



Deklaracja zgodności / Dokument specjalny, CE 621227 Śruby biowchłaniające

Linia produktowa Dossier Arthrex, Śruby biowchłaniające

Numer certyfikatu badania CE 621227

projektu

Nazwa i numer Jednostki

Notyfikowanej BSI 2797

Klasa MDD Klasa III, Reguła 8

Numery katalogowe Patrz dołączony wykaz

Producent Arthrex, Inc.

1370 Creekside Boulevard

Naples, FL 34108-1945 USA

Przedstawiciel w UE Arthrex GmbH

Erwin-Hielscher-Strasse 9



81249 Monachium, Niemcy

Dyrektywa 93/42/EWG

Ścieżka oceny zgodności Załącznik II (z włączeniem sekcji 4)

Oświadczenie do deklaracji zgodności: Niżej podpisany oświadcza, że wyżej wymienione urządzenia są zgodne z Europejską Dyrektywą dotyczącą Urządzeń Medycznych 93/42/EWG.

Upoważniony sygnatariusz, pieczęć:

Imię i nazwisko:	David L. Rogers
Stanowisko:	Dyrektor ds. Regulacyjnych Arthrex Inc
Podpis:	 
Data:	2022-01-06



Declaration of Conformity / Special DoC, CE 621227 Bio-Screws

Product Line Arthrex Dossier, Bioabsorbable Screws

**Design Examination
Certificate Number** CE 621227

Notified Body name & no. BSI 2797

MDD Class Class III, Rule 8

Catalog Numbers See attached list

Manufacturer Arthrex, Inc.
1370 Creekside Boulevard
Naples, FL 34108-1945 USA



EC Representative Arthrex GmbH
Erwin-Hielscher-Strasse 9
81249 München, Germany

Directive 93/42/EEC

Conformity route Annex II (including section 4)

Conformity Declaration Statement: The undersigned hereby declares that the above mentioned devices comply with the European Medical Device Directive 93/42/EEC.

Authorised Signatory, stamp:

Name:	David L. Rogers
Job Title:	Director Regulatory Affairs Arthrex Inc
Signature:	  1370 Creekside Boulevard Naples, Florida 34108-1945
Date:	2022-01-06

Catalogue Numbers	Device Descriptions
AR-1351C-01	Bio-Composite TransFix®, 5 x 40 mm
AR-1351C-02	Bio-Composite TransFix®, 5 x 50 mm
AR-1351LB	BIO-TRANSFIX
AR-1351LBT	BIO-TRANSFIX
AR-1360B	Bio-Interference Screw with Disposable Sheath, 6 x 23 mm
AR-1360C	Bio-Composite Interference Screw, Tapered Tip with Disposable Sheath, 6 x 23 mm
AR-1370B	Bio-Interference Screw with Disposable Sheath, 7 x 23 mm
AR-1370C	Bio-Composite Interference Screw with Disposable Sheath, 7 x 23 mm
AR-1370TB	Bio-Interference Screw, Full Thread 7 x 28 mm
AR-1370TC	Bio-Composite Interference Screw, Full Thread 7 x 28 mm
AR-1380B	Bio-Interference Screw with Disposable Sheath, 8 x 23 mm
AR-1380C	Bio-Composite Interference Screw with Disposable Sheath, 8 x 23 mm
AR-1380TB	Bio-Interference Screw, Full Thread 8 x 28 mm
AR-1380TC	Bio-Composite Interference Screw, Full Thread 8 x 28 mm
AR-1390B	Bio-Interference Screw with Disposable Sheath, 9 x 23 mm
AR-1390C	Bio-Composite Interference Screw with Disposable Sheath, 9 x 23 mm
AR-1390TB	Bio-Interference Screw, Full Thread 9 x 28 mm
AR-1390TC	Bio-Composite Interference Screw, Full Thread 9 x 28 mm
AR-1400B	Bio-Interference Screw with Disposable Sheath, 10 x 23 mm
AR-1400C	Bio-Composite Interference Screw with Disposable Sheath, 10 x 23 mm
AR-1400TB	Bio-Interference Screw, Full Thread 10 x 28 mm
AR-1400TC	Bio-Composite Interference Screw, Full Thread 10 x 28 mm
AR-1403TB	Bio-Interference Screw, Full Thread 11 x 28 mm
AR-1403TC	Bio-Composite Interference Screw, Full Thread 11 x 28 mm
AR-1404TB	Bio-Interference Screw, Full Thread 12 x 28 mm
AR-1404TC	Bio-Composite Interference Screw, Full Thread 12 x 28 mm
AR-1530BC	Tenodesis Screw™, BioComposite with Handled Inserter, 3 x 8 mm
AR-1540BC	Tenodesis™ Screw, BioComposite 4 x 10 mm

