



Advanced Medical Solutions Ltd

Advanced Medical Solutions Ltd  
Premier Park, 33 Road One  
Winsford Industrial Estate  
Cheshire. CW7 3RT. UK  
Tel : +44 (0)1606 863500 Fax : +44 (0)1606 545669  
Web : [www.admedsol.com](http://www.admedsol.com)  
Registered in England 2666957

TF-E – 005, rev 01

## EC DECLARATION OF CONFORMITY IN RELATION TO URGO HYDROGEL

Advanced Medical Solutions Ltd. (Premier Park, 33 Road One, Winsford Industrial Estate, Winsford, Cheshire, CW7 3RT, United Kingdom) declares that the Class IIb medical devices manufactured by Advanced Medical Solutions as listed below:

PRODUCT NAME	Size
UrgoHydrogel	15g

- GMDN Code: 47764 – Hydrogel dressing, sterile

are in conformity with the essential requirements and provisions of Council Directive 93/42/EEC (Medical Devices Directive) amended by Directive 2007/47/EC, as transposed into UK Regulations (Statutory Instrument 2002 No. 618 and Statutory Instrument 2012 No. 1426) subject to and in conformity with the applicable provisions of Annex II, Full Quality Assurance Certificate (CE01699), under the supervision of our Notified Body, the British Standards Institution (0086).

Standards Applied: Refer to the relevant section of Technical File E (TF-E)

Issued in Winsford, UK.

  
\_\_\_\_\_  
Kay McGrath  
Regulatory Affairs Manager

\_\_\_\_\_  
7<sup>th</sup> February 2019  
Date

Doc reference: Technical File E for Amorphous Hydrogel (AHG-3) - TF-E, Revision 03, Issue Date: August-2017