

This guidance was written prior to the February 27, 1997 implementation of FDA's Good Guidance Practices, GGP's. It does not create or confer rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both. This guidance will be updated in the next revision to include the standard elements of GGP's.

CLASSIFIED CONVENIENCE KITS			
Product Nomenclature	Classification Number	Class	Regulation Number
Kit, Balloon Repair, Catheter	74DQP	III	870.1350
Kit, Barium Enema, Disposable	90FCD	I	
Kit, Bone Marrow Collection/Transfusion	80LWE		
Kit, Conduction Anesthetic	73CAZ	II	868.5140
Kit, Decontamination	79MAC	II	
Kit, Denture Repair, OTC	76EBO	III	872.3570
Kit, Earmold, Impression	77LDG	II	
Kit, Enema, (For Cleaning Purposes)	78FCE	I	876.5210
Kit, First Aid <small>(except if contains only prepackaged, prelabeled devices)</small>	79LRR	I	
Kit, I.V. Start	79LRS		
Kit, Plastic Surgery and Accessories	79FTN	I	878.3925
Kit, Sampling, Arterial Blood	73CBT	II	868.1100
Kit, Sitz Bath, Manual (Not Heated)	89HHC	I	890.5125
Kit, Snake-Bite, Suction	80KYP	I	880.5740
Kit, Snake-Bite, Chemical Cold Pak		III	(PMA)
Kit, Surgical - General	79LRO		
Kit, Surgical Instrument, Disposable	79KDD	I	878.4800
Kit, Suture Removal	79MCZ	I	
Kit, Tracheostomy and Nasal Suctioning	79LRQ	I	878.4680
Kit, Urinary Drainage Collection, for indwelling catheter	78FCN	II	876.5250
Kit, Wound dressing	79MCY	II	

SOME DEVICES THAT ARE WIDELY USED IN KITS	
ITEM	COMMENTS
Absorbent fiber	Device, Class I, 510(k) exempt, 880.5300
Absorbent tip (Q-tips) applicator	Device, Class I, 510(k) exempt, 880.6025
Acetone preps or Alcohol preps	Device
Alcohol swabs	Drug if benzalkonium chloride & alcohol are used
Cleaning prep	Drug if it contains provodine iodine or tincture of green soap
Clean-up kit	Device, not classified
Gauze non-absorbable	Device, Class I, 878.4014
Provo iodine	Drug
Razor	Device, Class I, 510(k) exempt, 878.400
Saline	Drug if used for wound irrigation. Device if used to flush catheter or other device.
Surgical Apparel	Device, Class I 79LYU 878.4040
Surgical Cap, Dress, Gown, Mask, Suit	Device, Class II 878.4040
sponge, external	Device, Class I, 878.4060
Toothbrush	
Toothpaste	

Sample: KIT PACKAGE LABEL

WOUND DRESSING CHANGE TRAY

- 1 - SMALL FOAM TRAY
- 1 - 3" X 3" MICRO PAD
- 2 - 2" X 2" 8 PLY GAUZE SPONGE
- 2 - 3" X 3" 12 PLY GAUZE
- 1 - PVP SWABSTICK (3'S)
- 1 - TINC/BENZOIN SWABSTICK (1)
- 1 - ACETONE/ALCOHOL SWABSTICK
- 1 - ACETONE/ALCOHOL SWABSTICK TRIPLE
- 1 - PVP OINTMENT 1.2 GRAM
- 1 - SCISSOR S/S SINGLE USE
- 1 - PROLIFOPLAST 4" X 7"
- 1 - TAPE, TRANSPORE 1" X 54"
- 1 - WRAP/DRAPE 17" X 19"
- 2 - NATURAL RUBBER LATEX EXAM GLOVES

LOT NUMBER: 01192

USE BEFORE: 11/99

STERILE: Contents sterile unless package has been opened or damaged.

CAUTION: Federal law restricts this device to sale by or on the order of a physician.

CATALOG NO. DCM-DCT-333-03

Assembled by:
MEDI-CON™ KIT Inc.
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