



1. Deklaracja zgodności

Karta techniczna **Kotwy**

Kody GMDN Pełna lista wszystkich kodów GMDN objętych niniejszą kartą techniczną
znajduje się w Liście części, wersja 33

Wersja 33

Klasa MDD, Reguła Klasa IIb, Reguła 8

Ścieżka zgodności Załącznik II (z wyłączeniem Sekcji 4)

Jednostka BSI / CE 2797

Notyfikowana/Numer (Poprzednio – BSI / CE 0086)

Producent Arthrex, Inc.
1370 Creekside Boulevard
Naples, FL 34108 USA

Przedstawiciel w Unii Arthrex GmbH
Europejskiej Erwin-Hielscher-Strasse 9
81249 Monachium, Niemcy

1.1. Oświadczenie dotyczące Deklaracji Zgodności

Niżej podpisany oświadcza, że wyżej wymienione wyroby medyczne są zgodne z odpowiednimi sekcjami Dyrektywy 93/42/EWG w sprawie urządzeń medycznych.

William Heard

Przedstawiciel ds. Zarządzania Regulacjami Prawnymi

Data

1.2. Wykaz urządzeń wg numerów katalogowych

Wykaz Urządzeń wg numerów katalogowych znajduje się w Części B.

Section

1

1. Declaration of Conformity

Technical File	Anchors
GMDN Codes	Refer to Parts List Rev. 33 for a complete list of all GMDN Codes subject of this Technical File
Revision	33
MDD Class, Rule	Class IIb, Rule 8
Route of Compliance	Annex II (excluding Section 4)
Notified Body / Number	BSI / CE 2797 (Formerly - BSI / CE 0086)
Manufacturer	Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108 USA
EC Representative	Arthrex GmbH Erwin-Hielscher-Strasse 9 81249 München, Germany

1.1. Conformity Declaration Statement

The undersigned hereby declares that the medical devices specified above conform to relevant sections of the Medical Device Directive 93/42/EEC.

 

William Heard

Date

Regulatory Management Representative

1.2. List of Devices by Catalog Number

The *List of Devices by Catalog Number* is in Part B.

