

EC Certificate - Full Quality Assurance System

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

No. CE 585408
Issued To: **Advanced Medical Solutions
(Plymouth) 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 0086):



Gary Fenton, Global Assurance Director

First Issued: **03 July 2012**

Date: **17 July 2014**

Expiry Date: **20 March 2019**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.