EU- CE MARKING

DIVYA GANAPATHY

REGULATORY REQUIREMENT IN EU

- To market products in the European market, the products must have a CE mark which declares that a product meets all relevant European Medical Device Directives.
- The benefits of CE marking is that it is a legal requirement to trade your device in the European market.
- CE Mark is a conformity mark which all medical devices must have before they can be marketed. It is the declaration by the manufacturer that the product meets all the provisions of the relevant directive.
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MEDICAL DEVICE REGISTRATION

CE marking Technical file :

- Technical file or design dossier is a critical step in Europe’s CE certification process
- Applicable directives are
  - Medical Devices Directive 93/42/EEC,
  - In Vitro Diagnostic Medical Devices Directive 98/79/EC,
  - Active Implantable Medical Devices Directive 90/385/EEC.

MEDICAL DEVICE REGISTRATION

- For Class I device, a less complex CE Marking Technical File may be required.
- For Class IIa, IIb and Class III devices, a more complex CE Technical File or Design Dossier must be prepared.
- EU Technical File construction is subject to review by a Notified Body if the medical device is Class I with measuring or sterile function, Class IIa, IIb, and III (Design Dossier).
- Technical file compromises of design, function, composition, use, claims, and clinical evaluation of your medical device.
- Process:
  - Identify applicable Directives-→ applicable requirements→ Route of conformity → Assemble the data to comply with the requirement→ Assessment of product conformity→ Technical Dossier Compilation→ Make Declaration and affix CE

REGULATORY1

- We can help you in the process of making a defined and comprehensive technical file with all product details required for CE marking.
- We also provide assistance in your process of making technical file and review it at every step for compliance with CE Marking.
- We have the technical expertise and experience to provide CE marking services.
- Our team supports clients in meeting “European submission” standards that declares the product offered is in compliance with the Essential Requirements of relevant European safety, health and Environmental protecting regulation.

Contact us for more information:

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