



EC Declaration of Conformance

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

Manufacturer Address: Sidings Road, Lowmoor Road Business Park,
Kirkby-in-Ashfield, Nottinghamshire, NG17 7JZ

Device Name: Algivon Plus Range Including ribbons and probes

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

Classification: See attached sheet (Table I – Page 2).

Scope: The scope of this document is to state conformity of Enter Device Name to EC Regulations.

Conformity Assessment Route: Advancis Medical is in conformance with Directive 93/42/EEC amended to 2007/47/EC
CE Conformance Declaration according to annex II (Full Quality Assurance system).

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: December 16, 2019

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

We hereby declare that the device listed above comply with the European Medical Device Council Directive 93/42/EEC of the 14th 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 06 / 01 / 2020



Table I			
Reference Number	Description	Classification	Sterilised
CR4230	Algivon Plus 5cm x 5cm	Iib, Annex IX, Rule 4; Secondary Intent	Sterilised by Gamma Irradiation
CR4225	Algivon Plus 10cm x 10cm	Iib, Annex IX, Rule 4; Secondary Intent	Sterilised by Gamma Irradiation
CR4231	Algivon plus Ribbon and Probe 2.5cm x 20cm	Iib, Annex IX, Rule 4; Secondary Intent	Sterilised by Gamma Irradiation
CR4441	Algivon Plus Ribbon and Probe 1cm x 20cm	Iib, Annex IX, Rule 4; Secondary Intent	Sterilised by Gamma Irradiation
CR4236	Wound Probe pack of 10	I, Annex IX, Rule; Default Rule	Sterilised by Gamma Irradiation
CR4223	Wound Probe pack of 50	I, Annex IX, Rule; Default Rule	Sterilised by Gamma Irradiation