLEXIBLE ENDOSCOPIC	B1
474	LIGHT SOURCES, FIBEROPTIC, RIGID ENDOSCOPIC/MULTIPURPOSE	B1
475	LIGHTS, DENTAL	B1
476	LIGHTS, DENTAL, INTRAORAL	B1
477	LIGHTS, EXAMINATION	B1
478	LIGHTS, INFRARED	B1
479	LIGHTS, PERINEAL HEAT	B1
480	LIGHTS, SURGICAL	B1
481	LIGHTS, ULTRAVIOLET	B1
482	LIGHTS, ULTRAVIOLET, GERMICIDAL	B1
483	LITHOTRIPTERS, EXTRACORPOREAL	B4



484	LITHOTRIPTERS, EXTRACORPOREAL, ELECTROMECHANICAL	B4
485	LITHOTRIPTERS, EXTRACORPOREAL, PIEZOELECTRIC	B4
486	LITHOTRIPTERS, EXTRACORPOREAL, SPARK-GAP	B4
487	LITHOTRIPTERS, INTRACORPOREAL	B1
488	LITHOTRIPTERS, INTRACORPOREAL, ELECTROHYDRAULIC	B1
489	LITHOTRIPTERS, INTRACORPOREAL, IMPACT	B1
490	LITHOTRIPTERS, INTRACORPOREAL, IMPACT, ELECTROMECHANICAL	B1
491	LITHOTRIPTERS, INTRACORPOREAL, IMPACT, PNEUMATIC	B1
492	LITHOTRIPTERS, INTRACORPOREAL, IMPACT, ULTRASONIC	B1
493	LITHOTRIPTERS, INTRACORPOREAL, LASER	B1
494	LOUPES	B1
495	MAGNETS, EYE	A1
496	MAGNIFIERS, OPERATING	A1
497	MASSAGE MACHINES, PHYSICAL THERAPHY	B1
498	MATTRESS SYSTEMS, ALTERNATING-PRESSURE	B5
499	METABOLIC CARTS	B1
500	METAL DETECTORS	B5
501	MICROGASOMETERS	A3
502	MICROSCOPE, LIGHT, EXAMINATION	B5
503	MICROSCOPES	B5
504	MICROSCOPES, ELECTRON	B1
505	MICROSCOPES, ELECTRON, SCANNING	B1
506	MICROSCOPES, ELECTRON, TRANSMISSION	B5



507	MICROSCOPES, LIGHT, EXAMINATION, DERMATOLOGY	B5
508	MICROSCOPES, LIGHT, EXAMINATION, OPHTHALMOLOGY	B1
509	MICROSCOPES, LIGHT, EXAMINATION, OTORHINOLARYNGOLOGY	B5
510	MICROSCOPES, LIGHT, LABORATORY	B5
511	MICROSCOPES, LIGHT, LABORATORY, BRIGHTFIELD	B5
512	MICROSCOPES, LIGHT, LABORATORY, DARKFIELD	B5
513	MICROSCOPES, LIGHT, LABORATORY, FLUORESCENCE	B5
514	MICROSCOPES, LIGHT, LABORATORY, INTERFERENCE	B5
515	MICROSCOPES, LIGHT, LABORATORY, INVERTED STAGE	B5
516	MICROSCOPES, LIGHT, LABORATORY, PHASE CONTRAST	B5
517	MICROSCOPES, LIGHT, LABORATORY, POLARIZED LIGHT	B5
518	MICROSCOPES, LIGHT, LABORATORY, STEREO	B5
519	MICROSCOPES, LIGHT, OPERATING	B1
520	MICROSCOPES, LIGHT, OPERATING, GYNECOLOGY	B1
521	MICROSCOPES, LIGHT, OPERATING, HAND/PLASTIC SURGERY	B1
522	MICROSCOPES, LIGHT, OPERATING, NEUROSURGERY	B1



523	MICROSCOPES, LIGHT, OPERATING, OPHTHALMOLOGY	B1
524	MICROSCOPES, SCANNING LASER, OPTICAL	B1
525	MICROSURGICAL INSTRUMENTS	B1
526	MICROTOMES	B5
527	MICROTOMES, CRYOSTAT	B5
528	MICROTOMES, ROTARY	B5
529	MICROTOMES, SLIDING	B5
530	MICROTOMES, ULTRA	B5
531	MICROWAVE OVENS, PLASMA-THAWING	B5
532	MICROWAVE THERAPY SYSTEMS, DIATHERMY	B1
533	MIXERS	B5
534	MIXERS, BLOOD BANK, DONOR BLOOD	B5
535	MIXERS, BLOOD TUBE	B5
536	MIXERS, CLINICAL LABORATORY	B5
537	MIXERS, X-RAY FILM CHEMISTRY	B5
538	MODULAR MEDICAL FACILITIES, MOBILE, DENTAL	B1
539	MOIST HEAT THERAPY PACKS	B1
540	MONITORING SYSTEMS, PHYSIOLOGIC	B3
541	MONITORING SYSTEMS, PHYSIOLOGIC, ACUTE CARE	B3
542	MONITORING SYSTEMS, PHYSIOLOGIC, CARDIAC CATHETERIZATION	B3
543	MONITORING SYSTEMS, PHYSIOLOGIC, STRESS EXERCISE	B3
544	MONITORING SYSTEMS, PHYSIOLOGIC, STRESS EXERCISE, CARDIAC	B3
545	MONITORS, BEDSIDE, ANESTHETIC GAS	B3



546	MONITORS, BEDSIDE, BLOOD GAS, TRANSCUTANEOUS	B3
547	MONITORS, BEDSIDE, BLOOD GAS/PH, EXTRACORPOREAL	B3
548	MONITORS, BEDSIDE, ELECTROCARDIOGRAPHY	B3
549	MONITORS, BEDSIDE, ELECTROENCEPHALOGRAPHY	B3
550	MONITORS, BEDSIDE, FETAL	B3
551	MONITORS, BEDSIDE, FETAL, ANTEPARTUM	B3
552	MONITORS, BEDSIDE, FETAL, INTRAPARTUM	B3
553	MONITORS, BEDSIDE, NEUROLOGY	B3
554	MONITORS, BEDSIDE, PHYSIOLOGIC, NEONATAL	B3
555	MONITORS, BEDSIDE, RESPIRATION	B3
556	MONITORS, BEDSIDE, RESPIRATION, CARBON DIOXIDE/OXYGEN	B3
557	MONITORS, BEDSIDE, RESPIRATION, EXHALED CARBON DIOXIDE	B3
558	MONITORS, BEDSIDE, RESPIRATION, INSPIRED OXYGEN	B3
559	MONITORS, BEDSIDE, RESPIRATION, VENTILATION/APNEA	B3
560	MONITORS, BEDSIDE, RESPIRATION/ANESTHETIC GAS	B3
561	MONITORS, BEDSIDE, RESPIRATION/ANESTHETIC GAS, MASS SPECTROGRAPHY	B3
562	MONITORS, BEDSIDE, UTERINE ACTIVITY	B3
563	MONITORS, COMPRESSED AIR/GAS, CARBON MONOXIDE	B3



564	MONITORS, ENVIRONMENTAL, IONIZING RADIATION	B3
565	MONITORS, LABORATORY, CARBON DIOXIDE	B3
566	MONITORS, TELEMETRIC, ELECTROCARDIOGRAPHY	B3
567	MONITORS, TELEMETRIC, ELECTROENCEPHALOGRAPHY	B3
568	MONITORS, TELEMETRIC, ELECTROMYOGRAPHY	B3
569	MONITORS, TELEMETRIC, PHYSIOLOGIC	B3
570	MONITORS, VIDEO	B3
571	MONITORS, X-RAY TUBE POSITION	B2
572	MOTOR, LABORATORY, DENTAL	B1
573	ANALYZERS, LABORATORY, CLINICAL CHEMISTRY, MANUAL	C1
574	NASOPHARYNGOSCOPES	B2
575	NASOSCOPES	B2
576	NEBULIZERS	B1
577	NEBULIZERS, HEATED	B1
578	NEBULIZERS, NONHEATED	B1
579	NEBULIZERS, ULTRASONIC	B1
580	NEPHELOMETERS	C1
581	NEPHROSCOPES	B2
582	NERVE LOCATORS	B1
583	OLFACTOMETERS	B5
584	OPHTHALMOMETERS	B1
585	OPHTHALMOSCOPE/OTOSCOPES	B2
586	OPHTHALMOSCOPES	B2
587	OPHTHALMOSCOPES, DIRECT	B2
588	OPHTHALMOSCOPES, INDIRECT	B2



