Ortho Cape
172 Imp. Louis Lépine
Montauban, 82000, France

Date: 15 May 2024

Confirmation Letter
Reference: FR_028862_2024_01

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, HTCert, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 2803 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR from the following manufacturer:

Ortho Cape
172 Imp. Louis Lépine
Montauban, 82000, France
SRN: FR-MF-000028862

Application ID: FR_028862_24_04_03
Application Date: 02/05/2024

The devices covered by the formal application mentioned above are identified below. HTCert is also responsible for appropriate surveillance under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function

- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body,

Filippos Kottis
Certification Director

Devices covered by this letter

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Screws forefoot - PPDA	IIb	n/a	3585C04210501 NB 2803
Screws forefoot - MI- Screw	IIb	n/a	3585C04210501 NB 2803
Screws forefoot - MY- Screw	IIb	n/a	3585C04210501 NB 2803
Screws forefoot - MISS- Screw	IIb	n/a	3585C04210501 NB 2803
Screws Hind & Midfoot - Eagle Screw	IIb	n/a	3585C04210501 NB 2803
Screws Hind & Midfoot - Arthrostab Screw	IIb	n/a	3585C04210501 NB 2803
Self-breaking screws	IIb	n/a	3585C04210501 NB 2803
Varization staples	IIb	n/a	3585C04210501 NB 2803
Pin K-Wires	IIb	n/a	3585C04210501 NB 2803
Percutaneous Burr	IIa	n/a	3585C04210501 NB 2803
Drills	IIa	n/a	3585C04210501 NB 2803
Screwdriver	IIa	n/a	3585C04210501 NB 2803

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/05/15	FR_028862_2024_01	Initial issue

HTCert

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

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 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.

For and on behalf of HTCert

GEORGE PAPPOUS
Managing Director

FILIPPOS KOTTIS
Certification Director

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Health Technology Certification

Attachment to Certificate

No: 3585C04210501 **Issued:** 25/05/2021

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 A0

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 CANULATED

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

FILIPPOS KOTTIS
Certification Director

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