AR-1540CDS	BioComposite-Tenodesis™ Screw with Disposable Driver Pack, 4x10mm
AR-1540CDS-1	BioComposite-Tenodesis™ Screw with Disposable Driver Pack, 4x10mm
AR-1547BC	Tenodesis™ Screw, BioComposite 4.75 x 15 mm
AR-1547CDS	BioComposite-Tenodesis™ Screw with Disposable Driver Pack, 4.75x15mm
AR-1547CDS-1	BioComposite-Tenodesis™ Screw with Disposable Driver Pack, 4.75x15mm
AR-1555BC	Tenodesis™ Screw, BioComposite 5.5 x 15 mm
AR-1555CDS	BioComposite™ Tenodesis Screw™ with Disposable Driver Pack, 5.5x15mm
AR-1555CDS-1	BioComposite-Tenodesis™ Screw with Disposable Driver Pack, 5.5x15mm
AR-1555DS	Bio-Tenodesis™ Screw with Disposable Drive Pack, 5.5 x 15 mm
AR-1555DS-1	Bio-Tenodesis™ Screw with Disposable Driver Pack, 5.5x15mm
AR-1562BC	Tenodesis™ Screw, BioComposite 6.25 x 15 mm
AR-1562CDS	BioComposite-Tenodesis™ Screw with Disposable Driver Pack, 6.25x15mm
AR-1562CDS-1	BioComposite-Tenodesis™ Screw with Disposable Driver Pack, 6.25x15mm
AR-1570BC	Tenodesis™ Screw, BioComposite 7 x 23 mm
AR-1580BC	Tenodesis™ Screw, BioComposite 8 x 23 mm
AR-1586FRB-07	RetroScrew®, Femoral 7 x 20 mm
AR-1586FRB-08	RetroScrew®, Femoral 8 x 20 mm
AR-1586FRB-09	RetroScrew®, Femoral 9 x 20 mm
AR-1586FRB-10	RetroScrew®, Femoral 10 x 20 mm
AR-1586LB-07	RetroScrew®, Reverse Thread 7 x 20 mm
AR-1586LB-08	RetroScrew®, Reverse Thread 8 x 20 mm
AR-1586LB-09	RetroScrew®, Reverse Thread 9 x 20 mm
AR-1586LB-10	RetroScrew®, Reverse Thread 10 x 20 mm
AR-1586RB-06	RetroScrew®, Tibial 6 x 20 mm
AR-1586RB-07	RetroScrew®, Tibial 7 x 20 mm
AR-1586RB-08	RetroScrew®, Tibial 8 x 20 mm
AR-1586RB-09	RetroScrew®, Tibial 9 x 20 mm
AR-1586RB-10	RetroScrew®, Tibial 10 x 20 mm
AR-1586RC-07	BioComposite RetroScrew®, Reverse Thread 7 x 20 mm
AR-1586RC-08	BioComposite RetroScrew®, Reverse Thread 8 x 20 mm
AR-1586RC-09	BioComposite RetroScrew®, Reverse Thread 9 x 20 mm
AR-1586RC-10	BioComposite RetroScrew®, Reverse Thread 10 x 20 mm

