



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
The Black Church, St Mary's Place,
Dublin 7, Dublin, D07 P4AX, Ireland

Device Name: ***Advazorb Silfix Range***

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 ***Advazorb Silfix Range*** 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.***

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.

A handwritten signature in blue ink, appearing to read 'Edwin Lindsay', is written over a horizontal line.

QARA Director _____
Edwin Lindsay
(Authorised to sign on behalf of the manufacturer)

Date 17 May 2023



Table I			
Reference Number	Description	Classification	Sterilised
CR4177	Advazorb Silfix 7.5cm x 7.5cm	IIb, Annex IX, Rule 4; Secondary Intent	Sterilised by Ethylene Oxide
CR4178	Advazorb Silfix 10cm x 10cm	IIb, Annex IX, Rule 4; Secondary Intent	Sterilised by Ethylene Oxide
CR4179	Advazorb Silfix 12.5cm x 12.5cm	IIb, Annex IX, Rule 4; Secondary Intent	Sterilised by Ethylene Oxide
CR4180	Advazorb Silfix 15cm x 15cm	IIb, Annex IX, Rule 4; Secondary Intent	Sterilised by Ethylene Oxide
CR4181	Advazorb Silfix 10cm x 20cm	IIb, Annex IX, Rule 4; Secondary Intent	Sterilised by Ethylene Oxide
CR4182	Advazorb Silfix 20cm x 20cm	IIb, Annex IX, Rule 4; Secondary Intent	Sterilised by Ethylene Oxide
CR4185	Advazorb Silfix Lite 7.5cm x 7.5cm	IIb, Annex IX, Rule 4; Secondary Intent	Sterilised by Ethylene Oxide
CR4186	Advazorb Silfix Lite 10cm x 10cm	IIb, Annex IX, Rule 4; Secondary Intent	Sterilised by Ethylene Oxide
CR4187	Advazorb Silfix Lite 12.5cm x 12.5cm	IIb, Annex IX, Rule 4; Secondary Intent	Sterilised by Ethylene Oxide
CR4188	Advazorb Silfix Lite 15cm x 15cm	IIb, Annex IX, Rule 4; Secondary Intent	Sterilised by Ethylene Oxide
CR4189	Advazorb Silfix Lite 10cm x 20cm	IIb, Annex IX, Rule 4; Secondary Intent	Sterilised by Ethylene Oxide
CR4204	Advazorb Silfix Lite 20cm x 20cm	IIb, Annex IX, Rule 4; Secondary Intent	Sterilised by Ethylene Oxide