Manufacturer Name	Manufacturing Location	EC QA Cert. Number	Product Code	Product Name	Class	TF	Rule	Annex	First DoC
Corkscrew and Corkscrew II									
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1902SF	Suture Anchor, Corkscrew® II with #2 FiberWire® and #2 TigerWire®	IIb	ANCHORS	8	II	9/14/2002
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1902SF-1	Suture Anchor, Corkscrew® II with #2 FiberWire® and #2 TigerWire® (1 pack)	IIb	ANCHORS	8	II	8/20/2012
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1915S	Suture Anchor, Corkscrew® With # 2 Braided Polyester Suture	IIb	ANCHORS	8	II	6/8/2002
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1915S-1	Suture Anchor, Corkscrew® With # 2 Braided Polyester Suture (1 pack)	IIb	ANCHORS	8	II	8/20/2012
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1915SF	Suture Anchor, Corkscrew® With # 2 FiberWire®	IIb	ANCHORS	8	II	9/14/2002
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1915SF-1	Suture Anchor, Corkscrew® With # 2 FiberWire® (1 pack)	IIb	ANCHORS	8	II	8/20/2012
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1915SNF	Suture Anchor, Corkscrew® With Two Size 0 FiberWire® each with two 1/2 Circle Diamond Point Needles	IIb	ANCHORS	8	II	11/15/2004
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1915SNF-1	Suture Anchor, Corkscrew® With Two Size 0 FiberWire® each with two 1/2 Circle Diamond Point Needles (1 pack)	IIb	ANCHORS	8	II	8/20/2012
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1920NSF	Suture Anchor, Corkscrew® With attached #2 FiberWire® and #2 TigerWire®, each with two 1/2 Circle Diamond Point Needles	IIb	ANCHORS	8	II	9/14/2002
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1920NSF-1	Suture Anchor, Corkscrew® With attached #2 FiberWire® and #2 TigerWire®, each with two 1/2 Circle Diamond Point Needles (1 pack)	IIb	ANCHORS	8	II	8/20/2012
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1920S	Suture Anchor, Corkscrew® With # 2 Braided Polyester Suture	IIb	ANCHORS	8	II	6/8/2002
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1920S-1	Suture Anchor, Corkscrew® With # 2 Braided Polyester Suture (1 pack)	IIb	ANCHORS	8	II	8/20/2012
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1920SF	Suture Anchor, Corkscrew® with #2 FiberWire® and #2 TigerWire®	IIb	ANCHORS	8	II	9/14/2002
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1920SF-1	Suture Anchor, Corkscrew® with #2 FiberWire® and #2 TigerWire® (1 pack)	IIb	ANCHORS	8	II	8/20/2012
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1920SNF	Suture Anchor Corkscrew® With #1 FiberWire® and #1 TigerWire®, each with two 1/2 Circle Diamond Point Needles, Ti	IIb	ANCHORS	8	II	11/30/2010
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1920SNF-1	Suture Anchor, Corkscrew® With #1 FiberWire® and #1 TigerWire®, each with two 1/2 Circle Diamond Point Needles (1 pack)	IIb	ANCHORS	8	II	8/20/2012
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1925SF	Suture Anchor, Corkscrew® with #2 FiberWire® and #2 TigerWire®	IIb	ANCHORS	8	II	9/14/2002
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1925SF-1	Suture Anchor, Corkscrew® with #2 FiberWire® and #2 TigerWire® (1 pack)	IIb	ANCHORS	8	II	8/20/2012
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1927PNF-45	Suture Anchor, PEEK Corkscrew® with #1 FiberWire® and #1 TigerWire®, each with two 1/2 Circle Diamond Point Needles	IIb	ANCHORS	8	II	3/8/2012
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1941PS	PEEK Knotless Corkscrew® Suture Anchor, With #2 Suture, 3.9 x 11.2 mm	IIb	ANCHORS	8	II	6/30/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1941PS-1	PEEK Knotless Corkscrew® Suture Anchor, With #2 Suture, 3.9 x 11.2 mm (1 pack)	IIb	ANCHORS	8	II	6/30/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1941PSV	PEEK, 3.9 mm Knotless Corkscrew® with #5 Suture, 3.9 x 11.2 mm	IIb	ANCHORS	8	II	12/23/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1941PSV-1	PEEK, 3.9 mm Knotless Corkscrew® with #5 Suture, 3.9 x 11.2 mm (1 pack)	IIb	ANCHORS	8	II	12/23/2019
