



Health Technology Certification



# EC-CERTIFICATE

## FULL QUALITY ASSURANCE SYSTEM

This is to certify that the quality management system of

### ORTHO CAPE

13 Rue Mespoul, Toulouse,  
Occitanie 31400, France

for design and manufacture of

**Implantable orthopedic devices and surgical instruments for foot surger.**

*Further details are given overleaf*

fulfills the requirements of Annex II excluding (4) of Council Directive 93/42/EEC.

The use of CE Marking followed by the HTCert Notified Body identification number 2803 for the devices listed on the certificate is hereby authorised. The certificate remains valid subject to satisfactory surveillance audits, periodic or unexpected. Any significant changes in design or manufacture may render this certificate invalid. For class III devices covered by this certificate an EC Design Examination Certificate according to Annex II, Section 4 is required. For class I sterile devices the certificate covers only the aspects of manufacture concerned with securing and maintaining sterile conditions. For class I devices with a measuring function the certificate covers only the aspects of manufacture concerned with the conformity of the products with metrological requirements.

**Certificate No:** 3585C04210501  
**Issue Date:** 25/05/2021  
**Original Approval:** 25/05/2021  
**Valid until:** 26/05/2024  
**References:** W001 3585 01

HTCert is a Notified Body according to Council Directive 93/42/EEC concerning medical devices with identification number 2803

For and on behalf of HTCert

**GEORGE PAPPOUS**  
Managing Director

**FILIPPOS KOTTIS**  
Certification Director

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## Attachment to Certificate

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### Products included:

#### Class IIa products

#### INSTRUMENTS

##### PERCUTANEOUS BURR Ø2.32

- SHANNON SHORT BURR 2X8
- SHANNON LONG BURR 2X12
- SHANNON ISHAM BURR 2X12
- WEDGE BURR 3.1X13
- WEDGE BURR 4.1X13
- BROPHY BURR 5X15
- SHANNON XL BURR 2X20
- SHANNON XXL BURR 3X20
- SHANNON XXL BURR 3X30 LG 100
- CONICAL BURR 3.1

#### DRILLS

- AO PPDA SHORT DRILL
- AO PPDA LONG DRILL
- AO MINI PPDA SHORT DRILL
- AO MINI PPDA LONG DRILL
- DRILL FOR MI-SCREW Ø 3MM
- DRILL FOR HEAD MI-SCREW Ø 3MM
- DRILL FOR MI-SCREW Ø 4MM
- DRILL FOR HEAD MI-SCREW Ø 4MM
- DRILL AO MYSCREW
- DRILL AO MYSCREW XL
- DRILL EAGLE / ARTHROSTAB 4.6
- DRILL HEAD EAGLE / ARTHROSTAB 4.6
- DRILL EAGLE / ARTHROSTAB 7
- DRILL HEAD EAGLE / ARTHROSTAB 7

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### SCREWDRIVER BLADE AO

SHORT SCREWDRIVER BLADE

SCREWDRIVER BLADE FOR MI-SCREW Ø 3MM & PPDA Ø 2.6 & 3MM

SCREWDRIVER BLADE FOR MI-SCREW Ø 4MM

SCREWDRIVER BLADE TORX 7 CANNULATED

SCREWDRIVER BLADE TORX 7

SCREWDRIVER BLADE MISS

SCREWDRIVER BLADE EAGLE / ARTHROSTAB 4.6

SCREWDRIVER BLADE EAGLE / ARTHROSTAB 7

SCREWDRIVER BLADE TAKE-OFF EAGLE / ARTHROSTAB 7

### Class IIb products

#### IMPLANTS

#### PPDA Ø 3 SCREWS

DIAMETER: 4 MM (HEAD) AND 3MM (BODY)

LENGTHS: 10MM / 12MM / 14MM / 16MM / 18MM / 20MM / 22MM / 24MM / 26MM / 28MM / 30MM / 32MM / 34MM

HEAD: HEX 2MM – CANNULATED SCREW

#### PPDA Ø 2.6 SCREWS

DIAMETER: 3.6 MM (HEAD) AND 2.6MM (BODY)