589	OPHTHALMOSCOPES, SCANNING LASER	B2
590	OSMOMETERS	C1
591	OTOSCOPES	B2
592	OVENS, DRYING	B5
593	OXIMETERS, IN VITRO, LABORATORY	C1
594	OXIMETERS, PULSE	B3
595	OXYGEN CONCENTRATORS	B3
596	OXYGEN METERS	B1
597	OXYGEN-AIR PROPORTIONERS	B1
598	PACEMAKERS, CARDIAC	B1
599	PACEMAKERS, CARDIAC, EXTERNAL	B1
600	PACEMAKERS, CARDIAC, EXTERNAL, INVASIVE ELECTRODES, TRANSESOPHAGEAL	B1
601	PACEMAKERS, CARDIAC, EXTERNAL, INVASIVE ELECTRODES, TRANSVENOUS	B1
602	PACEMAKERS, CARDIAC, EXTERNAL, NONINVASIVE ELECTRODES	B1
603	PACKAGE SEALERS	B1
604	PERIMETERS	A1
605	PERIMETERS, DENTAL	B1
606	PERIMETERS, OPHTHALMIC, AUTOMATED	B1
607	PERIMETERS, OPHTHALMIC, MANUAL	B1
608	PERITONEAL DIALYSIS UNITS	B1
609	PH METERS	C1
610	PHONOCARDIOGRAPHS	B3
611	PHOTOMETER	B5
612	PHOTOMETERS, FILTER, AUTOMATED	B5
613	PHOTOMETERS, FILTER, MANUAL	B5
614	PHOTOMETERS, FILTER, REFLECTANCE	B5



615	PHOTOMETERS, FLAME	B5
616	PHOTOTHERAPY UNITS	B5
617	PHOTOTHERAPY UNITS, ULTRAVIOLET	B5
618	PHOTOTHERAPY UNITS, VISIBLE LIGHT, HYPERBILIRUBINEMIA	B5
619	PILL PACKAGING UNITS	B5
620	PIPETTERS	B5
621	PIPETTES	A3
622	PLETHYSMOGRAPHS	B3
623	PLETHYSMOGRAPHS, BODY	B3
624	PORCELAIN FURNACES, DENTAL	B1
625	POWER SUPPLIES	B5
626	POWER SUPPLIES, LINE-VOLTAGE STABILIZATION	B5
627	POWER SUPPLIES, REGULATED	B5
628	POWER SYSTEMS, UNINTERRUPTIBLE	B5
629	PRESS, DENTAL	A2
630	PRESSES, FLASK, DENTAL	A2
631	PRESSURE INFUSORS	B1
632	PRESSURE MEASURING UNITS	B1
633	PRESSURE MEASURING UNITS, ESOPHAGEAL	B1
634	PRINTERS, VIDEO	B5
635	PROCESSORS, ELECTRONIC IMAGE	B1
636	PROCTOSCOPES	B2
637	PROGRAMMER/TESTERS, IMPLANTABLE CARDIAC PACEMAKER	B1
638	PROJECTORS, CHART, EYE	B1
639	PROJECTORS, CINE	B1
640	PROPHYLACTIC UNITS, DENTAL	B1
641	PUMPS, BREAST	B5



642	PUMPS, ENTERAL FEEDING	B5
643	PUMPS, EXTRACORPOREAL PERFUSION	B5
644	PUMPS, INSUFFLATING	B5
645	PUMPS, LABORATORY	B5
646	RADIATION COUNTERS	B5
647	RADIATION SURVEY METERS, GEIGER-MULLER	B5
648	RADIATION SURVEY METERS, IONIZATION CHAMBER	B5
649	RADIOFREQUENCY THERAPY SYSTEMS, DIATHERMY	B4
650	RADIOFREQUENCY THERAPY SYSTEMS, TISSUE ABLATION	B4
651	RADIOGRAPHIC SYSTEMS, DIGITAL	B2
652	RADIOGRAPHIC SYSTEMS, FILM	B2
653	RADIOGRAPHIC SYSTEMS, FILM, BASIC (BRS)	B2
654	RADIOGRAPHIC UNITS, CHEST	B2
655	RADIOGRAPHIC UNITS, CHEST, AUTOMATED	B2
656	RADIOGRAPHIC UNITS, DENTAL	B2
657	RADIOGRAPHIC UNITS, DENTAL, EXTRAORAL	B2
658	RADIOGRAPHIC UNITS, DENTAL, INTRAORAL	B2
659	RADIOGRAPHIC UNITS, MAMMOGRAPHIC	B2
660	RADIOGRAPHIC UNITS, MOBILE	B2
661	RADIOGRAPHIC/FLUOROSCOPIC SYSTEMS, ANGIOGRAPHIC/INTERVENTIONAL	B2
662	RADIOGRAPHIC/FLUOROSCOPIC SYSTEMS, CARDIOVASCULAR	B2
663	RADIOGRAPHIC/FLUOROSCOPIC SYSTEMS, GENERAL-PURPOSE	B2
664	RADIOGRAPHIC/FLUOROSCOPIC UNITS, MOBILE	B2



665	RADIOGRAPHIC/TOMOGRAPHIC SYSTEMS, LINEAR	B2
666	RADIOTHERAPY SIMULATION SYSTEMS	B4
667	RADIOTHERAPY SYSTEMS, COBALT	B4
668	RADIOTHERAPY SYSTEMS, LINEAR ACCELERATORS	B4
669	RADIOTHERAPY SYSTEMS, ORTHOVOLTAGE	B4
670	REAGENTS, CLINICAL CHEMISTRY, CALIBRATION	A3
671	RECORDER GRAPHIC, EVOKED POTENTIAL, VISUAL	B5
672	RECORDERS, ELECTRONIC STORAGE, DATA, BAR-CODE	B5
673	RECORDERS, ELECTRONIC STORAGE, DATA, BLOOD PRESSURE	B5
674	RECORDERS, ELECTRONIC STORAGE, DATA, ELECTROCARDIOGRAPHY	B5
675	RECORDERS, GRAPHIC	B5
676	RECORDERS, GRAPHIC, PHYSIOLOGIC/GAS, ANESTHESIA	B5
677	RECORDERS, GRAPHIC, TREND, RESPIRATION RATE	B5
678	RECORDERS, TAPE, DATA, ELECTROCARDIOGRAPHY	B5
679	RECORDERS, TAPE, DATA, ELECTROCARDIOGRAPHY, CONTINUOUS	B5
680	RECORDERS, TAPE, DATA, PHYSIOLOGIC	B5
681	RECORDERS, TAPE, VIDEO	B5
682	REFRACTOMETERS, LABORATORY	C1
683	REFRACTOMETERS, LABORATORY, URINE	C1
684	REFRIGERATORS, BLOOD BANK	B5



685	REGULATORS	B1
686	REGULATORS, HIGH-PRESSURE GAS	B1
687	RESUSCITATOR	A1
688	RESUSCITATORS, CARDIAC	B1
689	RESUSCITATORS, CARDIOPULMONARY	B1
690	RESUSCITATORS, PULMONARY, EXHALED AIR	B1
691	RESUSCITATORS, PULMONARY, MANUAL	B1
692	RESUSCITATORS, PULMONARY, PNEUMATIC	B1
693	RETINOSCOPES	B2
694	ROTATORS	A1
695	SAMPLERS, ENVIRONMENTAL, AIR	B5
696	SANDBLASTERS, DENTAL	B1
697	SAWS	B1
698	SAWS, AUTOPSY	B1
699	SAWS, BONE, ELECTRICAL	B1
700	SAWS, BONE, PNEUMATIC	B1
701	SCALERS, DENTAL, ULTRASONIC	B1
702	SCALES, CLINICAL, AUTOPSY	B5
703	SCALES, CLINICAL, BLOOD COLLECTION	B5
704	SCALES, CLINICAL, LABORATORY	B5
705	SCALES, INFANT	B5
706	SCALES, PATIENT, CHAIR	B5
707	SCALES, PATIENT, FLOOR	B5
708	SCANNING SYSTEM, MAGNETIC RESONANCE IMAGING	B2
709	SCANNING SYSTEM, ULTRASONIC, VASCULAR	B2
710	SCANNING SYSTEMS, COMPUTED TOMOGRAPHY	B2
711	SCANNING SYSTEMS, COMPUTED TOMOGRAPHY, AXIAL, FULL-BODY	B2



