

ACB and Sulis

Radio Equipment Directive (RED),
compliance for radio enabled
equipment

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Why are you here?

- Who do we have here?
- Why are you here?
- 2018 EU Market Surveillance
 - 85% of 5 GHz WLAN found non-compliant with the RED administrative requirements
- 2019 EU Market Surveillance
 - 72% of domestic IoT products non-compliant with the RED administrative requirements

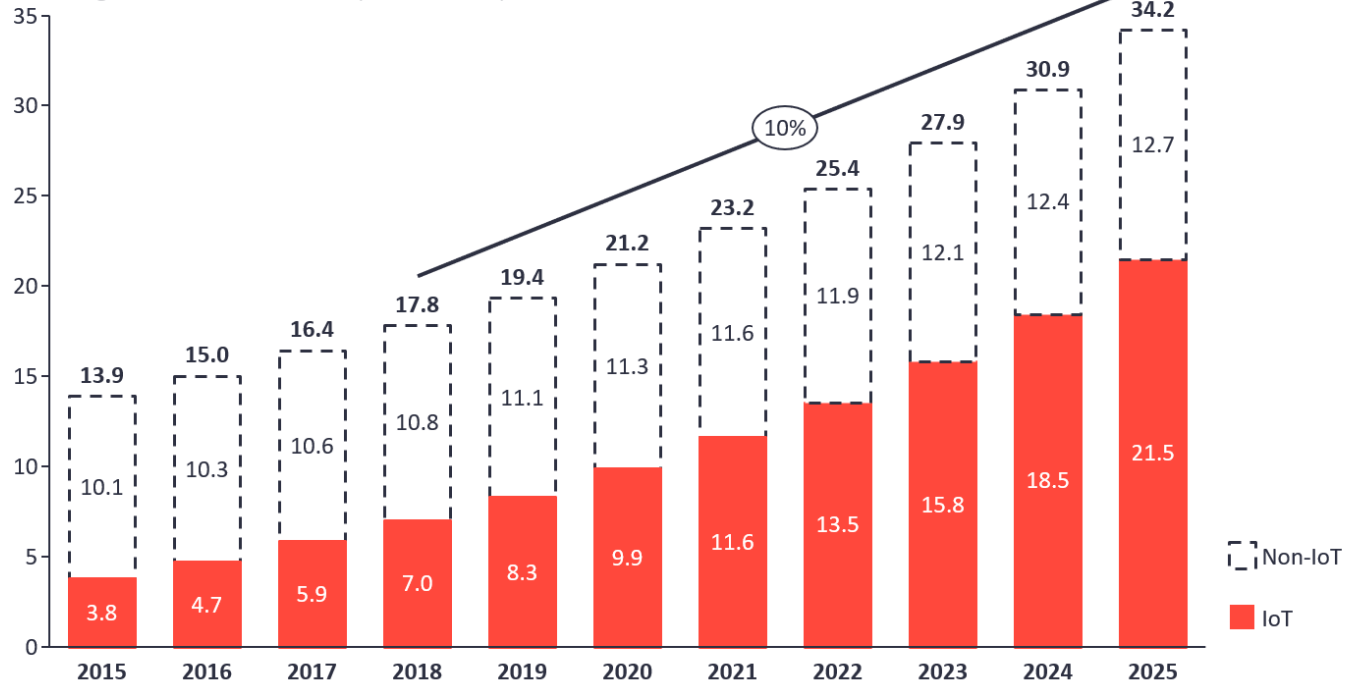
Agenda

- Why does the Radio Equipment Directive apply to my product?
- What tests or assessments are required?
- Radio modules in the EU
- Installing radio modules into other equipment
- Demonstrating compliance and Notified Bodies
- Compiling Technical Documentation

Why is this important?

Total number of active device connections worldwide

Number of global active Connections (installed base) in Bn



Note: Non-IoT includes all mobile phones, tablets, PCs, laptops, and fixed line phones. IoT includes all consumer and B2B devices connected – see IoT break-down for further details
Source: IoT Analytics Research 2018

EU Radio Equipment



RED Requirements

- Radio products into the EU
 - Radio Equipment Directive (known as RED)
 - It's not the "RED Directive"!
 - Directive 2014/53/EU
 - Why does the RED apply to my product?
 - Because there is some radio function within it
 - Transmitters, receivers, transceivers
 - Frequency range of "up to 3000 GHz"
 - Which means anything, including <9 kHz

RED Requirements

- The RED is Declaration of Conformity
 - Authorisation routes?
 - There is only one authorisation route
 - Declaration of Conformity (DoC)
 - The manufacturer declares compliance with the Radio Equipment Directive
 - Only the manufacturer can do this
 - Any company re-branding the product becomes the manufacturer, in the legal sense

