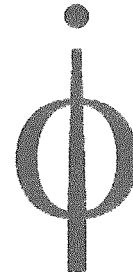


Declaration of Conformity

EC Declaration of Conformity
under the Medical Devices
Directive 93/42/EEC.



Intelligent Orthopaedics

PO Box 2681
Stoke on Trent
UK ST4 9BE

T +44 (0) 17 82 84 78 40

www.intelligent-orthopaedics.co.uk

Product: Bone Screw

Part Number: SIBS & SIBS - S

Details of product:

Single use bone screw for use with Intelligent
Orthopaedics Fracture Management Devices (t < 60 minutes)

EC Product Class Analysis:

Annex IX: Rule 6
Transient Use surgically invasive device
Class IIa

Notified Body

Amtac Medica

Technical Files are held at Intelligent Orthopaedics Ltd.

A Complaints and Vigilance Procedure is in action and details are supplied
with the purchase contract, they may also be obtained from <http://www.intelligent-orthopaedics.co.uk>.

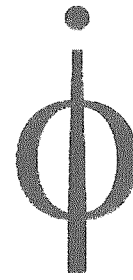
Approved by:

Date:

Dr C Ian Moorcroft
Technical Director
Intelligent Orthopaedics Ltd.

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Product: Bone Twist Drill
Part Number: SITD - DDDLLLSSS
Details of product:

Single use bone twist drill for use with Intelligent
Orthopaedics Fracture Management Devices (t < 60 minutes)

DDD = diameter

LLL = overall length

SSS = drill flute length

EC Product Class Analysis:

Annex IX: Rule 6

Transient Use surgically invasive device

Class IIa

Notified Body

Amtac Medica

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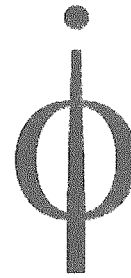
Approved by: 

Date: 4/1/06.

Dr C Ian Moorcroft
Technical Director
Intelligent Orthopaedics Ltd.

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Product: Kirschner Tension Wire
Part Number: SITW - DDDLLLSS
Details of product:

Single use 'kirschner' wire for use with Intelligent
Orthopaedics Fracture Management Devices

DDD = diameter

LLL = overall length

SS = tip style

EC Product Class Analysis:

T < 30 days Annex IX: Rule 7

Short Term Use surgically invasive device

T > 30 days Annex IX: Rule 8

Long Term Use surgically invasive device

Class IIb

Notified Body

Amtac Medica

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Approved by:

Date:

4/11/06

Dr C Ian Moorcroft
Technical Director
Intelligent Orthopaedics Ltd.

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