712	SCANNING SYSTEMS, COMPUTED TOMOGRAPHY, SPIRAL	B2
713	SCANNING SYSTEMS, GAMMA CAMERA	B2
714	SCANNING SYSTEMS, GAMMA CAMERA, MOBILE	B2
715	SCANNING SYSTEMS, MAGNETIC RESONANCE IMAGING, FULL-BODY	B2
716	SCANNING SYSTEMS, ULTRASONIC	B2
717	SCANNING SYSTEMS, ULTRASONIC, ABDOMINAL	B2
718	SCANNING SYSTEMS, ULTRASONIC, CARDIAC	B2
719	SCANNING SYSTEMS, ULTRASONIC, GENERAL-PURPOSE	B2
720	SCANNING SYSTEMS, ULTRASONIC, MAMMOGRAPHIC	B2
721	SCANNING SYSTEMS, ULTRASONIC, OBSTETRIC/GYNECOLOGIC	B2
722	SCANNING SYSTEMS, ULTRASONIC, OPHTHALMIC	B2
723	SCREEN, X-RAY FILM CASSETTE	B5
724	SEDIMENTATION RATE UNITS	C1
725	SENSITOMETERS, RADIOGRAPHIC	B2
726	SENSORS	B5
727	SEPARATORS, PLASMA	B5
728	SHAKERS, LABORATORY	B5
729	SHARPENERS, KNIFE	A1
730	SHARPENERS, MICROTOME KNIFE	A1
731	SHIELDS, X-RAY, BARRIER	A1
732	SIGMOIDOSCOPIES	B2
733	SIGMOIDOSCOPIES, FLEXIBLE	B2
734	SIGMOIDOSCOPIES, FLEXIBLE, VIDEO	B2
735	SIGMOIDOSCOPIES, RIGID	B2



736	SILVER RECOVERY SYSTEMS	B5
737	SILVER RECOVERY SYSTEMS, CHEMICAL PRECIPITATION	B5
738	SILVER RECOVERY SYSTEMS, ELECTROLYTIC PLATING CELL	B5
739	SIMULATORS	B1
740	SIMULATORS, CARDIAC, ELECTROCARDIOGRAPHY	B1
741	SLIDE STAINERS	B5
742	SLIT LAMPS	B1
743	SMOKE EVACUATION SYSTEMS, SURGICAL	B1
744	SOLVENT RECYCLING UNITS	B1
745	SPECIMEN CUTTERS	B1
746	SPECTROFLUOROMETERS	C1
747	SPECTROMETERS, MASS, LABORATORY	C1
748	SPECTROPHOTOMETER	C1
749	SPECTROPHOTOMETERS, ATOMIC ABSORPTION	C1
750	SPECTROPHOTOMETERS, INFRARED	C1
751	SPECTROPHOTOMETERS, ULTRAVIOLET	C1
752	SPECTROPHOTOMETERS, ULTRAVIOLET/VISIBLE	C1
753	SPECTROPHOTOMETERS, VISIBLE	C1
754	SPEECH AMPLIFIERS	B5
755	SPEECH THERAPY UNITS	B5
756	SPHYGMOMANOMETERS, ANEROID	A1
757	SPHYGMOMANOMETERS, ELECTRONIC	B1
758	SPHYGMOMANOMETERS, ELECTRONIC, AUTOMATIC	B1
759	SPHYGMOMANOMETERS, ELECTRONIC, MANUAL	B1
760	SPHYGMOMANOMETERS, MERCURY	A1



761	SPIROMETERS	B1
762	SPIROMETERS, BRONCHIAL	B1
763	SPIROMETERS, DIAGNOSTIC	B1
764	STEREOTACTIC SYSTEMS, BIOPSY, MAMMOGRAPHIC	B4
765	STEREOTACTIC SYSTEMS, RADIOSURGICAL, GAMMA	B4
766	STEREOTACTIC SYSTEMS, RADIOSURGICAL, LINEAR ACCELERATOR	B4
767	STERILIZATION PROCESS INDICATORS, BIOLOGICAL	D3
768	STERILIZING UNITS, DRY HEAT	D3
769	STERILIZING UNITS, HYDROGEN PEROXIDE	D4
770	STERILIZING UNITS, RADIATION TECHNIQUE	D5
771	STERILIZING UNITS, ETHYLENE OXIDE	D1
772	STERILIZING UNITS, STEAM, TABLETOP	D2
773	STIMULATORS	B1
774	STIMULATORS, CALORIC, PHYSICAL THERAPY	B1
775	STIMULATORS, CALORIC, PHYSICAL THERAPY, FLUIDIZED MEDIUM	B1
776	STIMULATORS, ELECTRICAL	B1
777	STIMULATORS, ELECTRICAL, BRAIN, ANESTHESIA	B1
778	STIMULATORS, ELECTRICAL, BRAIN, CONVULSIVE THERAPY	B1
779	STIMULATORS, ELECTRICAL, CARDIAC	B1
780	STIMULATORS, ELECTRICAL, NEUROMUSCULAR	B1
781	STIMULATORS, ELECTRICAL, NEUROMUSCULAR, DIAGNOSTIC	B1
782	STIMULATORS, ELECTRICAL, PERIPHERAL NERVE	B1



783	STIMULATORS, ELECTRICAL, PERIPHERAL NERVE, ANALGESIC	B1
784	STIRRERS	B5
785	SUCTION IRRIGATORS	B1
786	SYNOPTOPHORES	B1
787	SYNTHESIZERS, DNA/RNA	B5
788	TABLES, EXAMINATION/TREATMENT	B1
789	TABLES, IMAGING, RADIOGRAPHIC	B1
790	TABLES, OPERATING	B1
791	TESTER/CHARGERS, BATTERY	B5
792	TESTER/RECONDITIONERS, BATTERY	B5
793	TESTERS, BATTERY	B5
794	TESTERS, ELECTRICAL SAFETY	B5
795	TESTERS, HEARING AID	B5
796	TESTERS, IMPLANTABLE CARDIAC PACEMAKER, INTRAOPERATIVE	B5
797	TESTERS, IMPLANTABLE DEFIBRILLATOR/CARDIOVERTER	B5
798	THERMOMETER	A1
799	THERMOMETERS, ELECTRONIC	B3
800	THERMOMETERS, ELECTRONIC, INFRARED, EAR	B3
801	THERMOMETERS, ELECTRONIC, INFRARED, SKIN	B3
802	THROMBOMETERS	C1
803	THYROID UPTAKE SYSTEMS	B2
804	TIMERS, COAGULATION	C1
805	TISSUE EMBEDDING EQUIPMENT	B5
806	TISSUE PROCESSORS	B5
807	TITRATORS	B5
808	TONOMETERS, BLOOD GAS	C1



809	TONOMETERS, OPHTHALMIC	C1
810	TOURNIQUET	B1
811	TOURNIQUETS, PNEUMATIC	B1
812	TOURNIQUETS, PNEUMATIC, AUTOMATIC ROTATING	B1
813	TRACTION UNIT	B1
814	TRACTION UNITS, INTERMITTENT	B1
815	TRACTION UNITS, STATIC, BED	B1
816	TRAINING AID	B5
817	TRAINING MANIKINS, CARDIOPULMONARY RESUSCITATION	B5
818	TRANSFER SETS	A3
819	TRANSFORMERS	B5
820	TRANSFUSION KITS	A1
821	TRANSILLUMINATORS	B5
822	TRAYS, IMPRESSION, DENTAL	A2
822	TRAYS, IMPRESSION, EAR CANAL	A3
823	TREADMILLS	B1
824	TRIMMERS, MODEL, DENTAL	B1
825	TURBIDIMETERS	C1
826	ULTRASOUND CLEANING SYSTEMS	B5
827	ULTRASOUND SURGICAL UNITS	B1
828	ULTRASOUND THERAPY SYSTEMS, PHYSICAL THERAPY	B1
829	ULTRASOUND THERAPY/NEUROMUSCULAR STIMULATION SYSTEMS, PHYSICAL THERAPY	B1
830	UNIT-DOSE DISPENSERS	B5
831	URETERORENOSCOPES	B2
832	URETEROSCOPES	B2