Corkscrew FT and Corkscrew FTII									
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1317FT	Suture Anchor, Nano Corkscrew® FT, Titanium	IIb	ANCHORS	8	II	2/16/2018
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1317FT-1	Suture Anchor, Nano Corkscrew® FT, Titanium (1 Pack)	IIb	ANCHORS	8	II	2/16/2018
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1318FT	Suture Anchor, Micro Corkscrew® FT with 2-0 FiberWireand twoNeedles, Soft Bone K-Wire and Hard Bone K-wire	IIb	ANCHORS	8	II	9/19/2008
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1318FT-1	Suture Anchor, Micro Corkscrew® With 2-0 FiberWire and two Needles, Soft Bone K-wire and Hard Bone K-Wire (1 pack)	IIb	ANCHORS	8	II	10/2/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1318FT-40	Suture Anchor , Micro Corkscrew® FT with 4-0 FiberWire® and two Needles, Soft Bone K-Wire and Hard Bone K-Wire, 2.2 x 4 mm	IIb	ANCHORS	8	II	9/15/2011
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1318FT-40-1	Suture Anchor , Micro Corkscrew® FT with 4-0 FiberWire® and two Needles, Soft Bone K-Wire and Hard Bone K-Wire, 2.2 x 4 mm (1 pack)	IIb	ANCHORS	8	II	10/2/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1319FT	Suture Anchor, Mini Corkscrew® FT With 2-0 FiberWire and two Needles, Soft Bone K-wire and Hard Bone K-Wire, 2.7 x 7 mm	IIb	ANCHORS	8	II	9/19/2008
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1319FT-1	Suture Anchor, Mini Corkscrew® FT With 2-0 FiberWire and two Needles, Soft Bone K-wire and Hard Bone K-Wire, 2.7 x 7 mm (1 pack)	IIb	ANCHORS	8	II	10/2/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1915FT	Suture Anchor, Corkscrew® FT With #0 FiberWire®, each with Diamond Point Needles, and Guide Wire, 3.5 x10 mm	IIb	ANCHORS	8	II	4/14/2009
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1915FT-1	Suture Anchor, Corkscrew® FT With #0 FiberWire®, each with Diamond Point Needles, and Guide Wire, 3.5 x10 mm (1 pack)	IIb	ANCHORS	8	II	9/25/2013
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1915FT-2	Suture Anchor, Corkscrew® FT With #1 FiberWire® with two Tapered Needles and Guide Wire, 3.5 x 10 mm	IIb	ANCHORS	8	II	12/15/2012
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1915FT-2-1	Suture Anchor, Corkscrew® FT With #1 FiberWire® with two Tapered Needles and Guide Wire, 3.5 x 10 mm (1 pack)	IIb	ANCHORS	8	II	6/30/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1927PNF	Suture Anchor, PEEK Corkscrew® FT With #2 FiberWire® and #2 TigerWire®, each with two Needles, 5.5 x 14.7 mm	IIb	ANCHORS	8	II	9/10/2010
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1927PNF-1	Suture Anchor, PEEK Corkscrew® FT With #2 FiberWire® and #2 TigerWire®, each with two Needles, 5.5 x 14.7 mm (1 pack)	IIb	ANCHORS	8	II	9/13/2013
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1927PSF	Suture Anchor, PEEK Corkscrew® FT With #2 FiberWire® and #2 TigerWire®, 5.5 x 14.7 mm	IIb	ANCHORS	8	II	3/9/2007
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1927PSF-1	Suture Anchor, PEEK Corkscrew® FT With #2 FiberWire® and #2 TigerWire®, 5.5 x 14.7 mm (1 pack)	IIb	ANCHORS	8	II	8/20/2012
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1927PSF-3	Suture Anchor, PEEK Corkscrew® FT, Tripleplay, Vented With two #2 FiberWire® and one #2 TigerWire®, 5.5 x14.7 mm	IIb	ANCHORS	8	II	12/11/2008
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1927PSF-3-1	Suture Anchor, PEEK Corkscrew® FT, Tripleplay, Vented With two #2 FiberWire® and one #2 TigerWire®, 5.5 x14.7 mm (1 pack)	IIb	ANCHORS	8	II	8/20/2012
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1927PSF-45	Suture Anchor, PEEK Corkscrew® FT with #2 FiberWire® and #2 TigerWire®, 4.5 x 14 mm	IIb	ANCHORS	8	II	10/5/2006