Authorisation Route

- The RED assessment covers:
 - Product Safety (equivalent to the LVD)
 - Article 3.1a – Product Safety, RF Exposure, etc.
 - EMC performance (equivalent to the EMCD)
 - Article 3.1b – Emissions and Immunity
 - Radio performance
 - Article 3.2 – Transmitter and Receiver performance
 - IoT and 5G promises a world with radios everywhere
 - The radio spectrum is a finite resource
 - Spectrum sharing becomes a priority
 - “Efficient use of spectrum” is a requirement

Authorisation Route

- The RED is Declaration of Conformity
 - One DoC; always applies to the final product
 - All aspects of a device are covered by the one DoC, even if they were tested separately
 - DoC is dynamic to each new unit
 - No authorisation “Grandfathering” with the RED
 - Let’s discuss an example of a company with plans to make many (3000?) products over a period; but something changes

Authorisation Route

- How to show compliance to the RED?
 - Apply test standards!
 - Standards are provided for Safety, EMC, Radio
 - Assess (test) to the standards
 - Listed standard gives “presumption of conformity”
 - Create a risk assessment to catch anything else
 - Meeting the Directive is the important part; applying the standards is a good way to start

RED Assessment

- Separating the assessments (testing)
 - Modes or functions are often assessed separately, but the whole device must comply
 - Radio part assessed: Safety, EMC and Radio
 - Non-radio modes assessed: Safety and EMC
 - But, still it is all within the scope of the RED
 - May need to consider multiple standards
 - e.g., EN 301 489 EMC on radio, and EN 55035 for IT or AV; maybe EN 55014 for appliances

Other Directives

- Multiple Directives may apply
 - RED applies to anything with Radio in it
 - (So EMCD and LVD do not apply)
 - But other Directives may apply
 - Medical Device Directive
 - Machinery Directive
 - RoHS Directive
 - Other Directives (medical, machinery, RoHS) may apply in addition to RED

Changes to the device

- What if something changes?
 - Re-assess the device!
 - Any time something changes, the manufacturer (the company legally placing the final product on the market) must re-assess for their next units
 - Do I need to fully re-test everything?
 - Only need to reassess the things that have changed
 - What may have changed?
 - The EN standards, the product, the legislation, or the way in which people are using the device

RED Compliance

- Process is quite simple:
 - Assess or test it (check it passes)
 - Label it “CE Mark” (product and packaging)
 - NB EU-TEC if necessary
 - Create a DoC (when all aspects comply)
 - Maintain the Technical Documentation
 - Watch for changes to the product, the test standard, the rules, or the state of the art
 - In case of any changes, return to the top of the list