833	URETEROSCOPES, FLEXIBLE	B2
834	URETEROSCOPES, RIGID	B2
835	URETEROTOMES	A1
836	URODYNAMIC MEASUREMENT SYSTEMS	B5
837	UROFLOWMETERS	B5
838	VACUUM EXTRACTORS, OBSTETRICAL	B1
839	VACUUM-MIXING DEVICES, DENTAL	B1
840	VECTORCARDIOGRAPHS	B5
841	VENTILATORS, ANESTHESIA	B1
842	VENTILATORS, INTENSIVE CARE	B1
843	VENTILATORS, INTENSIVE CARE, ADULT	B1
844	VENTILATORS, INTENSIVE CARE, ADULT, HIGH-FREQUENCY	B1
845	VENTILATORS, INTENSIVE CARE, NEONATAL/PEDIATRIC	B1
846	VENTILATORS, TRANSPORT	B1
847	VIBRATORS	B5
848	VIBRATORS, BONE, AUDIOMETRIC	B5
849	VIDEO IMAGE PROCESSORS	B5
850	VIDEO IMAGE PROCESSORS, ENDOSCOPIC	B5
851	VIDEO SYSTEMS, ENDOSCOPIC	B5
852	VIEW BOXES, ULTRAVIOLET	B5
853	VIEW BOXES, X-RAY	B5
854	VISCOSIMETERS, PLASMA	B5
855	VISUAL FIELD PLOTTERS	B1
856	VITRECTOMY UNITS	B1
857	WARMING UNITS, BLANKET	B5
858	WARMING UNITS, BLOOD/SOLUTION	B5
859	WARMING UNITS, CONTRAST MEDIA	B5



860	WARMING UNITS, MICROSCOPE SLIDE	B5
861	WARMING UNITS, PATIENT, FORCED-AIR	B5
862	WARMING UNITS, PATIENT, RADIANT	B5
863	WARMING UNITS, PATIENT, RADIANT, ADULT	B5
864	WARMING UNITS, PATIENT, RADIANT, INFANT	B5
865	WARMING UNITS, PATIENT, RADIANT, INFANT, MOBILE	B5
866	WARMING/COOLING UNITS, PATIENT	B5
867	WARMING/COOLING UNITS, PATIENT, CIRCULATING-FLUID	B5
868	WARMING/COOLING UNITS, PATIENT, HEART-LUNG BYPASS	B5
869	WASHER/STERILIZING UNITS	B5
870	WASHERS, CELL	B5
871	WASHERS, FLEXIBLE ENDOSCOPE	B5
872	WASHERS, LABWARE	B5
873	WASHERS, MICROPLATE	B5
874	WASHERS, PIPETTE	B5
875	WASHERS, RIGID ENDOSCOPE	B5
876	WASTE-DISPOSABLE UNITS, SHARPS	A3
877	WATER BATH CIRCULATORS	B5
878	WATER PURIFICATION SYSTEMS	B5
879	WATER PURIFICATION SYSTEMS, DEIONIZATION	B5
880	WATER PURIFICATION SYSTEMS, REVERSE OSMOSIS	B5
881	WATER PURIFICATION SYSTEMS, ULTRAVIOLET	B5
882	WELDING UNITS, ORTHODONTIC	B1
883	WIRE DRIVERS	A3
884	XENON SYSTEMS	B1

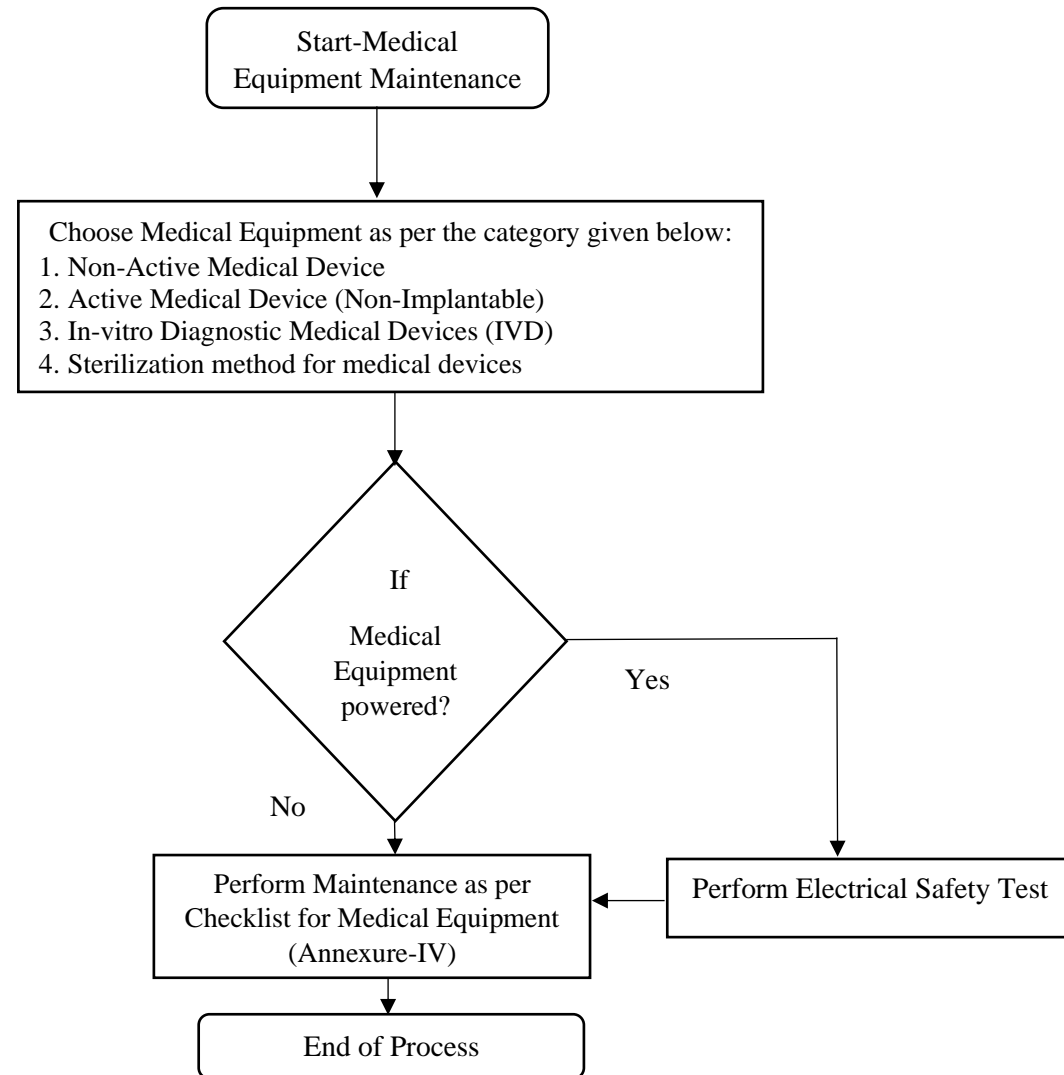


885	X-RAY FILM DRYERS	B5
886	X-RAY FILM DUPLICATORS	B5
887	X-RAY FILM HANDLING EQUIPMENT, AUTOMATIC, DAYLIGHT	B5
888	X-RAY FILM LABELERS	B5
889	X-RAY FILM PROCESSORS, AUTOMATIC	B5
890	X-RAY FILM PROCESSORS, AUTOMATIC, CINE	B5
891	X-RAY FILM PROCESSORS, AUTOMATIC, DENTAL	B5
892	X-RAY FILM PROCESSORS, AUTOMATIC, FLOOR	B5
893	X-RAY FILM PROCESSORS, AUTOMATIC, SHEET-FILM	B5
894	X-RAY FILM PROCESSORS, AUTOMATIC, TABLETOP	B5
895	X-RAY GENERATORS	B5
896	X-RAY QUALITY ASSURANCE TEST CASSETTE	B5
897	CIRCULATORY ASSIST UNIT, PERIPHERAL COMPRESSION, INTERMITTENT	B5
898	ELECTRONYSTAGMOGRAPHS	B1
899	MONITOR/CONTROLLER, OXYGEN	B1
900	POSITIONING AIDS, RADIOGRAPHIC / RADIOTHERAPEUTIC	A3
901	SCALERS	A3
902	SYRINGE/NEEDLE DESTROYERS	B5
903	ANALYZERS, LABORATORY, BODY FLUIDS, ELECTROLYTE	C1
904	FREEZER BLOOD	B5
905	SPECTROMETERS	B1
906	CYCLOTRON	B4



