

# Certificate



## Production Quality Assurance

No. CE 522599

Issued to:

**Adhezion Biomedical, LLC**  
506 Pine Mountain Road  
Hudson  
North Carolina  
28638  
USA

In respect of:

**The manufacture of cyanoacrylate wound closure tissue adhesive.**

on the basis of our examination under the requirements of Council Directive 93/42/EEC, Annex V, Section 3.2.

For and on behalf of the British Standards Institution, a Notified Body for the above Directive (Notified Body Number 0086):

Alastair Trivett, Managing Director, BSI Product Services – Global

First Issued: 1 Feb 2008

Date: 28 Apr 2008

Expiration Date: 31 Jan 2013

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**Conditions of Approval**

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive. 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.

## List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No. **CE 522599**  
Date: **28 Apr 2008**  
Issued to: **Adhezion Biomedical, LLC**  
**Hudson**  
**USA**

### Subcontractor

### Service(s) supplied

BeamOne LLC  
500 West 4th Street  
Lima  
OH 45804  
USA

E beam Sterilization

Klocke of America Inc, LLC  
14201 Jetport Loop  
Fort Myers  
Florida  
USA  
33913

Manufacture  
Packaging

## History of Quality Assurance Certificate

**Certificate No:** CE 522599  
**Issue Date:** 28 Apr 2008  
**Issued to:** Adhezion Biomedical, LLC  
Hudson  
USA

Date	Reference Number	Action
1 February 2008	7058677	First Issue
28 April 2008	7184110	Change of company name from 'Spartan Medical Products, LLC' to 'Adhezion Biomedical LLC'

BSI®  
Product Services