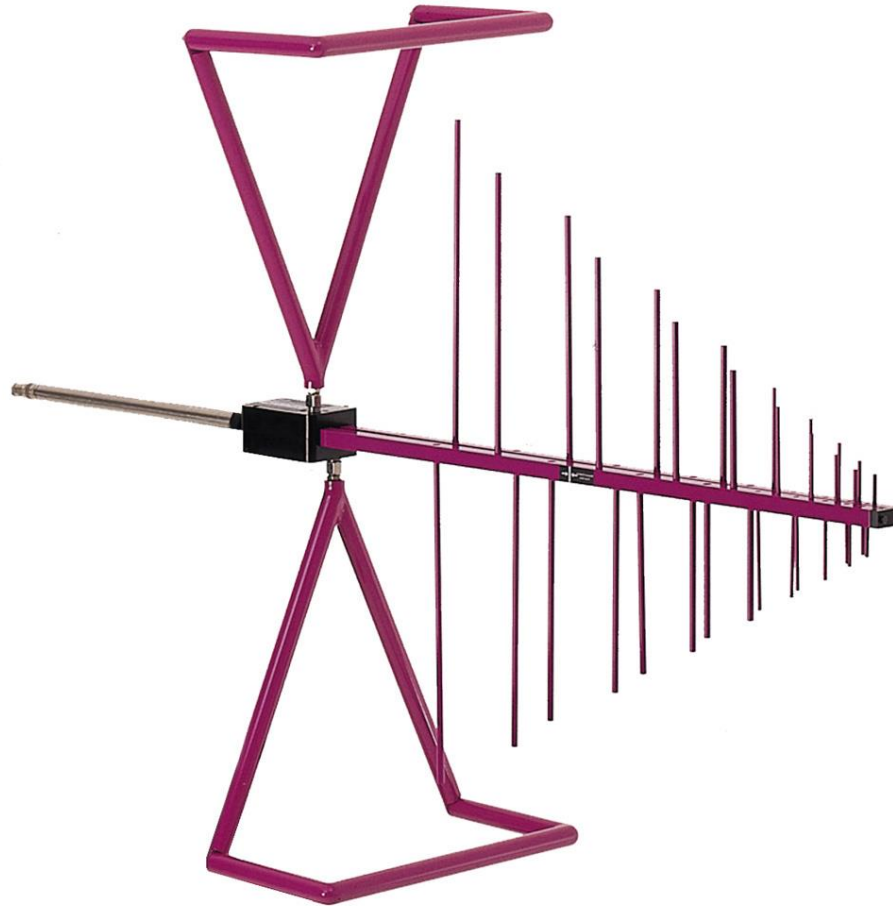
Test vs Approval

- Can you see this difference?
 - Testing to the EN standards shows it can technically comply with the limits
 - ‘Testing only’ does not make it a legal product
 - DoC and CE Mark is the approval process
 - Testing is needed for approval; but the manufacturer is responsible for maintaining technical compliance of their devices

EU Frequency Bands

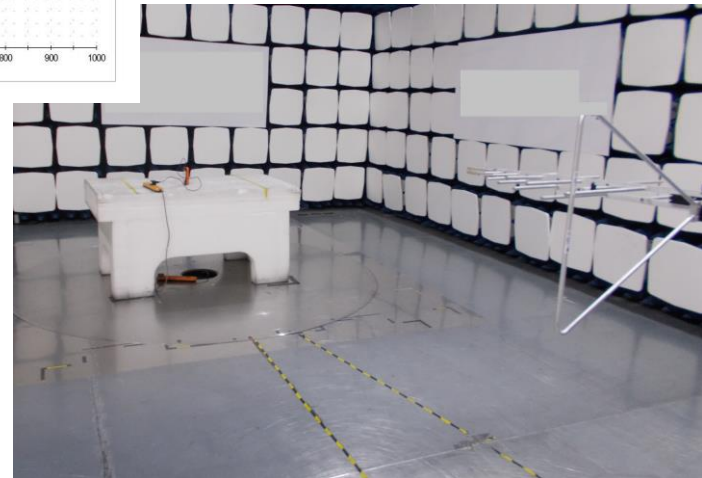
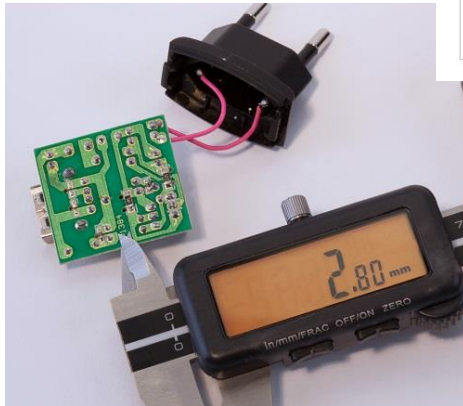
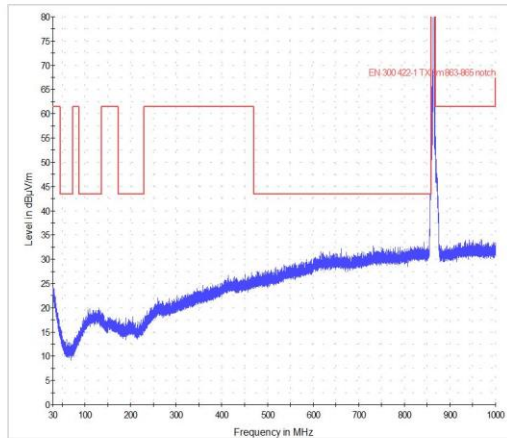
- EU Harmonisation of frequency bands
 - The EU is not all one country
- Restrictions of placing into service
 - Harmonised Bands; Licensing; Indoor only
 - If harmonised band and no restrictions:
 - “Class 1 device”
 - If band not harmonised, or restriction exists
 - “Class 2 device”

Testing



RED Requirements

- Testing requirements (Safety, EMC, Radio)



Testing requirements: safety

- No RED HS for “product safety”
- A few RED HS for EMF/SAR
- RED HS are not mandatory for 3.1(a)
 - Article 17 leaves decision to manufacturer
 - Perhaps look at LVD lists

Testing requirements: safety

- EMF (ICNIRP limits)
 - > 20 cm consider EMF
 - < 20 cm consider SAR
 - < 20mW exempt: EN 62479:2010 P_{max}
examples of higher powers that comply at
5mm and 25 mm; e.g. 801.11b 2.4 GHz WiFi:
 - 32 mW complies at 5 mm
 - 328 mW complies at 25 mm
(EU TX limit is 100 mW)

