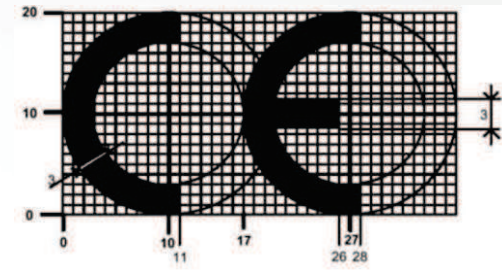The New Radio Equipment Directive
2014/53/EU

➜ RED

Content

> Background to RED

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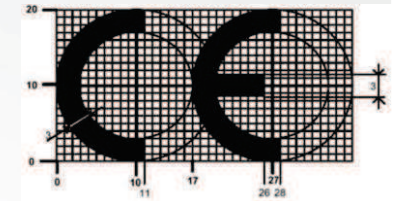gemalto
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What is RED and **WHY**?

Background:

- Radio Equipment Directive (RED) **2014/53/EU** Published on April 16, 2014
    - It replaces the EU Directive 1999/5/EC named **R&TTE**

- **RED** is part of EU work to align several different directive to the New Legislative Framework (NLF)
    - Toy Safety - Directive 2009/48/EU
    - Transportable pressure equipment - Directive 2010/35/EU
    - Restriction of Hazardous Substances in Electrical and Electronic Equipment - Directive 2011/65/EU
    - Construction products - Regulation (EU) No 305/2011
    - Pyrotechnic Articles - Directive 2013/29/EU
    - Recreational craft and personal watercraft - Directive 2013/53/EU
    - Civil Explosives - Directive 2014/28/EU
    - Simple Pressure Vessels - Directive 2014/29/EU
    - Electromagnetic Compatibility - Directive 2014/30/EU
    - Non-automatic Weighing Instruments - Directive 2014/31/EU
    - Measuring Instruments - Directive 2014/32/EU
    - Lifts - Directive 2014/33/EU
    - ATEX - Directive 2014/34/EU
    - **Radio equipment - Directive 2014/53/EU**
    - Low Voltage - Directive 2014/35/EU
    - Pressure equipment - Directive 2014/68/EU
    - Marine Equipment - Directive 2014/90/EU

➔ Common principles and clearer framework for conformity, accreditation and market surveillance
➔ Target to make the EU industry more competitive and improve the industry technological innovations
➔ Make the legislation more efficient and clear
➔ It corrects some old terminology like "*apparatus*" and "*telecommunications terminal equipment*" this is now simply replaced by "radio equipment"
➔ It clarifies the responsibilities between key stakeholders of the supply chain *manufactures*, *importers and distributors*
➔ Clarifies the meaning of **CE marking** and enhances its credibility

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Scope of new RED

> The new directive applies to

   ”**ALL radio equipment**” put on EU market after June 13, 2017

   “Radio equipment” now means an electrical product used for Radio communication or Radiodetermination.

   > Exceptions exist though:

   - Amateur radio equipment

   - Marine equipment (falls under Council Directive 96/98/EC)

   - RnD type of development kits

   - Radio equipment exclusively used for activities concerning public security, defense, State security, including the economic well-being of the State in the case of activities pertaining to State security matters, and the activities of the State in the area of criminal law.

   - Airborne products (falling within scope of Article 3 of Regulation (EC) No 216/2008)

> Transition period:

   - Products placed on the market **before**   June 13, 2016:   → R&TTE
   - Products placed on the market **between**   June 13, 2016 to June 12, 2017   → R&TTE or RED
   - Products placed on the market **after**   June 13, 2017:   → RED

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Overview of the new things in RED

> All radio receivers now fall under RED and not as in previous under the EMC directive.

> > Also sound and TV receive-only equipment, which has been excluded from the R&TTE Directive, now falls within the scope of the Directive;

> > The low limit of 9kHz is removed and equipment operating below 9 kHz, which has been excluded from the R&TTE Directive, now falls within RED.

