



## EC Declaration of Conformity

**Manufacturer Name:** Brightwake Limited also trading as Advancis Medical and Advancis Surgical

**Manufacturer Address:** Lowmoor Business Park, Kirkby in Ashfield, Nottinghamshire, NG17 7JZ, UK

**Authorised Representative:** CS Lifesciences Europe Limited  
3 Inns Quay, Dublin 7, Ireland

**Device Name:** *Actilite*

**Device Item No:** See attached sheet (Table I – Page 2).

**Classification:** *IIb, Rule 4 (Secondary Intent)*

**Scope:** The scope of this document is to state conformity of *Actilite* to EC Regulations.

**Conformity Assessment Route:** Advancis Medical is in conformance with Directive 93/42/EEC on medical devices, *Annex II (excluding Section 4)*

**Notified Body:** SGS Belgium NV, Notified Body 1639  
SGS House, Noorderlaan, 87 2030, Antwerp, Belgium


**EC Full Quality Assurance System Certificate Number:** GB19/964732.00

**EC Full Quality Assurance System Certificate Effective Date:** *Certified since 24 May 2002 and first certified by SGS Belgium NV since 16 December 2019. This certificate is valid from 27 February 2020.*

**EC Full Quality Assurance System Certificate Expiry Date:** *18 June 2023*

We hereby declare that the device listed above comply with the European Medical Device Council Directive 93/42/EEC of the 14<sup>th</sup> June 1993 as amended by Directive 2007/47/EC. This declaration is supported by the Quality System approval to ISO 13485.

All supporting documentation is retained at the premises of the manufacturer.

**Managing Director**   
Stephen Cotton  
(Authorised to sign on behalf of the manufacturer)

**Date** 18 / 03 / 2021



**Table I**

<b>Reference Number</b>	<b>Description</b>	<b>Classification</b>	<b>Sterilised</b>
CR4281 (CR4284 USA Code)	Actilite 5cm x 5cm	IIb, Annex IX, Rule 4; Secondary Intent	Sterilised by Gamma Irradiation
CR3849 (CR4285 USA Code)	Actilite 10cm x 10cm	IIb, Annex IX, Rule 4; Secondary Intent	Sterilised by Gamma Irradiation
CR3852 (CR4286 USA Code)	Actilite 10cm x 20cm	IIb, Annex IX, Rule 4; Secondary Intent	Sterilised by Gamma Irradiation
CR4366	Actilite 20cm x 30cm	IIb, Annex IX, Rule 4; Secondary Intent	Sterilised by Gamma Irradiation
CR4367	Actilite 30cm x 30cm	IIb, Annex IX, Rule 4; Secondary Intent	Sterilised by Gamma Irradiation
CR4368	Actilite 30cm x 60cm	IIb, Annex IX, Rule 4; Secondary Intent	Sterilised by Gamma Irradiation