Testing requirements: EMC

- EN 303 446-1 V1.2.1 (domestic)
- EN 303 446-2 V1.2.1 (industrial)
- Required **assessment**
 - EMC radiated emissions without radio transmitting to “product standard” and EN 53032 table 1
 - EMC conducted emissions with radio transmitting, but exclusion bands
 - EMC immunity of non-radio function
 - EMC immunity of radio function

Testing requirements: RF

- Whole product must comply with article 3.2
- All applicable HS must have been “applied in full” or a NB used
- Compliance evidence of module
- Confirmation that TX power is compliant
- Confirmation that TX RSE is compliant

Practical Example

- WiFi connected Slow Cooker



Practical Example

- Non-radio Function?
- Radio function?
- Article 3.1(a) EN 60335-2-15
- Article 3.1(a) EN 62311
- Article 3.1(b) EN 55014-x / EN 301 489-x
- Article 3.2 RF EN 300 328 / EN 301 893

EMC operating modes

- Can you test the radio at the same time as the non-radio function?
- Do you need to test the radio in more than one mode?
- Do you need test modes for the module or special support equipment?
- How do you define and determine correct operation of the radio?

Radio Modules



Why modules?

- A change in Industry
 - It's a wireless world
 - Entrepreneurs and marketing people
 - The IoT and M2M are a desired lifestyle but manufacturers of 'things' are not radio experts
 - A challenge for our industry
 - The solution
 - Radio manufacturers make modules
 - Other equipment manufacturers make their own products, and install a module

EU RED Modules

- Modular Approval in the EU?
 - There is no such thing
 - Radio Modules are not mentioned in the RED
 - Radio equipment is subject to the Directive, with DoC applied to the final radio product which is placed on the market
 - There is no “certification” which could be transferred or carried over from a module

EU RED Modules

- Modular Approval in the EU?
 - A radio module should comply with the RED if it meets the definition of radio equipment within the RED
 - Even sold business to business is considered 'placing on the market'
 - A radio module is therefore CE Marked as radio equipment

EU RED Modules

- Modular Approval in the EU?
 - Module manufacturer is responsible for the compliance of that module, as a radio device
 - No unique rules to assess a module
 - Nothing which states that the module must have a voltage regulator, or dedicated antenna, or shielding to minimize noise

EU RED Modules

- Modular Approval in the EU?
 - Module manufacturer is expected to assess the module for its intended environment
 - This means different things to different people
 - Not all CE Marks are equal
 - Instructions to the installer 'should' be very clear
 - Most radio modules are simply CE Marked for the environment of 'sitting on a test jig'
 - Anything else, is not covered

EU RED Modules

- Testing the radio module
 - Radio Performance tests should be easy
 - It may have an antenna or antenna port from which to make measurements
 - EMC is more complicated
 - Consider ESD (VCP/HCP) and Radiated Immunity
 - Or maybe add cables and do more
 - Conducted RF immunity, EFT, automotive, etc.
 - Safety is important but may be minimal
 - Includes RF exposure

EU RED Modules

- Testing the radio module
 - Testing a module seems strange
 - Mandatory for the radio module manufacturer
 - Assess their module for all of the RED; Safety, EMC and Radio Performance
 - DoC of the module must state accessories
 - Antenna
 - Any software relevant to compliance

EU RED Modules

- CE Mark on the radio module
 - The module then has a CE Mark
 - This allows the module manufacturer to place their module on the market
 - Modifying that radio or permanently installing it into another device, means a new company becomes the radio equipment manufacturer



American Certification Body
Your Certification Resource



Sulis Consultants
CE Marking and Product Approvals





American Certification Body
Your Certification Resource



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EU Integrating Modules



Modules: Technical issues

- Multiple transmitters in one device
 - Not yet clearly defined in any standard
 - Needs to be considered
 - Easy to test each function separately
 - Follow each standard
 - Consider impact of multiple radios for compliance
 - At least, make sure other radios are functioning
 - Inter-modulation products in emissions
 - Manufacturer is responsible for compliance

