

Technical Guidance from Element Experts



NEW RADIO EQUIPMENT DIRECTIVE (RED) 2014/53/EU

In April 2014, following the release of the nine directives to be updated under the New Legislative Framework (including EMC Directive and Low Voltage Directive), the European Parliament and Council issued a new RED aligned to the same framework. This new Directive 2014/53/EU will be applicable from 13 June 2016.

The existing Radio and Telecommunications Terminal Equipment Directive 1999/9/EC (R&TTE) will be repealed on 13 June 2016. However, Article 49 of RED allows for a transition period between 13 June 2016 and 13 June 2017 when equipment complying with the R&TTE before the 2017 date may still be placed on the market.



After the end of the transition period, all manufacturers, distributors and importers must apply the new Directive, and all of their regulatory documentation, including the new EU Declaration of Conformity, must be prepared accordingly.

THE KEY CHANGES TO THE RED 2014/53/EU

There have been major changes to the scope of this new radio directive. These are summarized as follows:

- Sound and TV receive-only equipment, which has previously been excluded from the R&TTE Directive (and effectively within the old EMC Directive 2004/108/EC), now falls only within the scope of RED
- Equipment operating below 9 kHz, which has previously been excluded from the R&TTE Directive, now falls only within the scope of RED
- Radio-determination equipment is now clearly included within the scope of RED
- Telecom Terminal Equipment now falls outside the scope of RED and will be covered by the LVD/EMC Directive if their scope covers this equipment
- Custom-built evaluation kits designed for professionals to be used solely at research and development facilities for such purposes are explicitly excluded from the RED

One of the other significant changes to the RED is the abolition of the Notified Body Opinion and the introduction of EU Type Examination Certificates in their place. The Notified Body number is not associated with issue of this EU Type Examination Certificate and hence will cease to be applied against the CE Mark under the new rules.

Under the new Directive, manufacturers must conduct and document a radio risk assessment prior to applying for certification and issue of their EU Declaration of Conformity.

In accordance with the New Legislative Framework, the new RED clarifies the obligations and responsibilities of the various economic operators. These include manufacturers, authorized representatives, distributors and importers. The new or enhanced requirements for importers include ensuring that their name and contact address is affixed to the equipment or packaging for ease of traceability.

R&TTE / RED NOTIFIED BODY

Element has already been assessed for transfer of our notification from the current to the new RED. We will thus be able to issue RED EU Type Examination Certificates from the start of the transition period on 13 June 2016. The European Commission has ruled that there will not be any active Notified Bodies under the new Directive until this date.

Since the R&TTE Directive can be applicable during the transitional period, the intention of the EU Commission is to keep valid, during the above transitional period, the references of the harmonized standards for the R&TTE Directive, as well as the Notified Bodies notified under the R&TTE.

If you are currently reliant on an R&TTE Notified Body Opinion for your CE Mark compliance then this will cease to be valid for all new equipment placed on the market after 13 June 2017. You will need to contact your Notified Body and ask for an upgrade to an EU Type Examination Certificate for RED.



Technical Guidance from Element Experts

IMPLEMENTING THE CHANGES IN YOUR COMPANY

For all R&TTE Directive users, your "EC Declaration of Conformity" must become an "EU Declaration of Conformity" by 13 June 2017. After this date the new declaration must reference the new RED and any other directives that apply.

Look carefully at the change of scope from the R&TTE Directive to RED and make changes to your EU Declaration of Conformity as appropriate.

Your marking plate will need to change to remove the Notified Body number after the CE Mark where this relates only to RED.

C€0891**→**C€

In line with practice under other directives, we are recommending that the manufacturer puts the EU Type Examination Certificate number on the equipment marking plate to show that they have a formal approval under the new (RED) Directive.

TECHNICAL DOCUMENTATION

Element's engaged experts can help review your regulatory documentation for conformity with the new requirements including the technical file and EU Declaration of Conformity. Please contact us for further information on our Early Stage Qualification services.

CONTACT ELEMENT