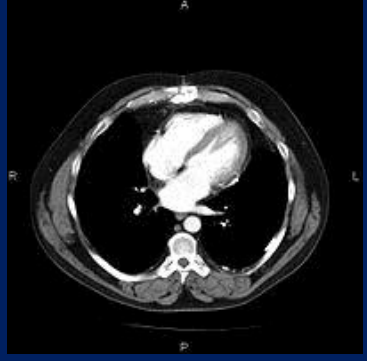
I 3 CONSULTING



# CE Marking of Medical Software

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|---|---|---|
| Step 01 | - | Identify device and versions. |
| Step 02 | - | Appoint technical expert with previous experience. |
| Step 03 | - | Identify Class and route of CE Marking |
| Step 04 | - | Implement ISO 13485 & ISO 62304 |
| Step 05 | - | Demonstrate compliance with MDD Directive |
| Step 06 | - | Develop User Instruction /manuals /Labels. |
| Step 07 | - | Software verification and test cases |
| Step 08 | - | Preparation of Technical File |
| Step 09 | - | Appoint NB for Certifying your medical software. |
| Step 10 | - | Submit Technical File to Notified Body |
| Step 11 | - | Correct / Update TF as per NB reviewer Comments. |
| Step 12 | - | Facility Audit by Notified Body auditor |
| Step 13 | - | Affix CE Mark on your Medical Software |


## Why to appoint I 3 Consulting ?

1. Previous experiences
2. In-house consultants and Auditors
3. Undertake turnkey projects
4. Cloud documentation and storage
5. Online and Onsite consultation in Europe, USA, Middle East & India.
6. 1238 Certified clients across the globe.
7. Phased Payments
8. Office in USA, India and Muscat.
9. 16 No. Consultants, 4 No. Team Leaders and 2 No. Project Heads
10. Certified Lead auditors for ISO 13485 & ISO 62304

More Information visit our informative website www.i3cglobal.com