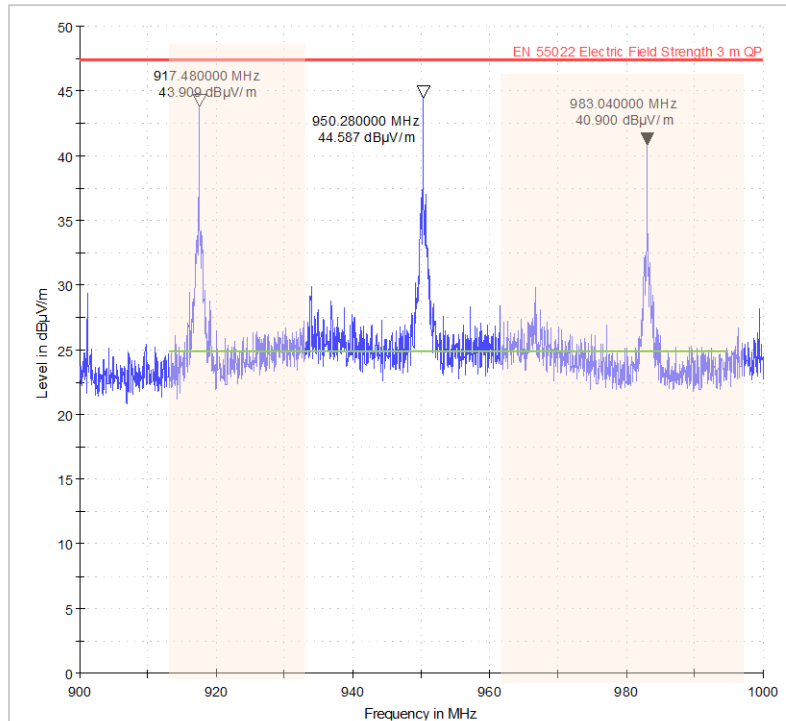
Modules: Receiver blocking

- EMC emissions blocking the receiver
 - Field strength: $E = \text{EIRP} - 20 \log D + 104.8$
 - Class B at 900 MHz; $E = 37 \text{ dB}\mu\text{V/m}$ at 10 m
- $\text{EIRP} = 37 + 20 - 104.8 = -47.8 \text{ dBm}$
- This is approximately:
 - 20 dB above Bluetooth Reference Sensitivity
 - 50 dB above GSM Reference Sensitivity

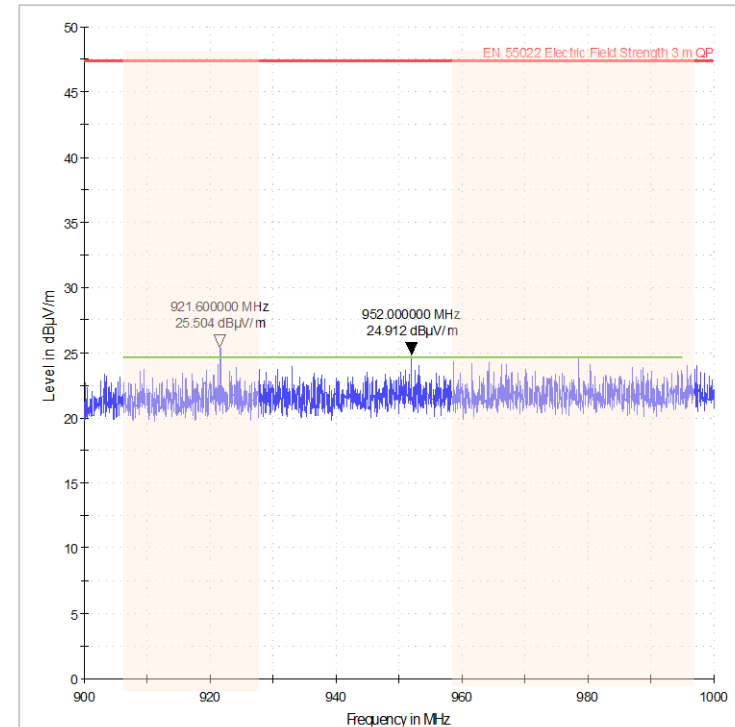
Modules: Receiver blocking

- Absolute receiver performance is not mandated in every standard, but:
 - A degradation of 24 dB reduces free space receive distance by factor of 15

