Radio Equipment Directive

Medical Devices complying with the Radio Equipment Directive

The Radio Equipment Directive (RED), 2014/53/EU is a new Directive that will replace the long established Radio and Telecommunications Terminal Equipment Directive (R&TTE Directive), 1999/5/EC. Published in the Official Journal of the European Union (OJEU) in March 2014, the RED is in a 2 year transition period and comes into force on 13th June 2016. The Directive is written in the new Legislative Framework and will bring significant changes for Medical Device manufacturers.

BSI are working towards designation under RED to be a Notified Body under Annex IV, Full Quality Assurance.

For products within the scope of the R&TTE Directive and that will remain within the scope of the RED:

- Products placed on the market before 13 June 2016 must use the R&TTE Directive.
- Products placed on the market between 13 June 2016 and 12 June 2017 can use either the R&TTE Directive or the RED.
- Products placed on the market after 12 June 2017 must use the RED

"'Radio equipment' means an electrical or electronic product, which intentionally emits and/or receives radio waves for the purpose of radio communication and/or radiodetermination, or an electrical or electronic product which must be completed with an accessory, such as antennae, so as to intentionally emit and/or receive radio waves for the purpose of radio communication and/or radiodetermination"

Definition of Radio Equipment from Directive 2014/53/EU.

How does RED interact with the Medical Device Directives?

The requirements of the relevant Medical Device Directives (MDD, AIMD or IVDD), must still be met in addition to the RED if the product meets the definition of a Medical Device, Active Implantable Device or In-vitro Diagnostic Device. The Medical Device and Radio Equipment Directives are applied independently but requirements may overlap, separate Notified Bodies can be used for each directive. BSI can provide complete access to Medical Device, Software and Radio Device certification in addition to Quality and Environmental Management system registration.

Do you need a Notified Body?

- Annex II: Internal Product Control, Self-Declaration by the manufacturer is allowed where the manufacturer complies with the relevant harmonized standards.
- Annex III: EU Type Examination and Conformity to Type, a Notified Body examines the Design and Technical Documentation.
- Annex IV: Full Quality Assurance, Notified Body examines Design, Manufacturing, Inspection and Testing documentation and processes.

bsi.

...making excellence a habit.™

Differences between the Radio Directive and R&TTE Directive

Changes in the new Directive include:

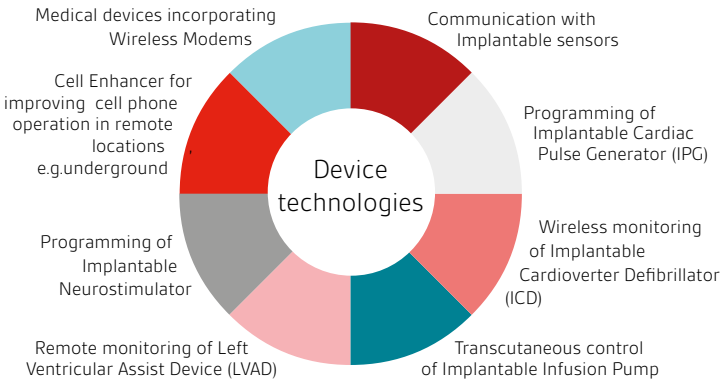
- A clearer requirement that radio receivers achieve a minimum level of performance so as to contribute to an efficient use of radio spectrum; it no longer covers receive only radio devices or wired modems;
- Clear obligations for manufacturers, importers and distributors;
- Improvements are made for market surveillance, in particular the traceability obligations of manufacturers, importers and distributors and the possibility to require prior registration of radio equipment within categories affected by low levels of compliance;
- Deletion of unnecessary administrative obligations, such as the prior notification of radio equipment using non-harmonized frequency bands;
- Certificate offered in place of a Notified Body opinion.

The new Directive also introduces some new specific requirements:

- It ensures that software can only be used with radio equipment after the compliance of that particular combination of software and the radio equipment has been demonstrated;
- The European Commission will have the possibility to require that mobile phones and other portable devices are compatible with a common charger.

Come and talk to BSI early regarding the regulatory framework and requirements to ensure all of the above are taken into account in the early stages of the design process.

BSI's experience includes:



Why choose BSI for your certification?

BSI assessors are available to assess quality management systems and the additional regulatory requirements of Annex IV of the RED and to review the technical documentation as required in Annex III of the Directive, in addition to assessing compliance with the requirements of the Medical Device Directives.

We can provide one stop access to Medical Device, Software and Radio Device certification and Quality and Environmental Management system registration.

For more information visit:
bsigroup.com/en-au

Your expert in worldwide compliance: Call BSI today on 1300 730 134 or visit bsigroup.com/en-au – to start your journey

---

BSI Group ANZ Pty Ltd
Suite 2, Level 7
15 Talavera Road,
Macquarie Park, NSW 2113
Australia

T: 1300 730 134
E: info.aus@bsigroup.com

BSI/UK/029/MD/0516/en/BLD