AR-1590BC	Tenodesis™ Screw, BioComposite 9 x 23 mm
AR-1670BC	Tenodesis™ Screw, BioComposite 7 x 10 mm
AR-1680BC	Tenodesis™ Screw, BioComposite 8 x 12 mm
AR-4005B-18	Chondral Dart, 18mm
AR-4020C-06	FastThread™ BioComposite™ Interference Screw with Disposable Sheath, 6x20mm
AR-4020C-07	FastThread™ BioComposite™ Interference Screw with Disposable Sheath, 7x20mm
AR-4020C-08	FastThread™ BioComposite™ Interference Screw with Disposable Sheath, 8x20mm
AR-4020C-09	FastThread™ BioComposite™ Interference Screw with Disposable Sheath, 9x20mm
AR-4020C-10	FastThread™ BioComposite™ Interference Screw with Disposable Sheath, 10x20mm
AR-4030C-07	FastThread™ BioComposite™ Interference Screw, 7x30mm
AR-4030C-08	FastThread™ BioComposite™ Interference Screw, 8x30mm
AR-4030C-09	FastThread™ BioComposite™ Interference Screw, 9x30mm
AR-4030C-10	FastThread™ BioComposite™ Interference Screw, 10x30mm
AR-4030C-11	FastThread™ BioComposite™ Interference Screw, 11x30mm
AR-4030C-12	FastThread™ BioComposite™ Interference Screw, 12x30mm
AR-4151B	Trim-It Drill Pin®, 1.5 x 100 mm
AR-4151DS	Implant Delivery System, TRIM-IT Drill Pin®, 1.5 x 100 mm [.062" x 4"] with one Pin, on K-Wire, one Tamp, and on Guide Sleeve
AR-4152B	Trim-It Drill Pin®, 2.0 x 100mm [.078" x 4"]
AR-4152DS	Implant System, TRIM-IT Drill Pin®, 2 x 100 mm [.078" x 4"] with one Pin, one Tamp, and one Guide Sleeve
AR-4156DS	Implant Delivery System, TRIM-IT™ Spin Pin™, 2 x 100 mm [.078" x 4"] with Disposable Ruler
AR-5025B-16	Bio-Compression Screw, 3 x 16 mm
AR-5025B-18	Bio-Compression Screw, 3 x 18 mm
AR-5025B-20	Bio-Compression Screw, 2.7 x 20 mm
AR-5025B-22	Bio-Compression Screw, 3 x 22 mm
AR-5025B-24	Bio-Compression Screw, 3 x 24 mm
AR-5025B-26	Bio-Compression Screw, 3 x 26 mm
AR-5028B-08	Bio-Interference Screw Round Delta Tapered with Disposable Sheath, 8 x 28 mm
AR-5028B-09	Bio-Interference Screw Round Delta Tapered with Disposable Sheath, 9 x 28 mm
AR-5028B-10	Bio-Interference Screw Round Delta Tapered with Disposable Sheath, 10 x 28 mm
AR-5028B-11	Bio-Interference Screw Round Delta Tapered with Disposable Sheath, 11 x 28 mm

AR-5028C-08	Bio-Composite Interference Screw Round Delta Tapered with Disposable Sheath, 8 x 28 mm
AR-5028C-09	Bio-Composite Interference Screw Round Delta Tapered with Disposable Sheath, 9 x 28 mm
AR-5028C-10	Bio-Composite Interference Screw Round Delta Tapered with Disposable Sheath, 10 x 28 mm
AR-5028C-11	Bio-Composite Interference Screw, Round Delta Tapered 11 x 28 mm
AR-5035TB-09	Bio-Interference Screw Cannulated Delta Tapered, 9 x 35 mm
AR-5035TB-10	Bio-Interference Screw Cannulated Delta Tapered, 10 x 35 mm
AR-5035TB-11	Bio-Interference Screw Cannulated Delta Tapered, 11 x 35 mm
AR-5035TB-12	Bio-Interference Screw Cannulated Delta Tapered, 12 x 35 mm
AR-5035TC-09	Bio-Composite Interference Screw Cannulated Delta Tapered, 9 x 35 mm
AR-5035TC-10	Bio-Composite Interference Screw Cannulated Delta Tapered, 10 x 35 mm
AR-5035TC-11	Bio-Composite Interference Screw Cannulated Delta Tapered, 11 x 35 mm
AR-5035TC-12	Bio-Composite Interference Screw Cannulated Delta Tapered, 12 x 35 mm
AR-1562CDS-1	BioComposite Tenodesis Screw with Disposable Driver Pack, 6.25 x 15 mm
AR-1351B	Bio-TransFix®, 5 x 40 mm
AR-1351BT	Bio-TransFix®, Bone Tendon, 3 x 40 mm