Modules: Receiver blocking

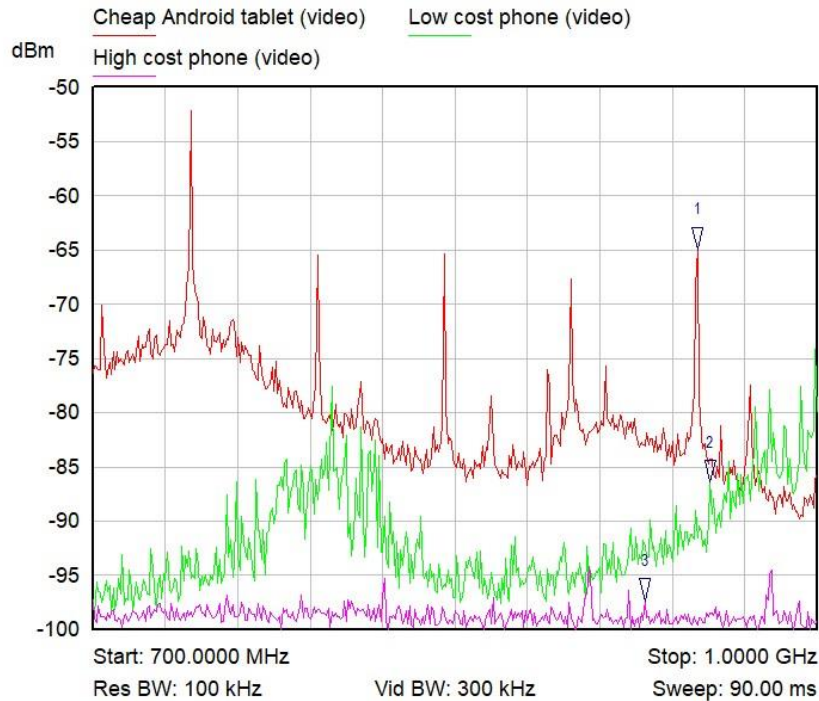


Cheap Anroid tablet



Nokia Lumia 900

Modules: Receiver blocking



Mkr	Trace	X-Axis	Value	Notes
1 ▽	Cheap Android tablet (video)	950.5000 MHz	-64.92 dBm	47 dB GSM desense
2 ▽	Low cost phone (video)	955.7500 MHz	-86.44 dBm	15 dB GSM desense
3 ▽	High cost phone (video)	928.7500 MHz	-97.34 dBm	5 dB GSM desense

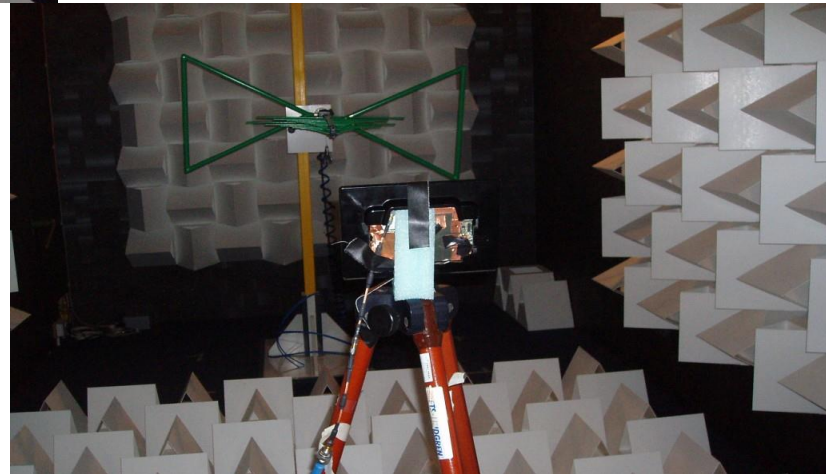
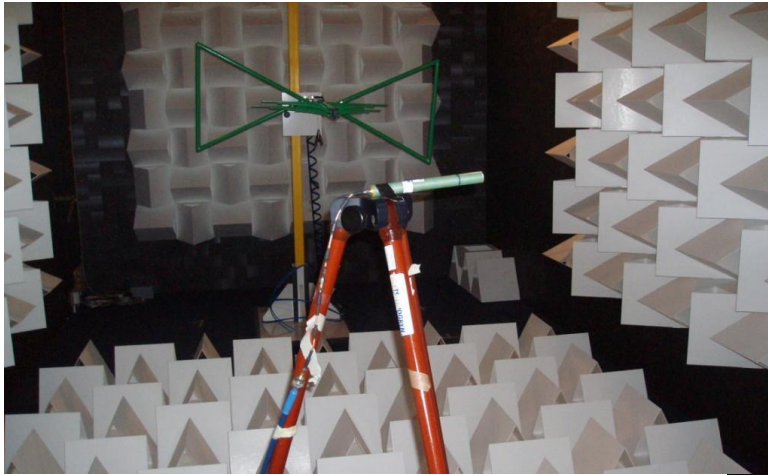


