



LifeLine Software, Inc.

Quality Software Products

EC Declaration of Conformity

LifeLine Software, Inc.
102 N College Ave
Suite 1014
Tyler, TX 75702
USA

having been issued the Single Registration Number US-MF-000012327 by the Competent Authority

Declare that the medical device described hereafter:

RadCalc Software

has been classified as IIb (Annex IX, Rule 10 of MDD 93/42/EEC Council Directive)

and has been issued the Basic UDI-DI of 00867520000206

and is in conformity with the essential requirements and provisions of Council Directive 93/42/EEC as amended by Directive 2007/47/EC

and is in conformity with the national standards transposing harmonized standards ISO 14971:2019, ISO 15223-1:2016, ISO 14969:2004 and EN 62304:2006

and is subject to the procedure set out in Annex II, excluding Section 4, of Directive 93/42/EEC as amended by Directive 2007/47/EC under the supervision of Notified Body Number 1639, SGS Belgium N.V., Noorderlaan 87, BE-2030 Antwerpen, Belgium, under certificate number US19/819943412.

Declare the appointment of LAP GmbH Laser Applikationen, Zeppelinstr. 23, 21337 Lueneburg, Germany, as Authorized Representative.

3-November-2021

Craig Laughton, CEO, LifeLine Software, Inc.

Signature: _____

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