

Steps to Get a CE marking

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graph TD; 1[1. Whether The Product Is A Medical Device As Per The Definition Of EU-MDR.] --- Center((Steps to Get a CE marking)); 2[2. Determine The Medical Directive Applies To The Device.] --- Center; 3[3. Identify The Class Of Medical Device] --- Center; 4[4. If Applicable Implement ISO 13485 (Except Class I)] --- Center; 5[5. Prepare The Technical File For CE Marking] --- Center; 6[6. Appoint An Authorized Agent If The Manufacturer Is Outside From European Union] --- Center; 7[7. Check Whether The Notified Body Is Required] --- Center; 8[8. Affix The CE Marking] --- Center;
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Whether The Product Is A Medical Device As Per The Definition Of EU-MDR.

1

Determine The Medical Directive Applies To The Device.

2

Identify The Class Of Medical Device

3

If Applicable Implement ISO 13485 (Except Class I)

4

Prepare The Technical File For CE Marking

5

Appoint An Authorized Agent If The Manufacturer Is Outside From European Union

6

Check Whether The Notified Body Is Required

7

Affix The CE Marking

8

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