



# ARTG 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 Description	Radiation therapy treatment planning system, application program software
Intended Purpose	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. 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.

Manufacturer(s) Details	Address	Manufacturing steps
LifeLine Software Inc	311 Hines Crossing Bullard, TX, 75757	

**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 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.
- 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.
- The sponsor shall provide to the Director, Office of Devices, Blood and Tissues, Therapeutic Goods Administration, three consecutive reports which include information of a kind specified in Regulation 5.8 that arises during the reporting period, concerning Class III, Class AIMD or implantable Class IIb medical devices. The reporting period for the first report commences on the date of inclusion and is to be at least a period of six months but not more than 18 months ending on 1 October. For subsequent reports the reporting period is 12 months ending on 1 October.
- 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.

**Product Standard Indications**

No standard indications have been recorded against this entry.

**Product Specific Indications**

No specific indications have been recorded against this entry.

**END OF CERTIFICATE**

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