LifeLine Software, Inc

Manufacturer's Declaration of Conformity

Australia

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:	102 N COLLEGE AVE SUITE 1014 TYLER TX 75702 United States Of America
Medical device(s):	RadCalc
Classification:	Class IIb (Schedule 2, Part 4, 4.3 (3))
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 United Kingdom Ltd** **MDSAP (ISO 13485:2016)** **US20/819943960** Australia: Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 1 - Full Quality Assurance System
Design examination certificate (if applicable):	**Not applicable.**
Standards applied:	ISO 14971:2019, ISO 15223-1:2021, and EN 62304:2006

Authorised signatory: Paul Pantalone Digitally signed by Paul Pantalone DN: cn=Paul Pantalone, o=LifeLine Software, Inc., ou, email=paul.pantalone@lap-laser.com, c=US Date: 2023.10.27 08:53:42 -05'00'

Date: Oct 27, 2023