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1927PSF-475	Suture Anchor, PEEK Corkscrew® FT, TriplePlay with three #2 TigerTail® , 4.75 x 14 mm	IIb	ANCHORS	8	II	8/2/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1927PSF-475 -1	Suture Anchor, PEEK Corkscrew® FT, TriplePlay with three #2 TigerTail® , 4.75 x 14 mm (1 pack)	IIb	ANCHORS	8	II	1/18/2018
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1927PSF-65	Suture Anchor, PEEK Corkscrew® FT With #2 FiberWire® and #2 TigerWire®, 6.5 x 14.7 mm	IIb	ANCHORS	8	II	3/9/2007
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1927PST-475	Suture Anchor, PEEK Corkscrew® FT, Double Loaded with two 1.3 mm SutureTape, 4.75 x 14 mm	IIb	ANCHORS	8	II	8/2/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1927PST-475 -1	Suture Anchor, PEEK Corkscrew® FT, Double Loaded with two 1.3 mm SutureTape, 4.75 x 14 mm	IIb	ANCHORS	8	II	1/18/2018
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1928SF	Suture Anchor, Corkscrew® FT With #2 FiberWire® and #2 TigerWire®, 5.5 x 15 mm	IIb	ANCHORS	8	II	1/28/2003
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1928SF-1	Suture Anchor, Corkscrew® FT With #2 FiberWire® and #2 TigerWire®, 5.5 x 15 mm (1 pack)	IIb	ANCHORS	8	II	6/30/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1928SF-2	Suture Anchor, Corkscrew® FT II With #2 FiberWire® and #2 TigerWire®, 5.5 x 16.3 mm	IIb	ANCHORS	8	II	11/15/2004
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1928SF-2-1	Suture Anchor, Corkscrew® FT II With #2 FiberWire® and #2 TigerWire®, 5.5 x 16.3 mm (1 pack)	IIb	ANCHORS	8	II	8/20/2012
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1928SF-3	Suture Anchor, Corkscrew® FT III With two #2 FiberWire® and one #2 TigerWire®, 5.5 x 16.3 mm	IIb	ANCHORS	8	II	10/5/2006
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1928SF-3-1	Suture Anchor, Corkscrew® FT III With two #2 FiberWire® and one #2 TigerWire®, 5.5 x 16.3 mm (1 pack)	IIb	ANCHORS	8	II	8/20/2012
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1928SF-45	Suture Anchor, Corkscrew® FT With #2 FiberWire® and #2 TigerWire®, 4.5 x 14 mm	IIb	ANCHORS	8	II	7/24/2007
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1928SF-45-1	Suture Anchor, Corkscrew® FT With #2 FiberWire® and #2 TigerWire®, 4.5 x 14 mm	IIb	ANCHORS	8	II	6/30/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1928SFT-2	Suture Anchor, Corkscrew® FT II With two #2 TigerTail®, 5.5 x 16.3 mm	IIb	ANCHORS	8	II	1/3/2006
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1928SFT-2-1	Suture Anchor, Corkscrew® FT II With two #2 TigerTail®, 5.5 x 16.3 mm(1 pack)	IIb	ANCHORS	8	II	8/20/2012
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1928SNF	Suture Anchor, Corkscrew® FT With #2 FiberWire® and #2 TigerWire®, each with two 1/2 Circle Diamond Point Needles, 5.5 x 15 mm	IIb	ANCHORS	8	II	6/21/2004
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1928SNF-2	Suture Anchor, Corkscrew® FT With #2 FiberWire® and #2 TigerWire®, each with two 1/2 Circle Diamond Point Needles, 5.5 x 16.3 mm	IIb	ANCHORS	8	II	7/25/2005
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1928SNF-2-1	Suture Anchor, Corkscrew® FT With #2 FiberWire® and #2 TigerWire®, each with two 1/2 Circle Diamond Point Needles, 5.5 x 16.3 mm (1 pack)	IIb	ANCHORS	8	II	8/20/2012
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1929SF-3	Suture Anchor, Corkscrew® FT III With two #2 FiberWire® and one #2 TigerWire®, 6.5 x 16.3 mm	IIb	ANCHORS	8	II	7/24/2007
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1929SF-3-1	Suture Anchor, Corkscrew® FT III With two #2 FiberWire® and one #2 TigerWire®, 6.5 x 16.3 mm (1 pack)	IIb	ANCHORS	8	II	8/20/2012
FASTak Suture Anchors									
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1322-752SF	Suture Anchor, FASTak™, Small Bone With 2-0 FiberWire® with two 3/8 Circle Taper Point Needless, 2.4 x 7.5 mm	IIb	ANCHORS	8	II	9/14/2002

