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:	***Activon Tube***
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 ***Activon Tube*** 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 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 _____ **Date** 18 / 03 / 2021

Stephen Cotton

(Authorised to sign on behalf of the manufacturer)

Table I			
Reference Number	**Description**	**Classification**	**Sterilised**
CR3830	Activon Tube 25g	IIb, Annex IX, Rule 4; Secondary Intent	Sterilised by Gamma Irradiation
CR4493	Activon Tube 20g	IIb, Annex IX, Rule 4; Secondary Intent	Sterilised by Gamma Irradiation