907	STIMULATORS, ELECTRICAL, PERIPHERAL NERVE, BLOCK MONITORING	B1
908	TABLES, IMAGING, RADIOGRAPHIC/FLUOROSCOPIC	B5
909	MONITORS, BEDSIDE, BLOOD PRESSURE	B3
910	STERILIZING UNITS, AGAR	D2
911	BUNSEN BURNER	A3
912	UNIT DOSE DISPENSERS, PILLS	B5
913	DENTAL RESTORATION POLISHERS, BURNISHERS	A2
914	WASHER MICROPLATE	B5

Annexure-III: Medical Equipment Maintenance Process Flowchart



Annexure-IV
Checklist for Medical Equipment
3a- Checklist for Non-Active Medical Devices

Category	Sub category	Scheme Category/ Sub Category Identification code	Sl.No.	General Checklist	Acceptable/Not Acceptable/Not Applicable	Remarks
Non-Active Medical Devices	General Non-Active, non-implantable Devices, Non-active dental devices, others	Common Check Point (CCP) for A1, A2, A3	A-CCP-01	External surface - verify physical integrity, cleanliness and condition.		
			A-CCP-02	Mount/ Fasteners - verify physical integrity.		
			A-CCP-03	Tubes/ Hoses - verify integrity		
			A-CCP-04	Fittings/ Connectors - check all fittings/connectors.		
			A-CCP-05	Controls/Switches - verify proper operation of controls.		
			A-CCP-06	Analog Indicators- Check the condition		
			A-CCP-07	Labeling - verify caution and warning labels.		
			A-CCP-08	Accessories - verify physical integrity and operation		
			A-CCP-09	Clean the Exterior		



			A-CCP-10	Inspect/ Clean Interior of unit		
			A-CCP-11	Align / Adjust mechanical components*		
			A-CCP-12	Functional Check- verify proper functioning of device		
			A-CCP-13	Lubricate the recommended parts if required*		



3b- Checklist for Active Medical Devices (Non-implantable)

Category	Sub category	Scheme Category/ Sub Category Identification code	Sl.No.	General Checklist	Acceptable/Not Acceptable/Not Applicable	Remarks
Active Medical Devices (Non-implantable)		Common Check Point (CCP) for B	B-CCP-01	Chassis - verify physical integrity, cleanliness and condition.		
			B-CCP-02	Mount/ Fasteners - verify physical integrity.		
			B-CCP-03	AC Plug - verify integrity		
			B-CCP-04	Line Cord - verify proper insulation and integrity		
			B-CCP-05	Strain Relief - verify physical integrity at both ends of line cord		
			B-CCP-06	Circuit Breaker/ Fuse - verify integrity of external circuit breaker and/or rating of external fuse		
			B-CCP-07	Tubes/ Hoses - verify integrity		
			B-CCP-08	Fittings/ Connectors - check all fittings/connectors.		
			B-CCP-09	Controls/Switches - verify proper operation of controls.		
			B-CCP-10	Battery/ Charger - verify operation of battery and charger		



		B-CCP-11	Indicators/ Displays - verify proper illumination and operation		
		B-CCP-12	Audible Signal - confirm appropriate volume and operation of volume controls		
		B-CCP-13	Labeling - verify caution and warning labels.		
		B-CCP-14	Accessories - verify physical integrity and operation		
		B-CCP-15	Inspect/Clean the Exterior		
		B-CCP-16	Inspect/ Clean Interior of unit		
		B-CCP-17	Calibrate Electrical Components*		
		B-CCP-18	Align / Adjust mechanical components*		
		B-CCP-19	Alarms - Check all the warning alarms*		
		B-CCP-20	Indicator/Displays- verify proper illumination and operation		
		B-CCP-21	Check printer operation - Verify paper is used as specified by manufacturer*		
		B-CCP-22	General sensor if available- Verify its operation*		
		B-CCP-23	Power On Self Test / All Functional Test -Verify Operation*		
		Note:	All tests shall conform to IEC 62353- Medical electrical equipment — Recurrent test and test after repair of medical electrical equipment		

General Active Medical Devices	B1-1	Devices for extra-corporal circulation, infusion and haemopheresis			
		B1-1-001	Volume Accuracy *		
		B1-1-002	Gear/Bearings/Shafts-verify physical condition and smooth operation*		
		B1-1-003	Pump/Motor- verify operation		
		B1-1-004	Air Detector/Sensor- verify operation*		
		B1-1-005	Blood-leak detector- verify operation*		
		B1-1-006	Inspect/Check A/V Fluid Transducers- replace if necessary*		
		B1-1-007	Check/Align Blood Pump assemble*		
		B1-1-008	Inspect/ Clean Hydraulic system		
		B1-1-009	Dialysate Flow*		
		B1-1-010	Dialysate Temperature*		
		B1-1-011	Conductivity*		
		B1-1-012	Transmembrane Pressure (TMP) meter accuracy*		
		B1-1-013	Arterial pressure*		
		B1-1-014	Venous pressure*		
B1-1-015	Blood Pump Flow Rate*				



		B1-1-016	Blood Pump Occlusion Pressure*		
		B1-1-017	Heparin Pump accuracy*		
		B1-1-018	Inlet water pressure*		
		B1-1-019	De-Gassing Pressure*		
		B1-1-020	Negative Pressure*		
		B1-1-021	Lubricate recommended parts*		
		B1-1-022	Valves/Clamps- verify operation		
		B1-1-023	Heater- verify condition & operation*		
		B1-1-024	Cooling Fan- verify operation		
		B1-1-025	Filters- verify condition		
		B1-1-026	Transducer- verify condition and operation*		
		B1-1-027	Eccentricity of Rollers- verify condition*		
		B1-1-028	Belts-verify physical condition		
		B1-1-029	Speed potentiometer linearity- verify		
		B1-1-030	Directional Switch Test- verify operation		
		B1-1-031	Speed knob zero crossing- verify operation		

		B1-1-032	Tubing Guide Rollers- verify condition and operation			
		B1-1-033	Pump Speed*			
		B1-1-034	Temperature Stability*			
		B1-1-035	Rotor symmetry and roundness- verify its condition			
		B1-1-036	Occlusion accuracy*			
	B1-2	Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia				
		B1-2-001	Casters/Brakes -verify integrity			
		B1-2-002	Tidal Volume Accuracy/Minute Volume*			
		B1-2-003	Breath Rate Control Accuracy*			
		B1-2-004	Inspiratory Time Control Accuracy*			
		B1-2-005	Expiratory Time Control Accuracy*			
		B1-2-006	I/E Ratio Control Accuracy*			
		B1-2-007	Peak Flow Accuracy*			
		B1-2-008	FiO2 Accuracy*			
		B1-2-009	Lubricate recommended parts*			

