LifeLine Software, Inc

Manufacturer's Declaration of Conformity

This is a declaration of conformity made under clause 1.8 of Schedule 3 to the Therapeutic Goods (Medical Devices) Regulations 2002

Manufacturer's name:	LifeLine Software, Inc
Business address:	3304 South Broadway Avenue Suite 200 Tyler, TX, 75701 United States Of America
Medical device(s):	RadCalc
Classification:	Class IIb (Annex IX, Rule 10 of MDD 93/42/EEC Council Directive)
GMDN code and term:	40887 - Radiation therapy treatment planning system, application program software
Scope of application:	All

Each kind of medical device to which the system has been applied complies with the applicable provisions of the essential principles, the classification rules, and the full quality assurance procedures, at each stage, from the design of the device until its final inspection before being supplied.

Full quality assurance procedures certificate:	**Assessment Body: SGS Belgium N.V.** **EC Certificate Full Quality Assurance System: Certificate US19/819943412** European conformity assessment certificate under Annex II (excluding Section 4) of the Directive 93/42/EEC on Medical Devices
Design examination certificate (if applicable):	**Not applicable.**
Standards applied:	ISO 14971:2007, ISO 15223-1:2016, ISO 14969:2004 and EN 62304:2006

Authorised signatory: Craig A. Laughton

Digitally signed by Craig A. Laughton
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Date: 2019.11.05 18:26:25 -06'00'

Date: Nov 5, 2019