LENGTHS: 10MM / 12MM / 14MM / 16MM / 18MM / 20MM / 22MM / 24MM / 26MM / 28MM / 30MM / 32MM / 34MM

HEAD: HEX 2MM – CANNULATED SCREW

#### MI-SCREW Ø 3

DIAMETER: 4 MM (HEAD) AND 3 MM (BODY)

LENGTHS: 18MM / 20MM / 22MM / 24MM / 26MM / 28MM / 30MM / 32MM / 34MM / 36MM / 38MM / 40MM / 42MM / 44MM / 46MM / 48MM / 50MM / 52MM / 54MM / 56MM / 58MM / 60MM

HEAD: HEX 2MM – CANNULATED SCREW





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### MI-SCREW Ø 4

DIAMETER: 5MM (HEAD) AND 4MM (BODY)

LENGTHS: 32MM / 34MM / 36MM / 38MM / 40MM / 42MM / 44MM / 46MM / 48MM / 50MM / 52MM / 54MM / 56MM / 58MM / 60MM

HEAD: HEX 2.5MM – CANNULATED SCREW

### MY-SCREW

DIAMETER: 3.4 MM (HEAD) AND 2.5MM (BODY)

LENGTHS: 10MM / 12MM / 14MM / 16MM / 18MM / 20MM / 22MM / 24MM / 26MM / 28MM / 30MM / 32MM / 34MM

HEAD: TORX 7 – CANNULATED SCREW

### MISS SCREW (SELF-BREAKING SCREWS)

DIAMETER: 2MM

LENGTHS: 13MM / 15MM / 17MM / 19MM / 22MM

### VARIZATION STAPLES (INOX 316L)

90° - 10MM

90° - 8MM

26° - 10MM

26° - 8MM

### EAGLE Ø 4.6 TITANIUM SCREWS

DIAMETER: 4.6MM

LENGTHS: 20 TO 60MM

### EAGLE Ø 7 TITANIUM SCREWS

DIAMETER: 7MM

16MM THREAD WITH 30 TO 90MM LENGTH

22MM THREAD WITH 55 TO 90MM LENGTH

28MM THREAD WITH 70 TO 90MM LENGTH

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### ARTHROSTAB Ø 4.6 TITANIUM SCREWS

DIAMETER: 4,6MM

LENGTHS: 20 TO 60MM

### ARTHROSTAB Ø 7 TITANIUM SCREWS:

DIAMETER: 7MM

LENGTHS: 30 TO 90MM

### PIN (K-WIRE) (STAINLESS STEEL 316L)

PIN 1 TIP 10/10 – 70MM

PIN THREADED 15/10 150MM

PIN 1 TIP 18/10 – 150MM

PIN 1 TIP 20/10 – 150MM

PIN 1 TIP 25/10 – 150MM

PIN 1 TIP 20/10 – 200MM

PIN 1 TIP 15/10 – 200MM

PIN 1 TIP 22/10 – 200MM

PIN 1 TIP 30/10 – 200MM

PIN 2 TIP 10/10 – 105MM

PIN 2 TIP 12/10 – 150MM

PIN THREADED 15/10 200MM

PIN 2 TIP 10/10 – 100MM

PIN 1 TIP 12/10 – 150MM

PIN 2 TIP 8/10 – 80MM

PIN 2 TIP 8/10 – 200MM

PIN 2 TIP 10/10 – 200MM

PIN 2 TIP 12/10 – 200MM

PIN 2 TIP 15/10 – 300MM

PIN 2 TIP 8/10 – 70MM

PIN 1 TIP 12/10 – 100MM

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PIN 1 TIP 20/10 – 120MM  
PIN 1 TIP 15/10 – 150MM  
PIN THREADED 1 TIP 22/10 – 200MM  
PIN 1 TIP 24/10 – 230MM  
PIN 1 TIP 24/10 – 200MM  
PIN 1 TIP 10/10 – 150MM

### PIN WITH BALL (STAINLESS STEEL 316L)

1 THREADED PIN  
LENGTH: 150MM  
DIAMETER: 1MM / 1.2MM / 1.5MM / 1.8MM / 2MM  
BALL DIAMETER: 5MM

For and on behalf of HTCert

**GEORGE PAPPOUS**  
Managing Director

A blue ink signature of George Pappous, written in a cursive style.

**FILIPPOS KOTTIS**  
Certification Director

A blue ink signature of Filippos Kottis, written in a cursive style.

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