		B1-2-010	Soda lime canister - verify the condition*			
		B1-2-011	Oxygen sensor- verify its operation*			
		B1-2-012	Anti-Hypoxic Mechanism			
		B1-2-013	O-Rings/Diaphragms - Inspect			
		B1-2-014	Scavenging System- verify operation			
		B1-2-015	Filter - verify physical and replace if necessary*			
		Devices for stimulation or inhibition				
	B1-3	B1-3-001	Paddle Continuity*			
		B1-3-002	Check energy delivery- (at least for 5-10 discharges)*			
		B1-3-003	Internal Paddle Energy Limit*			
		B1-3-004	Heart Rate Verify ECG waveform through paddle at set bpm			
		B1-3-005	Attenuator & Microphone - Verify operation*			
		B1-3-006	Earphone and Earphone Cushion- Inspect			
		B1-3-007	Headband - Inspect			
		B1-3-008	Bone Conductor – Inspect*			
		B1-3-009	Tone Interpreter- Verify operation*			

		B1-3-010	Synchronization Operation*			
		B1-3-011	Self Diagnostic Test- verify operation in all modes with patient circuit installed*			
		B1-3-012	Timer setting- verify*			
		B1-3-013	Power setting- verify*			
		B1-3-014	Pulse Mode - Verify operation in all selectable modes*			
		B1-3-015	Continuous Mode - Verify operation in all selectable modes*			
		Active surgical devices				
	B1-4	B1-4-001	Pulse Mode - Verify operation in all selectable modes*			
		B1-4-002	Continuous Mode - Verify operation in all selectable modes*			
		B1-4-003	Handheld Electrodes – Check integrity and operation			
		B1-4-004	Gas Flow – Verify its operation*			
		B1-4-005	Gas Leaks – Inspect and arrest			
		B1-4-006	Gas Cylinder Holders/Mount – Verify integrity			
		B1-4-007	In-line Gas Filters – Verify integrity and condition			
		B1-4-008	Lux/light intensity- check*			
		B1-4-009	Rotation speed- check *			

		B1-4-010	Pressure Regulators – Verify setting and operation*			
		B1-4-011	Power setting- verify*			
		B1-4-012	Timer- verify*			
		B1-4-013	Dispersive electrode- check integrity and operation*			
		B1-4-014	Footswitch/Handpiece - verify physical integrity, connection, and proper operation			
		Active ophthalmologic devices				
	B1-5	B1-5-001	Light Guide (Fiber Optic Cable)- verify physical integrity			
		B1-5-002	Camera attachment - verify physical integrity			
		B1-5-003	Focusing Knobs/Lever - verify integrity and operation			
		B1-5-004	Bent filaments- Verify condition*			
		B1-5-005	Light source/bulb- verify condition*			
		B1-5-006	Optical surfaces/lenses- verify condition			
		B1-5-007	Adjustment (x,y,z) knobs - verify integrity and operation*			
			Active Dental devices			
	B1-6	B1-6-001	Compressor- verify operation			
		B1-6-002	Delivery system- verify condition			

		B1-6-003	Vacuum and main water line availability check			
		B1-6-004	Central vacuum and main water-line filters- verify its condition			
		B1-6-005	Amalgam separator- verify if available			
		B1-6-006	Valves/Solenoids -Verify operation			
		B1-6-007	Inspect/ Replace Carbon Brush(es)*			
		B1-6-008	Optical surfaces/lenses- verify condition			
		B1-6-009	O-Rings/Diaphragms - Inspect			
		B1-6-010	Sterilizer filters- verify and perform a spore test*			
		Active Devices for Disinfection and Sterilization				
	B1-7	B1-7-001	Electrode/sensor- verify physical integrity and operation*			
		B1-7-002	Endoscopy camera- verify operation*			
		B1-7-003	External surface check			
		Active rehabilitation devices and active prostheses				
	B1-8	B1-8-001	All types of sensors/transducers- verify the operation*			
		B1-8-002	Motion- verify operation*			
		B1-8-003	Motor- operation check			

		B1-8-004	Gear mechanism- verify condition*			
	B1-9	Active devices for patient positioning and transport				
		B1-9-001	Mattress -verify the physical integrity			
		B1-9-002	Hydraulics System -Inspect			
		B1-9-003	Gear/Level/Handles/remote -verify operation*			
	B1-10	Active devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART)				
		B1-10-001	Check Sample Tray - For proper movement			
		B1-10-002	Check for dust or dirt on the lenses- verify the condition			
		B1-10-003	Check disposable items- non-embryo-toxic*			
		B1-10-004	Micromanipulator movement- verify its operation*			
		B1-10-005	Check the pressure gauge on the two-stage gas regulator*			
		B1-10-006	HEPA filter- verify its condition*			
		B1-10-007	Inlet filters- verify its condition*			
		B1-10-008	Flowmeters/Flow gauges- verify operation*			
		B1-10-009	CO2 gas pressure- verify*			
		B1-10-010	Gas Cylinders – Verify proper mounting			

Devices for imaging	B1-11	B1-10-011	Transducers- verify operation*				
		B1-10-012	Illuminator- verify the condition*				
		Medical gas supply systems and parts thereof					
		B1-11-001	Gas Cylinders – Verify proper mounting and storage area				
		B1-11-002	Pressure regulators/Gauges- Verify (manifold, line and supply pressure regulators)*				
		B1-11-003	Check valves, pressure relief valve and shut-off valve- verify operation*				
		B1-11-004	Compressor- verify operation*				
		B1-11-005	Primary (Left bank) and Secondary (Right bank) sources- Verify the set-up				
		B1-11-006	Pressure Check for various gases at the pipe outlet– Verify *				
		B1-11-007	Reserve source of supply- verify the set-up				
		B1-11-008	Flowmeters/Flowgauges- verify operation*				
		B1-11-009	Marking and color-coding- verify condition*				
		B1-11-010	Oxygen analysers- verify operation*				
		B2-1	Devices using Ionizing Radiation				
			B2-1-001	kVp/mAs/Sec/mA Selection -verify operation*			
B2-1-002	Collimator mounts& Rotation -Up/Down Movement &verify integrity						



		B2-1-003	Hardware test- Test functions of Processor, Graphics card, keyboard, mouse, monitor *		
		B2-1-004	Peripherals test- DAT, CDROM, CD Writer, LAN, Modem*		
		B2-1-005	Driving Mechanism -verify operation		
		B2-1-006	Exposure switch -verify condition		
		B2-1-007	Column stand- Check Up/Down movements		
		B2-1-008	Table operations- Check All positions		
		B2-1-009	Flat Panel Detector/Cassette - Verify Operation		
		B2-1-010	Light field activation switch- verify operation		
		B2-1-011	Tube/Detector - verify Rotation*		
		B2-1-012	Counter Weight Balance - verify integrity & operation		
		B2-1-013	C-arm X,Y,Z Movement- verify integrity & operation*		
		B2-1-014	PACS- Check Integration*		
		B2-1-015	Check Light/Illumination - Replace if required*		
		Devices using non-Ionizing Radiation			
	B2-2	B2-2-001	Check gain/depth control		
		B2-2-002	Check modes control*		

		B2-2-003	Track Ball operation- Verify and clean the trackball unit		
		B2-2-004	Keypad- Check all key operation		
		B2-2-005	Check the probe selector		
		B2-2-006	Transducer -verify integrity and operation*		
		B2-2-007	Hardware test- Test functions of Processor, Graphics card, keyboard, mouse, monitor*		
		B2-2-008	Peripherals test- DAT, CDROM, CD Writer, LAN, Modem*		
		B2-2-009	PACS-Check Integration*		
		B2-2-010	Check the Gradient Power Stage Fan Box*		
		B2-2-011	Check the Magnet Pressure*		
		B2-2-012	Check the Gradient System Fans*		
		B2-2-013	Check the Magnet System Helium Vessel*		
		B2-2-014	Table operations- Check All positions*		
	Monitoring devices		Monitoring devices of non-vital physiological parameters		
		B3-1	B3-1-001	Check Angulation-Verify Distal end Up/Down and Right/Left	
			B3-1-002	Perform Leak test*	
			B3-1-003	Check Light/Illumination - Replace if required*	