Modules: Antenna inefficiency

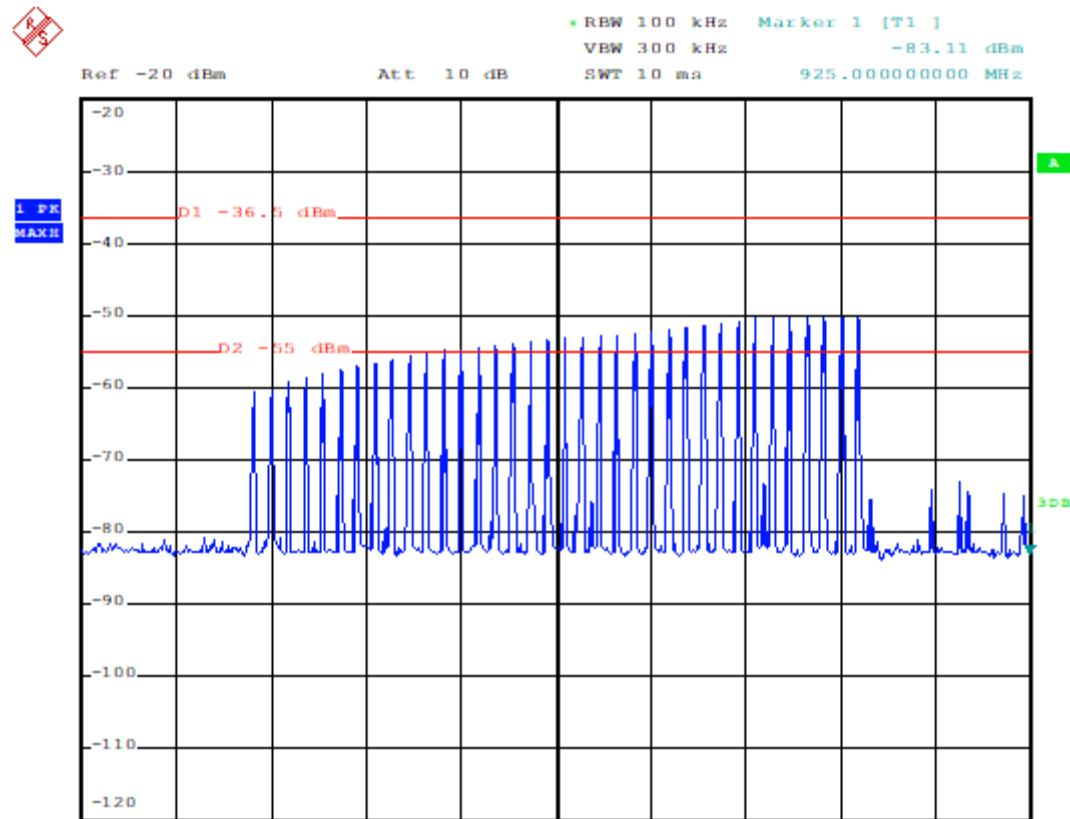


GSM/3G module installed in a netbook computer

Modules: Antenna inefficiency



Modules: Antenna inefficiency



GSM 900

EU Notified Body



NB Examination Process

- Testing is complete; but do you need a Notified Body Certificate?
 - “I’m sure Michael said there is no certification!”
 - The manufacturer may need or want a Notified Body EU Type Examination Certificate; before they create their DoC and fix their CE Mark
 - It is known as an EU-TEC
 - EU-TEC is used to support DoC
 - It is not Certification

Notified Body

- What is a Notified Body?
 - Technical Expert, authorised to examine
 - Industry body, designated by the EU Commission
 - Reviews the product Technical Documentation
 - Issues a certificate to state that the device meets the essential requirements of the Directive
.....or, does not issue the certificate!
 - This is not certification
 - Focus on the technical aspects only
 - Not for test planning or consultancy

Notified Body EU-TEC

- Is the Notified Body actually needed?
 - If the **Safety** or **EMC** test standard is not listed on the RED OJEU
 - It is the manufacturer's decision to proceed and must be justified in their Technical Documentation
 - Use of a Notified Body is not mandatory
 - But it is available, as an option
 - If the **Radio** standard is not on the RED OJEU
 - Application to a Notified Body for an EU Type Examination Certificate is mandatory

Notified Body EU-TEC

- Notified Body EU-TEC
 - NB reviewing the final radio product
 - Will need to see technical documentation of the radio equipment they are assessing
 - This will include any radio modules installed
 - Expect to see all test reports and results
 - May take other Notified Body EU-TECs into consideration as part of their review
 - Cannot transfer an EU-TEC from a radio module, to apply to the final radio product

Changes to the Product?

