



**Australian Government**

**Department of Health and Ageing**  
Therapeutic Goods Administration

# Australian Register of Therapeutic Goods Certificate

Issued to

**Emergo Asia Pacific Pty Ltd T/a Emergo Australia**

for approval to supply

**Emergo Asia Pacific Pty Ltd T/a Emergo Australia - MRI system,  
extremity imaging, permanent magnet**

<b>ARTG Identifier</b>	213111
<b>ARTG Start date</b>	12/08/2013
<b>Product Category</b>	Medical Device Included Class IIa
<b>GMDN</b>	37651
<b>GMDN Term</b>	MRI system, extremity imaging, permanent magnet
<b>Intended Purpose</b>	O-scan is a Magnetic Resonance (MR) system that produces transversal, sagittal, coronal and oblique section images of limbs and joints. It is designed for imaging portions of the arm, including hand, wrist, forearm, and elbow, but excluding the upper part of the arm and portions of the leg, including foot, ankle, calf, and knee, but excluding the thigh. The M.R. images produced by O-scan correspond to the spatial distribution of the protons (hydrogen nuclei) which verify the properties of magnetic resonance and depend on the MR parameters spin-lattice relaxation time(T1), spin-spin relaxation time (T2), nucleus density, flow velocity and "chemical shift". When interpreted by a medical expert trained in use of MR equipment, the images can provide diagnostically useful information.

Manufacturer Details	Address	Certificate number(s)
Esaote SPA	Viale Bianca Maria 25 , Milano, 20122 Italy	DV-2013-MC-04508-1

## ARTG Standard Conditions

The above Medical Device Included Class IIa has been entered on the Register subject to the following conditions:

- The automatic conditions applicable to the inclusion of all kinds of medical devices in the Register are as specified in section 41FN of the Therapeutic Goods Act 1989.,
- The standard conditions that are imposed under section 41FO of the Therapeutic Goods Act 1989 when kinds of medical devices are included in the Register are as set out in the following paragraphs.,
- For a medical device included in the Register under Chapter 4 and imported into Australia, the Sponsor must ensure that information about the Sponsor is provided in such a way as to allow the sponsor to be identified.,
- Where a medical device included in the Register, contains a substance which is included in the Fourth Schedule to the Customs (Prohibited Imports) Regulations or the Eighth Schedule to the Customs (Prohibited Exports) Regulations the Sponsor shall, at the time of importation or exportation of the medical device, be in possession of a licence and a permission for importation or exportation of each consignment of the goods as required by those regulations.,
- It is a condition of inclusion in the ARTG that the sponsor of a medical device that is an AIMD, Class III or implantable Class IIb provides three consecutive annual reports to the Head of the Office of Product Review, Therapeutic Goods Administration following inclusion of the device in the ARTG. (as specified in 5.8 of the regulations) Annual reports are due on 1 October each year. Reports should be for the period 1 July to 30 June. The first report following the date of inclusion in the ARTG must be for a period of at least six months but no longer than 18 months. Subsequent reports are to be provided on 1 October for a further 2 years. The annual report must include all complaints received by the manufacturer relating to problems with the use of the device that have been received by them over the year,
- The sponsor of a medical device included in the Register under Chapter 4 shall keep an up to date log

- of information of the kind specified in Regulation 5.8.,
- Each sponsor shall retain records of the distribution of all of the sponsor's medical devices included in the Register under Chapter 4. In the case of records relating to a Class AIMD medical device, Class III medical device, or Class IIb medical device that is an implantable medical device, the distribution records shall be retained for a minimum period of 10 years. In the case of records relating to any other device, the distribution records shall be retained for a minimum period of 5 years.,
  - A sponsor shall ensure that a medical device within their control is stored and transported in accordance with the instructions and information provided by the manufacturer.

### **Products Covered by This Entry**

#### **1. MRI system, extremity imaging, permanent magnet**

#### **Product Specific Conditions**

No specific conditions have been recorded against this entry.

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