

美国 GMP认证办理难点、时长

产品名称	美国 GMP认证办理难点、时长
公司名称	深圳市思博达管理咨询有限公司
价格	.00/件
规格参数	
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产品详情

GMP认证流程、需求、时长、和费用

- 1、确认GMP认证需求来源，GMP认证需求是来源于客户及哪一个品牌的客户。
- 2、确认GMP认证依据
- 3、工厂建立，运行，保持GMP体系，内审和管审
- 4、GMP认证申请
- 5、GMP认证实施
- 6、GMP 认证跟进
- 7、GMP认证证书发放
- 8、GMP认证证书维持和年度监督跟进。
- 9、GMP认证时长，我公司一般三个月时间可以获证。

10、费用依据FDA官方收费标准为依据，我司代理费来电注明顺企网有更多优惠！

11 FAD 通用医院和个人使用的医疗器械是什么？FDA 分类目录 880 即为通用医院和个人使用的医疗器械。

PART 880

GENERAL HOSPITAL AND PERSONAL USE DEVICES

Subpart A - General Provisions § 880.1 - Scope.

§ 880.3 - Effective dates of requirement for premarket approval. § 880.9 - Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act).

Subpart B [Reserved]

Subpart C - General Hospital and Personal Use Monitoring Devices § 880.2200 - Liquid crystal forehead temperature strip. § 880.2400 - Bed-patient monitor. § 880.2420 - Electronic monitor for gravity flow infusion systems. § 880.2460 - Electrically powered spinal fluid pressure monitor. § 880.2500 - Spinal fluid manometer. § 880.2700 - Stand-on patient scale. § 880.2720 - Patient scale. § 880.2740 - Surgical sponge scale. § 880.2750 - Image processing device for estimation of external blood loss. § 880.2800 - Sterilization process indicator. § 880.2900 - Clinical color change thermometer. § 880.2910 - Clinical electronic thermometer. § 880.2920 - Clinical mercury thermometer. § 880.2930 - Apgar timer.

Subparts D-E [Reserved]

Subpart F - General Hospital and Personal Use Therapeutic Devices § 880.5025 - I.V. container. § 880.5045 - Medical recirculating air cleaner. § 880.5075 - Elastic bandage. § 880.5090 - Liquid bandage. § 880.5100 - AC-powered adjustable hospital bed. § 880.5110 - Hydraulic adjustable hospital bed. § 880.5120 - Manual adjustable hospital bed. § 880.5130 - Infant radiant warmer. § 880.5140 - Pediatric medical crib. § 880.5145 - Medical bassinet. § 880.5150 - Nonpowered flotation therapy mattress.

emergencies. § 880.6265 - Examination gown. § 880.6280 - Medical insole. § 880.6300 - Implantable radiofrequency transponder system for patient identification and health information. § 880.6305 - Ingestible event marker. § 880.6310 - Medical device data system. § 880.6315 - Remote Medication Management System. § 880.6320 - AC-powered medical examination light. § 880.6350 - Battery-powered medical examination light. § 880.6375 - Patient lubricant. § 880.6430 - Liquid medication dispenser. § 880.6450 - Skin pressure protectors. § 880.6500 - Medical ultraviolet air purifier. § 880.6600 - Ultraviolet (UV) radiation chamber disinfection device. § 880.6710 - Medical ultraviolet water purifier. § 880.6730 - Body waste receptacle. § 880.6740 - Vacuum-powered body fluid suction apparatus. § 880.6760 - Protective restraint. § 880.6775 - Powered patient transfer device. § 880.6785 - Manual patient transfer device. § 880.6800 - Washers for body waste receptacles. § 880.6820 - Medical disposable scissors. § 880.6850 - Sterilization wrap. § 880.6860 - Ethylene oxide gas sterilizer. § 880.6870 - Dry-heat sterilizer. § 880.6880 - Steam sterilizer. § 880.6885 - Liquid chemical sterilants/high level disinfectants. § 880.6887 - Spore test strip. § 880.6890 - General purpose disinfectants. § 880.6900 - Hand-carried stretcher. § 880.6910 - Wheeled

stretcher. § 880.6920 - Syringe needle introducer. § 880.6960 - Irrigating syringe. § 880.6970 - Liquid crystal vein locator. § 880.6980 - Vein stabilizer. § 880.6990 - Infusion stand. § 880.6991 - Medical washer. § 880.6992 - Medical washer-disinfector. § 880.5160 - Therapeutic medical binder. § 880.5180 - Burn sheet. § 880.5200 - Intravascular catheter. § 880.5210 - Intravascular catheter securement device. § 880.5240 - Medical adhesive tape and adhesive bandage. § 880.5270 - Neonatal eye pad. § 880.5300 - Medical absorbent fiber. § 880.5400 - Neonatal incubator. § 880.5410 - Neonatal transport incubator. § 880.5420 - Pressure infusor for an I.V. bag.

§ 880.5430 - Nonelectrically powered fluid injector. § 880.5440 - Intravascular administration set. § 880.5445 - Intravascular administration set, automated air removal system. § 880.5450 - Patient care reverse isolation chamber. § 880.5475 - Jet lavage. § 880.5500 - AC-powered patient lift. § 880.5510 - Non-AC-powered patient lift. § 880.5550 - Alternating pressure air flotation mattress. § 880.5560 - Temperature regulated water mattress. § 880.5570 - Hypodermic single lumen needle. § 880.5580 - Acupuncture needle. § 880.5630 - Nipple shield. § 880.5640 - Lamb feeding nipple. § 880.5680 - Pediatric position holder. § 880.5700 - Neonatal phototherapy unit. § 880.5725 - Infusion pump. § 880.5730 - Alternate controller enabled infusion pump. § 880.5740 - Suction snakebite kit. § 880.5760 - Chemical cold pack snakebite kit. § 880.5780 - Medical support stocking. § 880.5820 - Therapeutic scrotal support. § 880.5860 - Piston syringe. § 880.5950 - Umbilical occlusion device. § 880.5960 - Lice removal kit. § 880.5965 - Subcutaneous, implanted, intravascular infusion port and catheter. § 880.5970 - Percutaneous, implanted, long-term intravascular catheter.

Subpart G - General Hospital and Personal Use Miscellaneous Devices § 880.6025 - Absorbent tipped applicator. § 880.6050 - Ice bag. § 880.6060 - Medical disposable bedding. § 880.6070 - Bed board. § 880.6080 - Cardiopulmonary resuscitation board. § 880.6085 - Hot/cold water bottle. § 880.6100 - Ethylene oxide gas aerator cabinet. § 880.6140 - Medical chair and table. § 880.6150 - Ultrasonic cleaner for medical instruments. § 880.6175 - [Reserved] § 880.6185 - Cast cover. § 880.6190 - Mattress cover for medical purposes. § 880.6200 - Ring cutter. § 880.6210 - Sharps needle destruction device. § 880.6230 - Tongue depressor. § 880.6250 - Non-powdered patient examination glove. § 880.6260 - Filtering facepiece respirator for use by the general public in public health medical

更多GPM认证相关信息，请联系深圳市思博达管理咨询有限公司，来电注明顺企网有更多优惠！