



Australian Government

Department of Health
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 - Radiation therapy treatment planning system, application program software

ARTG Identifier	159497
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	102 N College Ave Ste 1014 Tyler , TX , 75702-72 87 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 inclusion of the kind of device in the ARTG is subject to compliance with all conditions placed or imposed on the ARTG entry. Refer Part 4-5, Division 2 (Conditions) of the Therapeutic Goods Act 1989 and Part 5, Division 5.2 (Conditions) of the Therapeutic Goods (Medical Devices) Regulations 2002 for relevant information.
- Breaching conditions of the inclusion related to the device of the kind may lead to suspension or

cancellation of the ARTG entry; may be a criminal offence; and civil penalties may apply.

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.

Therapeutic Goods Administration
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