Manufacturer Name	Manufacturing Location	EC QA Cert. Number	Product Code	Product Name	Class	TF	Rule	Annex	First DoC
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1322-752SF-1	Suture Anchor, FASTak™, Small Bone With 2-0 FiberWire® with two 3/8 Circle Taper Point Needles, 2.4 x 7.5 mm (1 pack)	IIb	ANCHORS	8	II	6/30/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1322SXF	Suture Anchor FASTak™	IIb	ANCHORS	8	II	9/14/2002
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1324HF	Suture Anchor FASTak™ II With #2 FiberWire® and Handle Insert, 2.8 x 11.7 mm	IIb	ANCHORS	8	II	8/11/2003
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1324HF-1	Suture Anchor FASTak™ II With #2 FiberWire® and Handle Insert, 2.8 x 11.7 mm (1 pack)	IIb	ANCHORS	8	II	9/25/2013
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1324SF	Suture Anchor FASTak™ II With #2 FiberWire®, 2.8 x 11.7 mm	IIb	ANCHORS	8	II	9/14/2002
FiberTak									
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3600	FiberTak® Suture Anchor with #2 FiberWire® CL (White/Blue)	IIb	ANCHORS	8	II	4/28/2014
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3600-1	FiberTak® Suture Anchor with #2 FiberWire® CL (White/Blue) (1 pack)	IIb	ANCHORS	8	II	12/22/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3600-2	FiberTak® Suture Anchor, With #2 FiberWire® CL (Double Loaded)	IIb	ANCHORS	8	II	12/22/2015
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3600-2-1	FiberTak® Suture Anchor, With #2 FiberWire® CL (Double Loaded) (1 pack)	IIb	ANCHORS	8	II	6/30/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3600H	Hip FiberTak® Suture Anchor with #2 FiberWire CL, VE5	IIb	ANCHORS	8	II	12/2/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3600H-1	Hip FiberTak® Suture Anchor with #2 FiberWire CL (1 pack)	IIb	ANCHORS	8	II	12/2/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3602	FiberTak® Suture Anchor With 1.3 mm SutureTape (White/Blue)	IIb	ANCHORS	8	II	6/25/2015
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3602-1	FiberTak® Suture Anchor With 1.3 mm SutureTape (White/Blue) (1 pack)	IIb	ANCHORS	8	II	12/22/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3602-2	FiberTak® Suture Anchor, Double Loaded with 1.3 mm SutureTape (White/Black and White/Blue)	IIb	ANCHORS	8	II	5/3/2016
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3602-2-1	FiberTak® Suture Anchor, Double Loaded with 1.3 mm SutureTape (White/Black and White/Blue) (1 pack)	IIb	ANCHORS	8	II	12/22/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3602-2H	Hip FiberTak® Suture Anchor, Double Loaded, with 1.3mm SutureTapes (White/Black and White/Blue)	IIb	ANCHORS	8	II	12/2/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3602-2H-1	Hip FiberTak® Suture Anchor, Double Loaded, with 1.3mm SutureTapes (White/Black and White/Blue) (1 pack)	IIb	ANCHORS	8	II	12/2/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3602H	Hip FiberTak® Suture Anchor, with 1.3mm SutureTape (White/Blue), 5-pack	IIb	ANCHORS	8	II	12/2/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3602H-1	Hip FiberTak® Suture Anchor, with 1.3mm SutureTape (White/Blue), 1-pack	IIb	ANCHORS	8	II	12/2/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3603	FiberTak Suture Anchor, Single Loaded with #2 TigerTail (Blue/Black)	IIb	ANCHORS	8	II	5/3/2016
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3603-1	FiberTak Suture Anchor, Single Loaded with #2 TigerTail (Blue/Black) (1 pack)	IIb	ANCHORS	8	II	6/30/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3603-2	FiberTak Suture Anchor, Double Loaded with #2 TigerTail (Blue/Black and White/Black)	IIb	ANCHORS	8	II	5/3/2016
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3603-2-1	FiberTak Suture Anchor, Double Loaded with #2 TigerTail (Blue/Black and White/Black) - SINGLE PACK	IIb	ANCHORS	8	II	6/30/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3630	FiberTak RC Suture Anchor, Double Loaded with #2 Fiberwire CL (blue/white, black/white)	IIb	ANCHORS	8	II	8/2/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3630-1	FiberTak RC Suture Anchor, Double Loaded with #2 Fiberwire CL (blue/white, black/white) single pack	IIb	ANCHORS	8	II	8/2/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3631	FiberTak RC Suture Anchor, Triple Loaded with #2 Fiberwire CL (blue/white, black/white)	IIb	ANCHORS	8	II	8/2/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3631-1	FiberTak RC Suture Anchor, Triple Loaded with #2 Fiberwire CL (blue/white, black/white) single pack	IIb	ANCHORS	8	II	4/20/2018
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3632	FiberTak RC, Double Loaded with SutureTape (blue/white, black/white)	IIb	ANCHORS	8	II	3/22/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3632-1	FiberTak RC, Double Loaded with SutureTape (blue/white, black/white) - SINGLE PACK	IIb	ANCHORS	8	II	3/22/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3632SP	Self-Punching 2.6 FiberTak® Suture Anchor, Double Loaded With 1.3mm SutureTape (White/Blue, White/Black)	IIb	ANCHORS	8	II	10/15/2020
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3632SP-1	Self-Punching 2.6 FiberTak® Suture Anchor, Double Loaded With 1.3mm SutureTape (White/Blue, White/Black) (1pack)	IIb	ANCHORS	8	II	10/15/2020
