



Australian Government

Department of Health and Ageing
Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

Emergo Asia Pacific Pty Ltd

for approval to supply

Emergo Asia Pacific Pty Ltd - Radiation therapy treatment planning system, application program software

ARTG Identifier	159497 Class IIb
ARTG Start date	20/02/2009
Product Category:	Medical Device Included Class IIb
GMDN	40887
GMDN Term	Radiation therapy treatment planning system, application program software
Intended Purpose	<p>The RadCalc Software is a program utilized in a radiation therapy department for the determination of monitor units (MU) and/or the dose to various points of interest for external beam radiation therapy and/or brachytherapy treatments. For external beam treatments, RadCalc's monitor unit calculation can be used to validate the monitor units or dose previously determined by hand or by the primary radiation therapy planning system. RadCalc's function is to support the primary radiation therapy planning computer by validating its calculation as a means of quality assurance. RadCalc Software not only performs this secondary function but can also be used as the primary means of calculating monitor units for external beam radiation treatments in situations where the physician does not order the use of a radiation therapy treatment plan.</p> <p>RadCalc Software imports treatment planning parameters from the primary treatment planning system or a verify and record system; parameters can also be entered manually. The dosimetric calculations are then performed for photon or electron external beam radiation plans or LDR, HDR, and Permanent Implant brachytherapy treatment plans. The brachytherapy treatment module is only used to validate the dose to points of interest and not for brachytherapy treatment planning. RadCalc Software allows for the transfer of the treatment planning data from the primary radiation therapy planning computer or the Verify and Record system (system actually controlling the radiation beam) to RadCalc and then to the facility's Verify and Record system or radiation therapy planning computer. This transfer of treatment planning data electronically reduces the number of errors that could occur as a result of manually inputting the data.</p>

Manufacturer Details	Address	Certificate number(s)
LifeLine Software Inc	3304 South Broadway Avenue Suite 200 Tyler, TX, 75701 United States Of America	DV-2009-MC-01292-3

ARTG Standard Conditions

The above Medical Device Included Class IIb 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

identified.

- 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.
- 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.
- 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 Devices, Blood and Tissues, 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.
- 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.
- 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. Radiation therapy treatment planning system, application program software

Product Specific Conditions

No specific conditions have been recorded against this entry.

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