		B3-1-004	Check Air/Water - verify adapters & plugs			
		B3-1-005	Check Monitor settings-Verify tone/balance/sharpness/contrast/color/sharpness			
		B3-1-006	Check Focus- Do white balance if required			
		Monitoring devices of vital physiological parameters				
	B3-2	B3-2-001	Check all leads and cables- Ensure that cables are not twisted			
		B3-2-002	Check modules - Verify Modules are fixed properly			
		B3-2-003	Check Vital Parameters using required testing devices/simulators/Analyzers*			
		B3-2-004	Verify Paper Speed and Paper sensor*			
		B3-2-005	Electrode lead detection - Verify operation*			
		B3-2-006	IBP transducers zeroing - Verify operation*			
		B3-2-007	Check overpressure cut-off			
		B3-2-008	Transmitter - verify operation*			
		B3-2-009	Program Protocol - verify operation*			
		B3-2-010	Walk belt - verify integrity and operation			
		B3-2-011	Treadmill levelling screws - verify			
		B3-2-012	Motor- verify operation			

		B3-2-013	Filter- verify the condition*		
		B3-2-014	Sensors / Transducers-verify integrity and operation*		
	Devices for radiation therapy and thermo therapy		Devices utilising ionizing radiation		
		B4-1-001	Hardware test- Test functions of Processor, Graphics card, keyboard, mouse, monitor*		
		B4-1-002	Peripherals test- DAT, CDROM, CD Writer, LAN, Modem*		
		B4-1-003	Collimator focus and alignment- verify*		
		B4-1-004	Control Console- verify*		
		B4-1-005	Patient Couch movement- verify*		
		B4-1-006	Hand controls- verify*		
		B4-1-007	Dosimeter- Check functions and operation*		
		B4-1-008	Perform a visual review of the camera's motion		
		B4-1-009	Ensure fans are properly functioning, and filters are free of dust		
		B4-1-010	Check humidity levels*		
		B4-1-011	Verify that energy peaks are within the expected range*		
		B4-1-012	Check pixel maps*		
		B4-1-013	Perform a final gauge check to ensure there are no other issues		

		B4-1-014	Save all calibration backups to the server		
			Device utilising non-ionizing radiation		
	B4-2	B4-2-001	Check gain/depth control*		
		B4-2-002	Check modes control*		
		B4-2-003	Track Ball operation- Verify and clean trackball unit		
		B4-2-004	Keypad- Check all key operation		
		B4-2-005	Check the probe selector*		
		B4-2-006	Transducer -verify integrity and operation*		
		B4-2-007	Hardware test- Test functions of Processor, Graphics card, keyboard, mouse, monitor*		
		B4-2-008	Peripherals test- DAT, CDROM, CD Writer, LAN, Modem*		
		B4-2-009	PACS-Check Integration*		
		B4-2-010	Check the Gradient Power Stage Fan Box*		
		B4-2-011	Check the Magnet Pressure*		
		B4-2-012	Check the Gradient System Fans*		
		B4-2-013	Check the Magnet System Helium Vessel*		
		B4-2-014	Table operations- Check All positions*		



		Devices for hyperthermia/hypothermia			
	B4-3	B4-3-001	Check the temperature- Verify controls and operations*		
		B4-3-002	Check Infuser- Verify controls and operations*		
		B4-3-003	Check Air Detectors*		
		B4-3-004	Table operations- Check All positions*		
		B4-3-005	Check Safety valves*		
	B4-4	Devices for (Extracorporeal) Shock-wave therapy (Lithotripsy)			
		B4-4-001	Vacuum and Air Pressure- Verify*		
		B4-4-002	Water Pressure- Verify*		
		B4-4-003	Model Test Stone- Verify*		
		B4-4-004	Water release valve- verify operation*		
		B4-4-005	Over pressure relief valve- verify setting & operation*		
		B4-4-006	Filters- verify condition*		
		B4-4-007	Motors- verify operation		
		B4-4-008	Water quality - verify		
		B4-4-009	Water circulation system- verify operation		

		B4-4-010	Ultrasound Image-oriented movement- verify operation*		
		B4-4-011	Power setting- verify*		
Active (Non-implantable) medical devices other specified above	B5-1	Others			
		B5-1-001	Check door assembly and Locks		
		B5-1-002	Perform load test*		
		B5-1-003	Verify sample bucket - ensure that the level is balanced*		
		B5-1-004	Replace carbon brush if required		
		B5-1-005	Defrost the device- If there is ice formation		
		B5-1-006	Verify the temperature checkpoints*		
		B5-1-007	Check heater coil- Clean the coils		
		B5-1-008	Check compressor		
		B5-1-009	Check/Change the UV lamp*		
		B5-1-010	Check/Change the Fluorescent lamp*		
		B5-1-011	Replace HEPA filter - If required *		
		B5-1-012	Check/Clean the sash window		
B5-1-013	Verify Exhaust system				

3c- Checklist for In Vitro Diagnostic Medical Devices (IVD)

Category	Sub category	Scheme Category/ Sub Category Identification code	Sl.No.	General Checklist	Acceptable/Not Acceptable/Not Applicable	Remarks
In Vitro Diagnostic Medical Devices (IVD)	IVD Instruments	Common Check Point (CCP) for C	C-CCP-01	Chassis - verify physical integrity, cleanliness and condition.		
			C-CCP-02	Mount/ Fasteners - verify physical integrity.		
			C-CCP-03	AC Plug - verify integrity		
			C-CCP-04	Line Cord - verify proper insulation and integrity		
			C-CCP-05	Strain Relief - verify physical integrity at both ends of line cord		
			C-CCP-06	Circuit Breaker/ Fuse - verify integrity of external circuit breaker and/or rating of external fuse		
			C-CCP-07	Tubes/ Hoses - verify integrity		
			C-CCP-08	Fittings/ Connectors - check all fittings/connectors.		
			C-CCP-09	Controls/Switches - verify proper operation of controls.		
			C-CCP-10	Battery/ Charger - verify operation of battery and charger		
			C-CCP-11	Indicators/ Displays - verify proper illumination and operation		



		C-CCP-12	Audible Signal - confirm appropriate volume and operation of volume controls*			
		C-CCP-13	Labeling - verify caution and warning labels.			
		C-CCP-14	Accessories - verify physical integrity and operation			
		C-CCP-15	Clean the Exterior			
		C-CCP-16	Inspect/ Clean Interior of unit			
		C-CCP-17	Calibrate Electrical Components*			
		C-CCP-18	Align / Adjust mechanical components*			
		C-CCP-19	Alarms - Check all the warning alarms*			
		C-CCP-20	Indicator/Displays- verify proper illumination and operation			
		C-CCP-21	Check printer operation - Verify paper is used as specified by the manufacturer*			
		C-CCP-22	Power On Self Test / All Functional Test -Verify Operation*			
		C-CCP-23	General sensor if available- Verify its operation*			
		Note:	All tests shall conform to IEC 62353- Medical electrical equipment – Recurrent test and test after repair of medical electrical equipment			
	C1	In Vitro Diagnostic Medical Devices (IVD)				
		C1-001	Check Aspiration Needle- Auto sampler/Manual Sampler for proper functioning*			



		C1-002	Check Input Water quality- Verify that it meets standards as required by manufacturer*		
		C1-003	Check for Clogs in all fluid paths		
		C1-004	Check Electrodes if required use refill solution*		
		C1-005	Check the Lamp intensity, if needed make intensity adjustment*		
		C1-006	Check all Probes/Pipettes - Verify mechanism and positions*		
		C1-007	Check Incubators/refrigeration units - Verify Temperature Variance or Fluctuation*		
		C1-008	Check Robotic arms - Verify mechanism and positions*		
		C1-009	Check Waste Collector- Verify Biohazards are handled and discarded properly*		
		C1-010	Check Sample Tray - For proper movement*		
		C1-011	Check Volume Accuracy *		
		C1-012	Gear/Bearings/Shafts-verify physical condition and smooth operation*		
		C1-013	Pump/Motor- verify operation		
		C1-014	Air Detector/Sample Sensor- verify operation*		
		C1-015	Inspect/ Clean Hydraulic system		
		C1-016	Replace preventive maintenance kits if required - As recommended by manufacturer*		



3d- Checklist for Sterilization Method for Medical Devices						
Category	Sub category	Scheme Category/ Sub Category Identification code	Sl.No.	General Checklist	Acceptable/Not Acceptable/Not Applicable	Remarks
Sterilization Method for Medical Devices	Sterilization Medical Devices	Common Check Point (CCP) for D	D-CCP-01	Chassis - verify physical integrity, cleanliness and condition.		
			D-CCP-02	Mount/ Fasteners - verify physical integrity.		
			D-CCP-03	AC Plug - verify integrity		
			D-CCP-04	Line Cord - verify proper insulation and integrity		
			D-CCP-05	Strain Relief - verify physical integrity at both ends of line cord		
			D-CCP-06	Circuit Breaker/ Fuse - verify integrity of external circuit breaker and/or rating of external fuse		
			D-CCP-07	Tubes/ Hoses - verify integrity		
			D-CCP-08	Fittings/ Connectors - check all fittings/connectors.		
			D-CCP-09	Controls/Switches - verify proper operation of controls.		
			D-CCP-10	Battery/ Charger - verify operation of battery and charger		
			D-CCP-11	Indicators/ Displays - verify proper illumination and operation		
			D-CCP-12	Audible Signal - confirm appropriate volume and operation of volume controls*		
			D-CCP-13	Labeling - verify caution and warning labels.		