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3633	FiberTak RC, Triple Loaded with SutureTape (blue/white, black/white, white)	IIb	ANCHORS	8	II	3/22/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3633-1	FiberTak RC, Triple Loaded with SutureTape (blue/white, black/white, white) - SINGLE PACK	IIb	ANCHORS	8	II	3/22/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3633SP	Self-Punching 2.6 FiberTak® Suture Anchor, Triple Loaded With 1.3 mm SutureTape (White/Blue, Black/White, Blue)	IIb	ANCHORS	8	II	10/15/2020
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3633SP-1	Self-Punching 2.6 FiberTak® Suture Anchor, Triple Loaded With 1.3 mm SutureTape (White/Blue, Black/White, Blue) (1 pack)	IIb	ANCHORS	8	II	10/15/2020
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3638	Knotless FiberTak Pro, with #2 Suture	IIb	ANCHORS	8	II	8/2/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3638-1	Knotless FiberTak Pro, with #2 Suture (single pack)	IIb	ANCHORS	8	II	8/2/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3638-2	2.6mm Knotless FiberTak, Double Loaded with #2 Suture	IIb	ANCHORS	8	II	8/16/2018
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3638-2-1	2.6mm Knotless FiberTak, Double Loaded with #2 Suture (single pack)	IIb	ANCHORS	8	II	8/16/2018
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3638H	Knotless Hip FiberTak® Suture Anchor with #2 Suture, 5-pack	IIb	ANCHORS	8	II	12/2/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3638H-1	Knotless Hip FiberTak® Suture Anchor with #2 Suture, 1-pack	IIb	ANCHORS	8	II	12/2/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3641	Knotless FiberTak Pro, with #5 Suture	IIb	ANCHORS	8	II	8/2/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3641-1	Knotless FiberTak Pro, with #5 Suture (single pack)	IIb	ANCHORS	8	II	8/2/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3641SP	Self-Punching Knotless 2.6 FiberTak® Anchor With #5 Suture	IIb	ANCHORS	8	II	10/15/2020
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3641SP-1	Self-Punching Knotless 2.6 FiberTak® Anchor With #5 Suture (1 pack)	IIb	ANCHORS	8	II	10/15/2020
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3651	FiberTak DR with LabralTape (white) and TigerTail (blue/black)	IIb	ANCHORS	8	II	5/3/2016
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3651-1	FiberTak DR with LabralTape (white) and TigerTail (blue/black) - SINGLE PACK	IIb	ANCHORS	8	II	6/30/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3651SP	Self-Punching FiberTak DR With LabralTape™ (White) and #2 TigerTail® (Blue/Black)	IIb	ANCHORS	8	II	10/15/2020
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3651SP-1	Self-Punching FiberTak DR With LabralTape™ (White) and #2 TigerTail® (Blue/Black) (1 pack)	IIb	ANCHORS	8	II	10/15/2020
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3651T	FiberTak DR with LabralTape (white/black) and TigerTail (white/green/black)	IIb	ANCHORS	8	II	5/3/2016
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3651T-1	FiberTak DR with LabralTape (white/black) and TigerTail (white/green/black) - SINGLE PACK	IIb	ANCHORS	8	II	6/30/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3651TSP	Self-Punching FiberTak® DR With LabralTape™ (White/Black) and #2 TigerTail® (White/Green/Black)	IIb	ANCHORS	8	II	10/15/2020
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3651TSP-1	Self-Punching FiberTak® DR With LabralTape™ (White/Black) and #2 TigerTail® (White/Green/Black) (1 pack)	IIb	ANCHORS	8	II	10/15/2020
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3651TT	FiberTak DR with LabralTape (white/blue) and TigerTail (white/black)	IIb	ANCHORS	8	II	5/3/2016
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3651TT-1	FiberTak DR with LabralTape (white/blue) and TigerTail (white/black) - SINGLE PACK	IIb	ANCHORS	8	II	6/30/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3651TTSP	Self-Punching FiberTak® DR With LabralTape™ (White/Blue) and #2 TigerTail® (White/Black)	IIb	ANCHORS	8	II	10/15/2020
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3651TTSP-1	Self-Punching FiberTak® DR With LabralTape™ (White/Blue) and #2 TigerTail® (White/Black) (1 pack)	IIb	ANCHORS	8	II	10/15/2020
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3670	FiberTak® Biceps Implant System, FiberTak® Biceps, 1.9mm Drill, Drill Guide and Free Needle	IIb	ANCHORS	8	II	4/18/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3671	FiberTak® Biceps Implant, with 1.3 mm SutureTape (White/Blue, White/Black) with Needles	IIb	ANCHORS	8	II	4/18/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3680	FiberTak® Button Implant system With FiberTak Button Implant, 2.6 mm Drill, Drill Guide, #2 FiberLoop® Suture with Straight Needle and Free Needle	IIb	ANCHORS	8	II	10/23/2020
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3681	FiberTak® Button With 2-0 FiberLink™ Shutting Suture (Blue, White/Black)	IIb	ANCHORS	8	II	10/23/2020
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-8990	FiberTak DX with #1 FiberWire Suture and Needles	IIb	ANCHORS	8	II	10/2/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-8990-1	FiberTak DX with #1 FiberWire Suture and Needles (single pack)	IIb	ANCHORS	8	II	10/2/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-8990ST	FiberTak DX Suture Anchor with 1.3 mm SutureTape With 1.3 mm FiberWire SutureTape (White/Blue) and Needles	IIb	ANCHORS	8	II	6/22/2018
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-8990ST-1	FiberTak DX Suture Anchor with 1.3 mm SutureTape With 1.3 mm FiberWire SutureTape (White/Blue) and Needles (1 pack)	IIb	ANCHORS	8	II	6/22/2018

