CE Marking & Telehealth: Stay Mobile Through the Regulation Maze

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Is it a Medical Device?

• Depends on Intended Use as specified by the manufacturer

• Does it have a diagnostic or therapeutic purpose as defined in the MDD?
  • Diagnosis, prevention, monitoring, treatment or alleviation of disease... for an injury or handicap... of the anatomy or of a physiological process...

• Does its use benefit an individual patient?

References
• Medical Device Directive 93/42/EEC, Article 1
What is the Medical Device?

- Is it a medical device or an accessory to a medical device?
- Using 3rd party devices which are already CE marked?
- Software on the web, PC, tablet, mobile phone?
Classification

- Depends on Intended Use as specified by the manufacturer

- Diagnosis or monitoring of vital physiological processes in routine check ups and in self-monitoring => Class IIa by Rule 10

- If device has alarms to signify an immediate life-threatening condition => Class IIb by Rule 10

- Accessories classified in their own right

References
- MEDDEV 2.1/6 Qualification and Classification of stand alone software
- MEDDEV 2.4/1 Classification of medical devices
Risk Analysis

- Risk Management Process
- Design, process & usability risks
- Risk/benefit analysis
- Production and post-production information

References

- IEC/TR 80002-1 Guidance on the application of ISO 14971 to medical device software
- 21 CFR Part 11 / EU GMP regulations for computerized systems (Annex 11)
- EU Regulation 207/2012 on electronic instructions for use of medical devices
Usability

- Harmonised standard: EN 62366:2008
- Usability Engineering Process
- Application specification
- Studies on samples of target users
- Readability of user documentation

References
- EU Regulation 207/2012 on electronic instructions for use of medical devices
- Central Management Committee Statement on “Improvement of Readability of Instructions for Use (IFU)”
Software Development

• Harmonised standard: EN 62304:2006

• Software safety classification (A, B or C)

• Processes

• Software validation

• Local language requirements

References

• MEDDEV 2.1/6 Qualification and Classification of stand alone software

• IEC/TR 80002-1 Guidance on the application of ISO 14971 to medical device software

• FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices

• FDA Guidance: General Principles of Software Validation

• FDA Guidance: Off-The-Shelf Software Use in Medical Devices
Electromagnetic Compatibility

• Harmonised standard: EN 60601-1-2:2007
  • Emissions: EN 55011/CISPR 11 (Class B limits for residential use) & EN 61000-3-
  • Immunity: EN 61000-4-

• R&TTE Directive
  • EN 301 489 series – collateral standards for GSM, WiFi/Bluetooth, RFID etc

• RF wireless coexistence testing

References
• FDA Draft Guidance: Radio-Frequency Wireless Technology in Medical Devices
• FDA Draft Guidance: Mobile Medical Applications
• R&TTE Directive 1999/5/EC
Safety & Essential Performance

• EN 60601-1 General requirements

• EN 60601-1-8 Alarms

• EN 60601-1-11 Home healthcare

• EN 60601-2-x

• EN ISO 10993-x Biocompatibility

References
• List of Harmonised Standards: Official Journal of the European Union
Clinical Evaluation

• Demonstrate safety and performance of device

• Literature review and/or clinical investigation

• Risk/benefit

• Suitably qualified author(s)

• Post Market Surveillance Plan including Post Market Clinical Follow-up

References

• MEDDEV 2.7.1 Evaluation of Clinical Data
• NB-MED/2.7/Rec1 Guidance on clinical
• NB-MED/2.12/Rec1 Post-Marketing Surveillance
• MEDDEV 2.12-2 Post Market Clinical Follow-up
CE marking is not just affixing a CE label!

- You need to meet all the requirements of the MDD
- Regulations and Standards are always changing
- State of the art
Questions?