> Telecom terminal equipment (that has no radio) now falls outside the scope of the Directive; this equipment will be covered by the LVD/EMC Directive if their scope covers this equipment;

> It is not longer OK to use the conformity procedure laid out in the LVD or EMC directive to demonstrate compliancy

> A product that supports several different configuration must comply to all configurations.

> New information (traceability etc.) on shipping box/on product is required

> safeguards and features to protect from fraud/tampering and ensuring personal data and assuring privacy are kept.

> Manufacturers will need to keep a eye on the Official Journal for additional updates

> > Directive specifies that EU can provisions for adopt at later date → "delegated acts"

> > https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/rtte_en

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How to qualify?

> ## *1. Via Annex II - Internal production control*

> > The manufacturer undertakes the compilation of the Technical Documentation (testing can be internal or external), the Manufacturing process (involving internal quality control) and the CE Marking and issuing the Declaration of Conformity. No Notified Body involvement is needed. This option can only be used if harmonized standards have been applied in full for articles 3.2 and 3.3
> > => device can be marked as "CE"

> ## *2. Via Annex III - EU type examination*

> > The manufacturer is responsible for the Technical Documentation (can be internal or external), the Internal Production control, the product CE Marking and issuing the Declaration of Conformity. The Notified Body will be involved in examining the Technical Documentation verifying the design, testing and the issuing of an **EU type Examination Certificate**.
> > => device can be marked as "CE"

> ## *3. Via Annex IV - FQA agreement with a Notified Body*

> > The manufacturer comes into agreement with a Notified Body for a Full Quality Assurance program. The Notified Body takes part in the auditing of the Manufacturing Process, the Quality System, the Product Design and Testing, as well as taking on Surveillance duties of the Quality system. The Notified Body also oversees the CE Marking and issuing of the Declaration of Conformity. The Notified Body's numerals appear on the product labelling, only under a FQA agreement with the manufacturer.
> > => device can be marked as "CE + NB# (number according to used NB)

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Gemalto Status and Assumptions

> Gemalto has engage with NB in updating its product portfolio in accordance with new RED

> Gemalto will provide module approval for all running products as well as most of its EOL products in time.
  > For details on EOL product not targeted for RED please contact your local support

> Currently no technical changes has been identified
  > NO HW change
  > NO SW change needed
  → only paperwork is expected

> An update of the label printed on the module and on the package are foreseen in accordance with the Annex III requirements. The new marking will no longer contain the NB nr.
  > Old marking: **CE 1588 CE 0682**

  > New marking: **CE**

> Customer can start upfront the Gemalto approval by conducting the required application immunity test
  > A smart migration package from Gemalto Test House partner Cetecom and 7 Layers is targeted for B03/2017

> All harmonized standards will <u>NOT</u> be published in time before RED transition timeline 13.06.2017
  → Gemalto will base our certification on draft standards
  → if no draft standard is available, latest R&TTE version to be used
  → A potential recertification could be necessary, when technical changes in the standard will occur afterwards

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GEMALTO Next Step

Summary:

- "**ALL radio equipment**" put on EU market after June 13, 2017 need RED
- Gemalto made decision to go with *Annex III - EU type examination (Confirmation by external Notified Body that GTO products fulfilling current requirements)*
- There will be a label change for all Gemalto products (CE-Mark w/o NB number).
- For interim time, modules with CE mark + notified body number and modules with CE mark but without notified body number, will be possible.
- All the harmonized standards will not be ready in time before RED transition timeline 13.06.2017
- Gemalto decided to do RED also on most of its EOL portfolio, might come later
- PCN will be distributed along side this document for all modules
- Useful link for the directive:
    - http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:JOL_2014_153_R_0002&from=EN

KEY DATES:
- Gemalto Certification starts: November 2016
- Gemalto Target to finish all: April 2017

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