Manufacturer Name	Manufacturing Location	EC QA Cert. Number	Product Code	Product Name	Class	TF	Rule	Annex	First DoC
Implant Systems									
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1778P-CP	InternalBrace™ Implant System, Ligament Augmentation Repair, PEEK	IIb	ANCHORS	8	II	12/2/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-2600SBS-6	SpeedBridge™ Implant System with PEEK SwivelLock® Anchors With two Anchors with #2 FiberWire® Suture, one Anchor with FiberTape® Loop Suture, one Anchor with TigerTape™ Loop Suture, and Punch	IIb	ANCHORS	8	II	11/28/2016
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-2600SBS-7	SpeedBridge™ Implant System with PEEK SwivelLock® SP Anchors With two 5.5 x 24.5 mm Self Punching Anchors with #2 FiberWire® Suture, one 4.75 x 19.1 mm Anchor with FiberTape® Loop Suture, one 4.75 x 19.1 mm Anchor with TigerTape™ Loop Suture, and Punch	IIb	ANCHORS	8	II	11/28/2016
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-4550P	Implant System, Meniscal Root Repair with PEEK SwivelLock® (Kit)	IIb	ANCHORS	8	II	8/23/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-8826DS	Implant Delivery System, Graft Anchor	IIb	ANCHORS	8	II	4/13/2012
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-8928P-CP	Implant System, PEEK Achilles SpeedBridge™ With four PEEK 4.75 mm SwivelLock® Suture Anchors, two with #2 FiberWire®, one with #2 FiberWire and FiberTape® Loop with Needle, one with #2 FiberWire and TigerTape™ Loop with Needle, Punch/Tap, Punch/Tap with Handle, Drill Guide and Drill Bit	IIb	ANCHORS	8	II	2/28/2012
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-8978-CP	Implant System, Hand/Wrist InternalBrace™ Ligament Augmentation Repair With two PEEK SwivelLock® SL Suture Anchors (3.5 x 8.5 mm), 1.3 mm FiberWire® SutureTape with Needle, two 2-0 FiberLoop® Sutures with Tapered Needle, 3.0 mm Cannulated Drill Bit, 3.5 mm Cannulated Drill Bit, Drill Guide, 1.35 mm Guidewires, and 2.0/2.5 mm Tendon Sizer	IIb	ANCHORS	8	II	10/27/2017
PushLock									
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1663PC-8	PEEK PushLock Tenodesis Anchor, Closed Eyelet, 8 x 13.4 mm	IIb	ANCHORS	8	II	9/21/2018
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1922PS	Suture Anchor, PushLock®, 4.5 x 24 mm	IIb	ANCHORS	8	II	6/2/2006
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1922PS-1	Suture Anchor, PushLock®, 4.5 x 24 mm (1 pack)	IIb	ANCHORS	8	II	9/25/2013
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1922PSM	Suture Anchor, PEEK PushLock® SP, 4.5 x 28 mm	IIb	ANCHORS	8	II	7/24/2007
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1922PSM-1	Suture Anchor, PEEK PushLock® SP, 4.5 x 28 mm (1 pack)	IIb	ANCHORS	8	II	9/25/2013
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1923PHS	Suture Anchor, Hip PushLock®, 2.9 x 15.5 mm	IIb	ANCHORS	8	II	9/19/2008
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1923PHS-1	Suture Anchor, Hip PushLock®, 2.9 x 15.5 mm (1 pack)	IIb	ANCHORS	8	II	6/30/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1923PS	Suture Anchor, PEEK PushLock®, 2.9 x 15.5 mm	IIb	ANCHORS	8	II	7/24/2007
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1923PS-1	Suture Anchor, PEEK PushLock®, 2.9 x 15.5 mm (1 pack)	IIb	ANCHORS	8	II	9/25/2013
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1926PHS	Suture Anchor, Hip PushLock®, 3.5 X19.5 mm	IIb	ANCHORS	8	II	3/9/2007
