

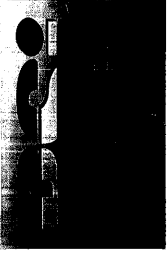
EC Certificate

Design Examination

No. CE 507064

Issued to:

**Smith & Nephew Inc.
Endoscopy Division
150 Minuteman Road
Andover
Massachusetts
01810-1031
USA**



In respect of:

**PLLA Suture Anchors BioRaptor 2.9mm Suture Anchor with Ultrabraid Co-Braid Suture
and TwinFix AB with Ribbed Handle**

on the basis of our examination under the requirements of Council Directive 93/42/EEC, Annex II, Section 4.

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: 30 Jun 2006

Date: 29 Jun 2007

Expiration Date: 29 Jun 2011

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EC Certificate

Supplementary Information to CE 507064

Issued to:
Smith & Nephew Inc.
Endoscopy Division
Andover
USA

Model #	Description
7210705	BIORAPTOR 2.9mm Suture Anchor with one ULTRABRAID Suture
7210706	BIORAPTOR 2.9mm Suture Anchor with two ULTRABRAID Suture
72200801	BIORAPTOR 2.9mm Suture Anchor, Hip with one ULTRABRAID Suture
72200774	BIORAPTOR 2.9mm Suture Anchor with one 38" ULTRABRAID Co-Braid Suture (#2)
72200775	BIORAPTOR 2.9mm Suture Anchor with two 38" ULTRABRAID Suture (#2)
72200777	TWINFIX AB 5.0mm Suture Anchor, PLLA, with two #2 preloaded ULTRABRAID Sutures
72200778	TWINFIX AB 5.0mm Suture Anchor, PLLA, with two #2 preloaded ULTRABRAID Sutures, packaged with 5.0mm threaded dilator with inserter guide
72200779	TWINFIX AB 6.5mm Suture Anchor, PLLA, with two #2 preloaded ULTRABRAID Sutures
72200780	TWINFIX AB 6.5mm Suture Anchor, PLLA, with two #2 preloaded ULTRABRAID Sutures, packaged with 5.0mm threaded dilator
72200785	TWINFIX AB 5.0mm Suture Anchor, PLLA, with two #2 preloaded DURABRAID Sutures
72200786	TWINFIX AB 5.0mm Suture Anchor, PLLA, with two #2 preloaded DURABRAID Sutures, packaged with 5.0mm threaded dilator with inserter guide

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Model #	Description
72200787	TWINFIX AB 6.5mm Suture Anchor, PLLA, with two #2 preloaded DURABRAID Sutures
72200788	TWINFIX AB 6.5mm Suture Anchor, PLLA, with two #2 preloaded DURABRAID Sutures, packaged with 5.0mm threaded dilator

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History of Certificate

Date	Reference Number	Action
30 June 2006	10079536	First issue
22 September 2006	10081052	Addition of TwinFix AB with ribbed handle
29 June 2007	10089315	Addition of 2 catalogue numbers "72200774 & 72200775".

First Issued: 30 Jun 2006
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29th June 2007

Julie Acker
Smith & Nephew Inc.
Endoscopy Division
150 Minuteman Road
Andover
Massachusetts
01810-1031
USA

Dear Julie Acker

Design Examination Certificate

Following the examination of the amendments to the design dossier for PLLA Suture Anchors BioRaptor 2.9mm Suture Anchors with Ultrabraid Co-Braid Suture, I am pleased to confirm to Smith & Nephew Inc. that BSI has reissued your design examination certificate in accordance with Annex II Section 4 of the Medical Device Directive (93/42/EEC). The details and scope of the approval are set out in the attached certificate CE 507064 (3 copies enclosed).

It is a requirement of the above Directive that BSI as your Notified Body is informed of any modification made to the approved design and where it affects conformity with the essential requirements of this Directive or the conditions prescribed for use of this product, supplementary approval must be obtained.

If you have any questions please do not hesitate to contact Shahida Kumar.

Yours sincerely



Suzanne Halliday
Product Specialist - Orthopaedics TL
BSi Notified Body, Healthcare

Encs - CE 507064
By courier- UPS