

Brightwake limited also trading as Advancis Medical and Advancis Surgical

Sidings Road,
Lowmoor Road Business Park
Kirkby-in-Ashfield, Nottinghamshire
NG17 7JZ
UK

11/07/2023

Confirmation Letter Reference: CLNB1639 GBPC227286

To whom it may concern,

Confirmation of receipt of a formal application and conclusion of written agreement in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, SGS Belgium NV, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 1639 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Brightwake limited also trading as Advancis Medical and Advancis Surgical

Sidings Road,
Lowmoor Road 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
SRN: IE-AR-000004113

The devices covered by the formal application and the written agreement mentioned above are shown at the end of this letter.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or

Directive 93/42/EEC (MDD) that expired prior to the publication of the Regulation EU 2023/607 on 15 March 2023, this letter also confirms that:

- the manufacturer submitted the MDR application and signed the written agreement by the date of MDD/AIMDD certificate expiry;
- the certificates expired after 26 May 2021 by course of time and were valid at the date of their expiry neither having been suspended nor withdrawn.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3 of MDR (as amended by EU 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body SGS Belgium NV 1639,



Virginie SILORET
Global Medical Device Certification Manager
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Devices covered by this letter:

Device name / Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
-Alvigon Plus Plastic Wound Probe 506003147WoundProbesCX	Class IIa	N/A	GB19/964734; GB19/964732; NB1639

Device name / Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
- Advadraw-T – Non adherent woven dressing 506003148AdvadrawTQE -Advasil Conform Silicone sheet 506003147AdvasilConformB4	Class Is	N/A	GB19/964734; GB19/964732; NB1639
Sterile Blood Filtration Devices: Hemosep Device – Blood Concentration Devices (1000mL and 500mL Cell Concentration Bags, tubing and resevoir) 506003148Hemosep9L -Activon - Honey Tube 506003148ActivonTubeRV -Activon Tulle – Honey/Woven Cellulose Dressing 506003147ActivonTulleJ2 -Algivon - Honey/Alginate Dressing 506003147Algivon62 -Algivon Plus - Honey/Alginate Dressing 506003147Algivon62 -Algivon Plus Ribbon - Honey/Alginate Dressing 506003147Algivon62 -Actilite – Honey Dressing 506003147ActiliteVE -Advazorb – Foam Dressing 506003147AdvazorbXM	Class IIb	N/A	GB19/964734; GB19/964732; NB1639

Device name / Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
-Advazorb Lite – Foam Dressing 506003147AdvazorbXM			
-Advazorb Silfix - Foam/Silicone Dressing 506003147AdvazorbXM			
-Advazorb Silfix Lite - Foam/Silicone Dressing 506003147AdvazorbXM			
-Advazorb Border - Foam/Silicone Dressing 506003147AdvazorbXM			
-Advazorb Border Lite - Foam/Silicone Dressing 506003147AdvazorbXM			
-Advazorb Heel 506003147AdvazorbXM			
Advazorb Fixation 506003147AdvazorbXM			
-Advazorb Plus T 506003147AdvazorbXM			
-Advazorb T Lite 506003147AdvazorbXM			
-Advazorb Sacral 506003147AdvazorbXM			
-Advazorb Areola 506003147AdvazorbXM			
-Eclipse Contour Eclipse - Super Absorbents/Hydrogel Dressing 506003147Eclipse8L			

Device name / Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
-Eclipse Adherent Sacral - Super Absorbents/Hydrogel Dressing 506003147Eclipse8L			
-Eclipse Boot & Foot - Super Absorbents/Hydrogel Dressing 506003147Eclipse8L			
-Eclipse - Super Absorbents/Hydrogel Dressing 506003147Eclipse8L			
Eclipse Boot 506003147Eclipse8L			
Eclipse Foot 506003147Eclipse8L			
Eclipse Contour 506003147Eclipse8L			
Eclipse Adherent 506003147Eclipse8L			
Eclipse Adherent Sacral Eclipse Border 506003147Eclipse8L			
Eclipse Border Oval 506003147Eclipse8L			
Eclipse Non Backed 506003147Eclipse8L			
Vellafilm – Silicone Dressing 506003147Vellafilm49			
Silflex – Silicone Dressing			

Device name / Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
506003147SilflexDK			

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2023/07/11	Version 1	Initial issue