By Royal Charter

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 695793**

Issued To: **Advanced Medical Solutions Limited**
Western Wood Way
Langage Science Park
Plymouth
Devon
PL7 5BG
United Kingdom

In respect of:

The design, development and manufacture of sterile cyanoacrylate tissue adhesives for topical application and hernia mesh fixation. Those aspects of Annex II concerned with securing and maintaining sterility of cyanoacrylate skin sealants and cyanoacrylate bandages.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Albert Roossien, Regulatory Lead

First Issued: **2018-08-15** Date: **2019-03-20** Expiry Date: **2024-03-20**

...making excellence a habit.™

bsi.

By Royal Charter

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 695793

Issued To:

Advanced Medical Solutions Limited
Western Wood Way
Langage Science Park
Plymouth
Devon
PL7 5BG
United Kingdom

Number	Device Name	Intended purpose per IFU
Class IIb		
58777	Hernia Mesh Fixation Devices	Internal application to affix mesh to abdominal wall with secondary use of peritoneal closure and topical wound closure
Class IIa		
34164	Topical Wound Closure Devices	Topical application to hold wounds closed
Class Is		
46700	Microbial Barrier Devices	Topical application to intact skin to immobilise skin flora

First Issued: **2018-08-15** Date: **2019-03-20** Expiry Date: **2024-03-20**

...making excellence a habit.™