DERINGER
Managing Your Logistics / Maximizing Your Opportunities

FDA Template – Medical Devices

Customer Name & Address:	**Account Number:**	
	DUNS Number:	
Harmonized Tariff Schedule (HTS)#:	**Intended Use Code*:**	**Radiation Emitting Device? Yes or No:**
Product Invoice/Item Description:	**FDA Country of Mfr:**	**Customs Country of Origin:**
Product Market, Trade or Brand Name:	**FDA Product Code:**	**Affirmation of Compliance Code**:**
Packaging: (the number and types of packages from largest outer shipping container to the base unit of reporting)		**Affirmation of Compliance Code**:**
		Affirmation of Compliance Code:**
FDA Manufacturer Name & Address:	**DUNS Number:**	
	Registration Number:	
FDA Shipper Name & Address:	**DUNS Number:**	
	Registration Number:	
Prior Notice Submitter Info:		
Contact Name:		
Contact Number:		
Contact Email:		

*APPENDICES

Intended Use Codes & Descriptions:

- Medical Device – Human Use: 081.001
- Medical Device – Human Use for Refurbishment: 081.002
- Medical Device – Human Use, domestically manufactured which is part of a convenience kit: 081.003
- Medical Device – Human Use, foreign manufactured which is part of a convenience kit: 081.004
- Device Constituent Part – Finished device for use in a medical product regulated as a drug (drug/device combination) under CDER: 081.005
- Medical Device – Imported under enforcement discretion provisions per final guidance document: 081.006
- Medical Device – Personal use as a non-food product (non-commercial): 100.000
- Public Exhibition or Display – e.g. trade show: 110.000
- Charitable Organization – For use as non-food product: 140.000
- Component for further manufacturing into a finished medical device: 155.010
- Device component for use in a medical product regulated as a drug (drug/device combination) under CDER: 155.011
- For Repair of a Non Food product: 170.000
- Research and Development – For research and development as a medical device: 180.010
- Research and Development – Bench testing or non-clinical use (includes samples for customer evaluation): 180.014
- Research and Development – Clinical investigation use: 180.015
- U.S. goods returned to manufacturer (refund/overstock): 920.001
- U.S. goods returned for sale to a third party: 920.002
- Compassionate use/Emergency use: 940.000
- Single use device for reprocessing: 950.001
- Multiple use device for reprocessing: 950.002
- Import for Export – Device or accessory to be further manufactured and exported: 970.000
- Import for Export – Device component to be further manufactured and exported: 970.002

TABLE 1: AFFIRMATION OF COMPLIANCE CODES:

***When it is necessary to submit affirmation of compliance codes*

Import Scenarios	Mandatory Aff Code	Conditional Aff Code [1]	Optional Aff Code
• Standard import of device, accessories, or components regulated as a finished device • Import of refurbished device • Import of a reprocessed device	DEV, DFE, LST	DI, IRC, LWC, PM#	
Import of a device for domestic refurbishing	DEV, DFE, LST	DI, IRC, LWC, PM#	
domestically manufactured device that is part of a medical device convenience kit	DDM, DFE, KIT, LST	DI, IRC, LWC, PM#	
foreign manufactured device that is Part of a medical device convenience kit	KIT, DEV, DFE, LST	PM#, DI, LWC;IRC	
Device constituent part for drug-device combination product	DEV, DFE, LST	DA, IND	
Import of a device for charity	DEV, DFE, LST	DI, IRC, LWC, PM#	
Component for further manufacturing into a finished medical device	CPT		LST, PM#
Device component for use in a drug-device combination product	CPT	DA, IND	
Repair of medical device and re-exportation	DDM, IFE	DFE, DI, LST	

		IRC, LWC, PM#	
Import of research or investigational use in vitro diagnostic devices			
• Import of a device for non-clinical use/bench testing * • Import of device sample for customer evaluation *			
Import of a medical device for clinical investigational use*	IDE		
Import of a device that is U.S. goods returned for refund/overstock (to the manufacturer)	DDM, LST	DFE, DI, IRC, LWC, PM#	
Import of device that is U.S. goods returned for sale to a third party	DFE, DDM, LST	DI, IRC, LWC, PM#	
Import of a single use device for domestic reprocessing*	DDM, LST	DFE. DI, IRC, LWC, PM#	
Import of a multi-use device for domestic reprocessing*		DDM, DFE, DI, IRC, LST, LWC, PM#	
Import for Export: • Import of a medical device for further processing and re-exportation • Importation of a medical device or accessory for further manufacturing into an export-only medical device	DEV, DFE, IFE, LST		
Import for Export: • Importation of a medical device component for further manufacturing into an export-only medical device	IFE, CPT, DDM, LST		
• Public Exhibition/Trade Show * • Device For Personal Use * • Compassionate Use/Emergency device * • Import under enforcement discretion provisions			

[1] The conditional affirmations are required if applicable to the product being declared. For example, if the product requires premarket clearance (510(k)), then the PM# must be provided.
* Annotates that additional information may be needed at time of entry in order for FDA to make a final admissibility decision.

Glossary of Affirmation of Compliance Codes:

- Device Premarket Number (PM#)
- Device Domestic Manufacturer (DDM)
- Device Foreign Manufacturer Registration Number (DEV)
- Device Foreign Export Registration Number (DFE)
- Device Identifier (DI)
- Component Identifier (CPT)
- Import for Export (IFE)
- Investigational Device Exemption Number (IDE)
- Device Impact Resistance Lens Certification (IRC)
- Device Imported Kit of Finished Device (KIT)
- Device Listing Number (LST)
- Biologics New Drug or Abbreviated New Drug Application Number or Therapeutic Biologic Application Number (DA)
- Biologics Investigation New Drug Application Number (IND)
- Electrode Lead Wire or Patient Cable (LWC)