

Medical devices

Under the *Telecommunications Act 1997* and the *Radiocommunications Act 1992*, the Australian Communications and Media Authority (the ACMA) is responsible for technical regulation, including making mandatory requirements for appropriate labelling, of:

- telecommunications customer equipment and customer cabling;
- radiocommunications devices; and
- specified electrical and electronic devices.

Labelling requirements for these items are published in the relevant labelling notices. Each notice lists the types of items covered. In addition, each labelling notice also details the applicable standards and the required level of compliance. Australian manufacturers or importers or their authorised agents (suppliers) need to satisfy the requirements before these items are sold or supplied in Australia.

The relevant labelling notices are:

- > [Telecommunications Labelling \(Customer Equipment & Customer Cabling\) Notice 2001](#) [TLN];
- > [Radiocommunications Devices \(Compliance Labelling\) Notice 2003](#) [RLN];
- > [Radiocommunications \(Compliance Labelling – Electromagnetic Radiation\) Notice 2003](#) [EMR LN]; and
- > [Radiocommunications Labelling \(Electromagnetic Compatibility\) Notice 2008](#) [EMC LN].

Many medical devices are regulated by the [Therapeutic Goods Administration \(TGA\)](#). Part of the regulations by the TGA includes EMC testing of the devices.

The EMC LN and the corresponding Radiocommunications (Electromagnetic Compatibility) Standard 2008 exempts devices that comply with a radio emission standard that applies to the device under a law of the Commonwealth or of a state or territory.

Therefore, medical devices that are regulated by the TGA are exempt from the ACMA's EMC requirements because they are required to meet the TGA's EMC requirements.

However, medical devices will still need to comply with any of the other labelling notices and standards as applicable.

Examples:

- > A medical device that has a telecommunications port will need to comply with the TLN.
- > A medical device that includes a bluetooth transmitter will need to comply with the RLN and possibly the EMR LN.

Note: It is important to remember that the C-Tick compliance mark is not just for EMC, but is also the compliance mark for Radiocommunications and EMR. Therefore a medical device may be exempt from EMC labelling, but may still need to be labelled with the C-Tick for Radiocommunications and/or EMR.

More information

The ACMA's [compliance and labelling booklets](#) are available from the ACMA's website.

More information about medical devices regulation is available on the [TGA website](#).

For more information suppliers may also contact comply.label@acma.gov.au.

Please note: this document is intended as a guide only and should not be relied on as legal advice or regarded as a substitute for legal advice in individual cases.