

## Steps to Get a CE marking

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

# How Is The 2014 B E C E Marking Is

**Yi-Tong Ma**



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