Pepgra
Drives Innovation

EUROPE

MEDICAL DEVICES-THE REGULATORY PROCESS

Current MDD Process

MEDICAL DEVICE DIRECTIVE - WHICH ONE IS APPROPRIATE TO YOUR DEVICE?: 93/42/EEC – MEDICAL DEVICES DIRECTIVE (MDD)

DECIDE ON THE CLASSIFICATION OF YOUR DEVICE THROUGH ANNEX IX OF THE MDD. ACTIVE IMPLANTABLE MEDICAL DEVICES GENERALLY HAVE THE SAME REGULATORY ESSENTIALS AS CLASS III DEVICES.

NON-STERILE CLASS I NON-MEASURING	STERILE CLASS I MEASURING	CLASS IIA	CLASS IIB	CLASS III
IMPLEMENTATION OF A PMS PROCEDURE THAT NEED NOT BE AUDITED BY A NB.	IMPLEMENT A QUALITY MANAGEMENT SYSTEM (QMS) AS PER ANNEX II OR V OF 93/42/EEC. MOST COMPANIES MAKE USE OF THE ISO 13485 STANDARD TO ACHIEVE QMS COMPLIANCE.			
COMPREHENSIVE MEDICAL TECHNICAL FILE PREPARATION SHOWING COMPLIANCE WITH 93/42/EEC.			DESIGN DOSSIER PREPARATION	
APPOINT AN AUTHORIZED REPRESENTATIVE (EC REP) IN EUROPE WHO IS QUALIFIED TO HANDLE REGULATORY ISSUES IN CASE YOU ARE NOT SITUATED IN EUROPE. KEEP EC REP NAME AND ADDRESS ON INSTRUCTIONS FOR USE OR OUTER PACKAGING OR DEVICE LABEL.				
NOTIFIED BODY AUDIT OF QMS OR TECHNICAL FILE WILL NOT HAPPEN.			YOUR QMS AND TECHNICAL FILE OR DESIGN DOSSIER MUST BE AUDITED BY A THIRD PARTY NOTIFIED BODY ACCREDITED BY EUROPEAN AUTHORITIES TO AUDIT MEDICAL DEVICE COMPANIES AND PRODUCTS	
ISSUE OF CE MARKING CERTIFICATE FOR YOUR DEVICE AND AN ISO 13485 CERTIFICATE FOR YOUR FACILITY AFTER YOUR NOTIFIED BODY AUDIT. RENEWAL OF ISO 13485 CERTIFICATION MUST HAPPEN EVERY YEAR . A PERIOD OF 3 YEARS IS THE VALIDITY OF CE MARKING CERTIFICATE				
DECLARATION OF CONFORMITY FORMATION –THE MANUFACTURER'S LEGALLY BINDING STATEMENT THAT THE DEVICE IS IN COMPLIANCE WITH THE APPLICABLE DIRECTIVE. AFFIX THE CE MARKING. CE				
CLASS I DEVICES MUST BE REGISTERED WITH COMPETENT AUTHORITY IN THE COUNTRY WHERE YOU, OR YOUR EC REP, IS SITUATED.			SOME EU MEMBER STATES NEED EXTRA REGISTRATION OF CLASS LLA, LLB OR LLL DEVICES THAT ARE AVAILABLE ON THEIR MARKETS.	
YOU SHOULD HAVE A VALID CE CERTIFICATE. CER UPDATES AND PMS FUNCTIONS ARE MANDATORY.			AUDIT FOR EACH YEAR WILL BE DONE BY A NOTIFIED BODY TO ASCERTAIN CONSISTENT COMPLIANCE WITH 93/42/EEC OR 90/385/EEC. YOU HAVE TO PASS THE AUDIT TO VALIDATE YOUR CE MARKING CERTIFICATE. CER UPDATES AND PMS ACTIVITIES ARE ESSENTIAL.	