

	Activon Manuka Honey Barrier Cream	
	Revision: 06	Page: 1 of 3
	Approved Date: 25 th September 2025	
EU Declaration of Conformity		

Statement of Use: Verify status before each use

This declaration is issued under the sole responsibility of Brightwake Limited (trading as Advancis Medical and Advancis Surgical).

We, the manufacturer hereby declare that the below-mentioned medical device complies with the relevant provisions of the European Communities' Council Regulation 2017/745/EC in accordance with Annex I, General Safety and Performance Requirements and Annex IX. This declaration is supported by the Quality System approval to ISO 13485 certified by KIWA.

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

Legal Manufacturer		Brightwake Limited (trading as Advancis Medical and Advancis Surgical)			
Legal Manufacturer Address		Lowmoor Business Park, Kirkby-in-Ashfield, Nottinghamshire, NG17 7JZ, UK			
SRN (Single Registration Number)		GB-MF-000012039			
Product Family		Activon Manuka Honey Barrier Cream			
Product/Trade Name		Activon Manuka Honey Barrier Cream			
Product Code		Reference schedule			
Intended Purpose		Activon Manuka Honey Barrier Cream is designed to moisturise and provide transparent, quick drying, protection from Moisture-Associated Skin Damage (MASD) on vulnerable, intact and mildly irritated/damaged skin. Its application helps to prevent irritation and skin breakdown from incontinence, other bodily fluids (sweat, wound exudate, stoma leakage), adhesive products, and friction.			
Basic UDI-DI		506003148ActivonBarrierLV			
GMDN Code	46206- Dry skin moisture barrier dressing	EMDN Code	M9002- Protective devices, lubricants and soothing devices (sprays, gels, fluids and creams)	CND Code (MDA/MDN)	M9002- Protective sprays and lubricant sprays (gel, fluid and cream) (MDN 1213)
Risk Classification – (according to Annex VIII of regulation 2017/745)		Class 1		Rule 1 (non-active, non-measuring, non-sterile)	
Sterilization Method		Non-sterile			
Conformity Assessment		Article 52, section 7 of the Medical Device Regulation 2017/745/EC			

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	Technical Documentation: Annex II and Annex III of regulation 2017/745
Common Specifications	None

Standards	• BS EN ISO 13485:2016+A11:2021 (Harmonized Version) • EN 1041:2008 (Harmonized Version) • ISO 20417:2021 • EN ISO 10993-1:2009/AC:2010 (Harmonized Version) • BS EN ISO 10993-1:2020 • ISO 10993-1: 2018 • EN ISO 10993-5:2009 (Harmonized Version) • EN ISO 10993-10:2013 • ISO 15223-1:2016 • ISO 15223-2:2010 • EN ISO 15223-1:2016 (Harmonized version) • EN ISO 15223-1:2021 (Harmonized version) • EN ISO 14971:2019 • EN ISO 14971:2019/A11:2021 (Harmonized Version) • ISTA 2A • MEDDEV 2.7/1 Rev.4 • MDR 2017/745	
Authorised Representative	CS Lifesciences Europe Limited	The Black Church, St Mary's Place, Dublin 7, Dublin, D07 P4AX, Ireland
	Email: eurep@cslifesciences.com	
	SRN (Single Registration Number)	
	IE-AR-000004113	
Notified Body for CE Mark	Not Applicable	Not Applicable
EC Certificate for CE Mark	Not Applicable	Not Applicable
Quality System Certificate	KIWA -Certificate No: M 12325	Expiry: 17 June 2027

Approved on behalf of Brightwake Limited (trading as Advancis Medical and Advancis Surgical)

Edwin Lindsay RA/QA Director	
Date, town, and country of signing	25 th of September 2025, Kirkby-in-Ashfield, United Kingdom

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Schedule: Product Codes/ Catalogue Numbers

Product Code/Catalogue Number	Description and Size
CR4546	Activon Manuka Honey Barrier Cream 100g
CR4552	Activon Manuka Honey Barrier Cream 10g