

Medical Equipment

This guidance material results from a request to clarify if electrical medical equipment is in-scope or not.

Question

Is electrical medical equipment in-scope electrical equipment under the EESS?

In this question electrical medical equipment is equipment that is connected to low voltage supply and intended by the manufacturer to be used in the diagnosis, treatment, or monitoring of a patient; or for compensation or alleviation of disease, injury or disability.

Answer

Medical equipment that is regulated by the Therapeutic Goods Authority (TGA) and used by professionals as part of their treatment process (i.e. as part of their work) or is equipment that requires specific professional instruction and is used under that instruction, even if used in a home, is not in-scope electrical equipment.

Any other medical equipment, even if the equipment is also registered by TGA, that can be purchased by a householder and used in home by a householder and does not require a medical professional, is in scope electrical equipment under the EESS.

For example:

Equipment that is in-scope:

- Equipment displayed for sale to householder, such as blood pressure machine or a TENS therapy device that comes with a power supply and used in the home - the power supply would be in-scope electrical equipment in the EESS.
- A steam vaporiser would be in-scope electrical equipment in the EESS

Equipment that is not in-scope:

- An electric ventilation device
- An electric insulin infusion pump