

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 (with and without wound closure strips) 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):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2018-08-15**

Date: **2020-06-26**

Expiry Date: **2024-03-20**

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Page 1 of

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.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

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Supplementary Information to CE 695793

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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		
MD 0303	Topical Cyanoacrylate Wound Closure Devices	NA for class IIa devices
MD 0303 MD 0302	Topical Cyanoacrylate Wound Closure Devices with wound closure strips	NA for class IIa devices
Class Is		
MD 0303	Microbial Barrier Devices	NA for class Is devices

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Page 2 of

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