- What if I had a Notified Body Certificate?
 - Product is changed
 - If the product, standard or state of the art changes
 - Notified Body EU-TEC becomes invalid
 - Manufacturer would need to re-assess in any case
 - Manufacturer would need to discuss with the Notified Body if they need a new EU-TEC

Technical Documentation



Technical Documentation

- Technical File
- Risk Assessment
- User Manual
- Product label
- Packaging label
- DoC supplied with product

Technical Documentation

- The “Technical File”
 - Typical contents are expected to include:
 - Block Diagram, Schematics, Parts List, etc.
 - Technical Datasheet and/or Operation Description
 - Test reports and/or test results and calculations
 - Articles 3.1a, 3.1b, 3.2, (also 3.3 if applicable)
 - User manual and/or installation instructions
 - Packaging markings (for Class 2 devices)
 - External photos, including markings and features
 - Internal photos, including layout and components

Technical Documentation

- Typical contents are expected to include:
 - A copy of the Declaration of Conformity
 - NB EU type examination certificate (if it exists)
 - Proof that the product can be used in at least one EU member state
 - Explanation regarding any restrictions of use
 - If there are any restrictions, they must be explained
 - If there are no restrictions, this must be stated
 - Manufacturer's risk assessment

Technical Documentation

- Let's look at some of the items in the Technical Documentation which have the most questions (concerns):

Technical Documentation

- Risk Assessment
 - The manufacturer looks at their compliance approach to consider if they missed anything
 - Maybe multiple standards may apply
 - Device has features , functions, modes or accessories not included in the testing
 - Product has features not yet in the standards
 - Multiple transmitters in one final product
 - Intended for an unusual environment
 - Explain if you didn't use harmonised standards

User Manual

- Information for the user or installer
 - CE Mark not needed in the user manual
 - Technical data must be in the user manual
 - Frequency range
 - Output power (rated power, plus tolerance)
 - Accessories and other influencing factors, such as the software and firmware version
 - Items that could influence compliance (cables, antennas, etc.)
 - If these can be changed by the user

User Manual

- Information for the user or installer
 - Safety instructions for compliance
 - Information about any restrictions of use
 - (e.g. Class 2)
 - What the restriction is, and where it exists
 - Picture or words as per Commission Decision
 - If there are no restrictions, this must be stated

DoC

- Single Declaration of Conformity (DoC)
 - All applicable Directives on one DoC
 - Created by the manufacturer.
 - Must contain all information of traceability
 - Manufacturer name and address
 - Notified Body (if used)
 - Product (hardware, software, accessories)
 - List standards used
 - Signed and dated

Key points to remember



Remember

- Product and packaging label including CE mark
- Instructions to include: details of intended use; accessories; components; software; radio bands and powers.
- Supply a full DoC or a Simplified DoC and hyperlink
- Restrictions of use if required (e.g. 5 GHz WiFi) on the packaging and user manual

Remember

- If your product has radio functionality it falls under the RED
- The manufacturer of the whole product is responsible for the compliance of the whole product
- Don't mess up the labelling and documentation and make it look like you don't know what you're doing!

Useful links

- ADCO RED Report on 9th RED Market Surveillance Campaign on WLAN 5 GHz (rev 1):
<https://ec.europa.eu/docsroom/documents/35443>
- ADCO RED Report on 10th RED Market Surveillance Campaign on IoT (performed in 2019):
<https://ec.europa.eu/docsroom/documents/38101>
- ElectroMagnetic Compatibility (EMC) standard for combined and/or integrated radio and non-radio equipment; Part 1: Requirements for equipment intended to be used in residential, commercial and light industry locations: EN 303 446-1 V1.2.1 (2019-10)
https://www.etsi.org/deliver/etsi_en/303400_303499/30344601/01.02.01_60/en_30344601v010201p.pdf
- ElectroMagnetic Compatibility (EMC) standard for combined and/or integrated radio and non-radio equipment; Part 2: Requirements for equipment intended to be used in industrial locations EN 303 446-1 V1.2.1 (2019-10)
https://www.etsi.org/deliver/etsi_en/303400_303499/30344602/01.02.01_60/en_30344602v010201p.pdf
- ETSI Electromagnetic compatibility and Radio spectrum Matters (ERM); Using the EN 301 489 series of EMC standards:TR 103 088 V2.1.1 (2019-07)
https://www.etsi.org/deliver/etsi_tr/103000_103099/103088/02.01.01_60/tr_103088v020101p.pdf
- ETSI Guide to the application of harmonised standards covering articles 3.1b and 3.2 of the Directive 2014/53/EU (RED) to multi-radio and combined radio and non-radio equipment
https://www.etsi.org/deliver/etsi_eg/203300_203399/203367/01.01.01_60/eg_203367v010101p.pdf
- EU Radio Equipment Directive, including Directive text, Guide, Commission Implementing Regulation 2017/1354, Harmonised Standards, Class 1 equipment https://ec.europa.eu/growth/sectors/electrical-engineering/red-directive_en

Finished!



Questions?

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