FDI in Medical Device Sector

FDI policy for pharmaceutical sector has been reviewed by Indian Government and it has been decided that there would be a special carve out for medical devices as per press note no 2 of 2015:-

1. FDI upto 100% under the automatic route is permitted for manufacturing of medical devices. The below mentioned conditions shall not be applicable to greenfield as well as brownfield projects:

   a. 'Non compete' clause would not be allowed except in special circumstances with the approval of the Foreign Investment Promotion Board.
   b. The prospective investor and the prospective investee are required to provide a certificate along with the FIPB application.
   c. Government may incorporate appropriate conditions for FDI in brownfield cases at the time of granting approval.

2. Medical device means:

   a. Any instrument, apparatus, appliance, implant, material or other article, whether used alone or in combination, including the software, intended by its manufacturer to be used specifically for human beings or animals for one or more of the specific purposes of-

      i. diagnosis, prevention, monitoring, treatment, or alleviation of any disease or disorder;
      ii. diagnosis, monitoring, treatment, or alleviation of, or assistance for, any injury or handicap;
      iii. investigation, replacement or modification or support of the anatomy or of a physiological process;
      iv. supporting or sustaining life;
      v. disinfection of medical devices;
      vi. control of conception;

      and which does not achieve its primary intended action in or on the human body or animals by any pharmacological or immunological or metabolic means, but which may be assisted in its intended function by such means;

   b. an accessory to such an instrument , apparatus, appliance, material or other article;

c. a device which is reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system whether used alone or in combination thereof intended to be used for examination and providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body or animals.

The above mentioned definition of medical device would be subject to the amendment in Drugs and Cosmetics Act.

WHAT INDIA JURIS CAN DO FOR YOU

Broadly the legal and regulatory service and assistance provided by the firm in the area of medical devices and equipment are as under:

- Technical and Regulatory services required exclusively for medical device manufacturer.
- Drafting the preparation of all legal and technical documents under one umbrella exclusively for medical device manufacturer,
- Liaison with different Government Authorities in India on behalf of the medical device manufacturer
- Preparation and submission of query response to the clarification letter (query letter) issued by DCGI, New Delhi or other state licensing authority.
- Medical Device Registration in India - Registration Certificate (Form-41), Re-Registration Certificate, Import License (Form-10), Test license (Form-11) for Drugs, CLAA Scheme
- Medical device registration in Europe, US, South Africa, GCC countries, Sri Lanka,
- QMS compliance, ISO 13485 documentation, CE Mark technical support and documentation, Documentation as per US FDA 21 CFR
- Regulatory Consulting
- Technical and Regulatory assistance for CDSCO works
- Assistance for Clinical Evaluation of Medical Devices
- Assistance in appointing EU or US Representatives.
- Review of labels and art work corrections as per Rule 96 of Drug & Cosmetic Act 1940.
- Conduct Internal Audit – Technical, Regulatory and Legal Compliance
- Key point of reference for all correspondence with regulatory/competent authority - DCGI, MHRA, USFDA, SFDA, NAFDAC, KFDA for all kinds of approval and registration.
- Assistance with DSIR for IRD - R&D approval, Clinical Trials, BIRAC funding scheme/projects