

## Surgical Specialties Corporation

100 Dennis Drive, Reading,  
PA 19606, USA

Device Identification:  
**Monoderm™ Synthetic Absorbable Surgical Suture**

Medical Purpose of Device:  
**For use in general soft tissue approximation and/or ligation, but not for  
use in cardiovascular or neurological tissues, microsurgery or  
ophthalmic surgery.**

has been assessed and certified as meeting the requirements of

## EC Directive 93/42/EEC

on Medical Devices Annex II, section 4

It is certified that the manufacturer's design dossier (and product, where applicable) for the above device has been examined and, based on the evidence submitted, it is considered that the device conforms to the relevant Essential Requirements of EC Directive 93/42/EEC.

This certificate is issued in conjunction with a certificate covering the full quality assurance system to Annex II, which must be subject to regular compliance visits.

This certificate is valid from 08 March 2006 until 08 March 2011  
Issue 1

Certification is based on report number(s) PC DDE 213551 dated 17 February 2006

Addenda to that report have been issued on the following dates:

Addendum Date  
N/A

Reason for Addendum  
N/A

Notified Body Number 0120

Authorised by



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