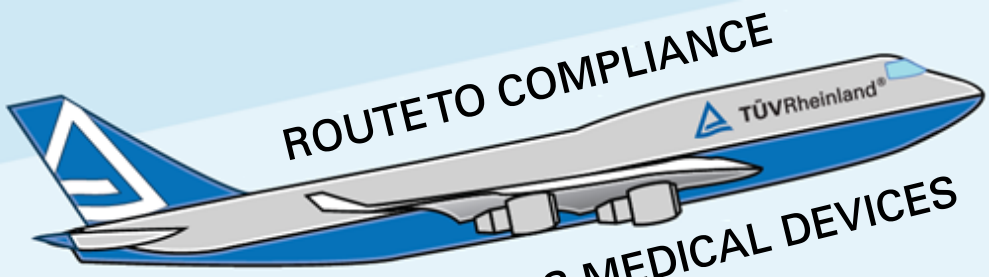
5 MINUTE GUIDE:



ROUTE TO COMPLIANCE WIRELESS MEDICAL DEVICES

Product Safety & EMC

- Safety Testing and Assessment
- EMC Directive
- North American and European Standards

Integration of Wireless Modules

- Approved Module vs unapproved module (FCC, CE, IC, Japan and Korea)

Market Access

- MRA's (Mutual Recognition Agreement) with countries
- Market Atomization

Organizations to Know:

Food & Drug Administration's (FDA)

Federal Communications Commission's (FCC)

FCC Process:

Use the FCC pre-certified radio modules:
- Limited testing on the system level
- Saves time and money

OR

Design and manufacture radios:
- Full scope of wireless testing required

Telecommunication Certification Body (TCB) Program:
- Product in final form
- Testing by approved laboratory

Considerations for FDA Approvals:

- ✓ **Features:**
  - ✓ Frequencies
  - ✓ Power
  - ✓ Radio
- ✓ **Wireless:**
  - ✓ Why and how for specific technology
  - ✓ Coexistence with other radio equipment
  - ✓ EMC
  - ✓ Quality
- ✓ **Security** (confidential patient information).
- ✓ Clear **operations** instructions (maintain and care)

Medical Device Directive (93/42/EEC):

- Starting in 2016
- Transition period of 3 years.
- **NEW** Medical Device Regulation (MDR)
- Product safety compliance
- Electromagnetic Compatibility (EMC)
- European Communications Office (ECO) Tool to investigate the harmonized radio spectrum use in Europe called ECO Frequency Information System (EFIS)

IEC 60601-1-2:

More Wireless Devices has led to

NEW Updated Electromagnetic Radiation Requirements

Mandatory for both FDA and EU after 12/31/2018

	New Manufacturer Responsibilities	New Test Lab Responsibilities
Documentation	• Essential performance	• Requirements specified in Table 10 & clause 9
Testing Plan / Criteria	• Detailed, product-specific performance criteria (during immunity testing) • Specific plan (performance of device during immunity testing)	• Testing according to test plan provided by manufacturer • Changes must be documented & included in test report
EMC Spec.	• EMC test plan • EMC risks in risk management file	• Review risk management. • EMC entries (sect. 4.1 & Annex F)
Manuals & Labelling	• Instructions for use • Accompanying documents for review against section 5 of standard	• Documentation and labeling (sect. 5)

Top Tips:

- ✓ Consider compliance during product development
- ✓ Determine your global markets
- ✓ Pick a testing **partner**
- ✓ Establish processes and procedures
- ✓ **Give us a call and we will help you get started!**

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