			D-CCP-14	Accessories - verify physical integrity and operation		
			D-CCP-15	Clean the Exterior		
			D-CCP-16	Inspect/ Clean Interior of unit		
			D-CCP-17	Calibrate Electrical Components*		
			D-CCP-18	Align / Adjust mechanical components*		
			D-CCP-19	Alarms - Check all the warning alarms*		
			D-CCP-20	Indicator/Displays- verify proper illumination and operation		
			D-CCP-21	Check printer operation - Verify paper is used as specified by manufacturer*		
			D-CCP-22	Power On Self Test / All Functional Test -Verify Operation*		
			D-CCP-23	General sensor if available- Verify its operation*		
			Note:	All tests shall conform to IEC 62353- Medical electrical equipment – Recurrent test and test after repair of medical electrical equipment		
Ethylene Oxide Gas Sterilization (EOG)	D1	Ethylene Oxide Gas Sterilization (EOG)				
		D1-001	Check the gas distributor and cap			
		D1-002	Check Pressure test cooling system*			
		D1-003	Check Ethylene Oxide level- Refill if required*			
		D1-004	Check exhaust unit			
		D1-005	Perform blank load test - Ensure that no error occurs during the cycle			
		D1-006	Replace Preventive Maintenance Kit if required*			
Moist Heat	D2	Moist Heat				
		D2-001	Check the heater assembly			
		D2-002	Check Pressure test cooling system*			
		D2-003	Check exhaust unit			

			D2-004	Perform blank load test - Ensure that no error occurs during the cycle			
			D2-005	Replace Preventive Maintenance Kit if required*			
	Thermic Sterilization with dry heat	D3	Thermic Sterilization with dry heat				
			D3-001	Check the heater assembly			
			D3-002	Check Pressure test cooling system*			
			D3-003	Check exhaust unit			
			D3-004	Perform blank load test - Ensure that no error occurs during the cycle			
			D3-005	Replace Preventive Maintenance Kit if required*			
			Sterilization with Hydrogen Peroxide	D4	Sterilization with Hydrogen Peroxide		
	D4-001	Check the gas distributor and cap					
	D4-002	Check Pressure test cooling system*					
	D4-003	Check Hydrogen Peroxide level - refill if required*					
	D4-004	Check exhaust unit					
	D4-005	Perform blank load test - Ensure that no error occurs during the cycle					
	D4-006	Replace Preventive Maintenance Kit if required*					
	Radiation sterilization (e.g., gamma, x-ray, electron beam)	D5	Radiation sterilization (e.g., gamma, x-ray, electron beam)				
			D5-001	Verify the product density range covered by sterilization cycle*			
			D5-002	Check the condition- exchange of cleaning media and disinfection media*			
			D5-003	Verify environmental conditions as required*			
			D5-004	Verify barrier material condition*			
D5-005			Check Sterilization process/process category*				
D5-006			Verify radiation monitoring device function and operation*				
D5-007			Perform blank load test - Ensure that no error occurs during the cycle				



			D5-008	Verify performance of dose mapping*		
			D5-009	Verify/check- hydraulic/mechanical/electrical component if applicable*		
			D5-010	Verify the condition- safety interlock system and access control systems*		

*Refer to the manufacturer's guideline for performing the particular task



ANNEXURE-V

Competence requirement for the person responsible for the medical equipment maintenance

Organizations shall have at least one person responsible for maintenance of medical equipment as per the scheme requirement who possesses the requisite expertise in the field of medical devices

- i. a Graduate in Engineering or Pharmacy from a University recognized by the Central Government for such purposes and has had at least eighteen-month practical experience in the manufacturing or Quality Assurance or testing of medical devices after his/her graduation; or
- ii. a Graduate in Science, from a University recognized by the Central Government for such purposes and has had at least three years practical experience in the manufacturing or Quality Assurance or testing of medical devices after his/her graduation; or
- iii. a Diploma in Engineering or Pharmacy from a Board or Institute recognized by the Central Government or the State Government, as the case may be, for such purposes and has had at least four years practical experience in the manufacturing or Quality Assurance or testing of medical devices after his/her diploma; or
- iv. having a foreign qualification, the quality and content of training of which are comparable with those specified in clause (i), clause (ii) and clause (iii) above and is permitted to work as competent technical staff; or
for other geographical regions, the qualifications and experiences shall be as prescribed by the local regulations
- v. Irrespective of the above qualifications, it is desirable that Person with other qualifications should be certified professional from Indian Biomedical Skill Consortium (IBSC)- Certificate in Biomedical Maintenance (NSQF code- 2019/HLT/AMTZ/3576) or The Association for Advancement of Medical Instrumentation (AAMI)- Certified Biomedical Equipment Technician (CBET) or any certification of international equivalence. Final qualification decision rests with CB, this shall be supported by the necessary justification such as experiences in relevant sub-category.



Annexure-VI

List of Committee Members (Steering Committee and Technical Committee)

COMPOSITION	
Steering Committee Members:	
Chair	
Dr. G.N. Singh	Advisor to Hon'ble Chief Minister-Uttar Pradesh, Former-DCGI, Eminent Expert in Regulatory
Co-Chair	
Mr. Anil Jauhri	Former-CEO, NABCB, Expert in Accreditation Framework
Members	
Mr. Rajiv Nath	Forum Coordinator, Association of Indian Medical Device Industry (AIMED)
Dr. Aparna Dhawan	Executive Director, TIC Council
Dr. Girdhar Gyani	Director General, Association of Healthcare Providers (AHPI)
Dr. Jitendra Kumar Sharma	Managing Director & CEO, Andhra Pradesh MedTech Zone Ltd. (AMTZ)
Mr. Mrutunjay Jena	Scientist-G, Andhra Pradesh MedTech Zone Ltd. (AMTZ)
Mr. Dilip Chekuri	CEO, Medi Valley Incubation Council
Mr. N. Venkateswaran	CEO, National Accreditation Board for Testing and Calibration Laboratories (NABL)
Dr. Harish Nadadkarni	Medical Device Expert
Mr. Raj Nathan	President, International Accreditation Services (IAS)
Mr. Ravinder Singh	Senior Scientist, Indian Council of Medical Research (ICMR)
Technical Committee Members: (Principal & Alternate)	
Chair	
Mr. Prakash Bachani	Independent Expert (Ex-BIS)
Co-Chair	
Ms. Valli	Executive Director, Panacea Medical Technologies Pvt Ltd, AIMED Representative
Members	
Dr. George Anastasopoulos	Medical Device Expert, International Accreditation Services (IAS)
Mr. Deepak Agarkhed	Medical Device Expert, Association of Healthcare Providers (AHPI)
Mr. Ravi Singh	Member, TIC Council, Med Device WG
Mr. Avijit Das	Senior Director, National Accreditation Board for Testing and Calibration Laboratories (NABL)
Dr. Vivekanandan Kalaiselvan	Senior Principal Scientific Officer, Intergovernmental Panel on Climate Change (IPCC)
Mr. Om Prakash Sadhyani	Medical Regulatory Expert
Mr. Kalyan Varma	Medical Device Expert (Hon Fellow, KIHT)