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1926PS	Suture Anchor, PushLock®, 3.5 X19.5 mm	IIb	ANCHORS	8	II	7/25/2005
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1926PS-1	Suture Anchor, PushLock®, 3.5 X19.5 mm (1 pack)	IIb	ANCHORS	8	II	9/25/2013
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-2922PS	Suture Anchor, PEEK PushLock®, 2.4 x 11 mm	IIb	ANCHORS	8	II	11/19/2012
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-2922PS-1	Suture Anchor, PEEK PushLock®, 2.4 x 11 mm (1 pack)	IIb	ANCHORS	8	II	6/30/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-2923PHS	Suture Anchor, PEEK, Hip PushLock®, Short, 2.9 x 12.5 mm	IIb	ANCHORS	8	II	12/20/2016
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-2923PHS-1	Suture Anchor, PEEK, Hip PushLock®, Short, 2.9 x 12.5 mm (1 pack)	IIb	ANCHORS	8	II	10/2/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-2923PS	Suture Anchor, PEEK PushLock®, Short, 2.9 x 12.5 mm	IIb	ANCHORS	8	II	10/22/2012
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-2923PS-1	Suture Anchor, PEEK PushLock®, Short, 2.9 x 12.5 mm (1 pack)	IIb	ANCHORS	8	II	6/30/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-2924PHS	Suture Anchor, PEEK, Mini Hip PushLock®, 2.4 x 8.9 mm	IIb	ANCHORS	8	II	8/23/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-2924PHS-1	Suture Anchor, PEEK, Mini Hip PushLock®, 2.4 x 8.9 mm (1 pack)	IIb	ANCHORS	8	II	8/23/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-8825P	Suture Anchor, PEEK, Mini Hip PushLock®, 2.5 x 8 mm	IIb	ANCHORS	8	II	12/8/2006
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-8825P-1	Suture Anchor, PEEK, Mini Hip PushLock®, 2.5 x 8 mm (1 pack)	IIb	ANCHORS	8	II	9/25/2013
SutureTak									
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1934PF-20-1	Suture Anchor Mini SutureTak, 2 x 12 mm	IIb	ANCHORS	8	II	6/30/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1934PF-24	Suture Anchor, PEEK SutureTak® with #2 FiberWire®, 2.4 x 12.4 mm	IIb	ANCHORS	8	II	3/22/2010
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1934PF-24-1	Suture Anchor, PEEK SutureTak® with #2 FiberWire®, 2.4 x 12.4 mm (1 pack)	IIb	ANCHORS	8	II	6/30/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1934PHS-20	Suture Anchor, PEEK, Mini Hip SutureTak® With #1 FiberWire®, 2.0 x 8.6 mm	IIb	ANCHORS	8	II	11/17/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1934PS	Suture Anchor, PEEK SutureTak® with #2 FiberWire®, 3.0 x 12.4 mm	IIb	ANCHORS	8	II	7/25/2005
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1934PS-1	Suture Anchor, PEEK SutureTak® with #2 FiberWire®, 3.0 x 12.4 mm (1 pack)	IIb	ANCHORS	8	II	8/20/2012
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1934PS-2	Suture Anchor, PEEK SutureTak® with #2 FiberWire® and #2 TigerWire®, 3 x 12.2 mm	IIb	ANCHORS	8	II	9/16/2009
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1934PS-2-1	Suture Anchor, PEEK SutureTak® with #2 FiberWire® and #2 TigerWire®, 3 x 12.2 mm (1 pack)	IIb	ANCHORS	8	II	8/20/2012
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1938PHS	Suture Anchor, PEEK, Knotless Hip SutureTak® With #2 Suture, 3 x 12.7 mm	IIb	ANCHORS	8	II	8/30/2018
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1938PHS-1	Suture Anchor, PEEK, Knotless Hip SutureTak® With #2 Suture, 3 x 12.7 mm (1 pack)	IIb	ANCHORS	8	II	8/30/2018
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1938PS	Suture Anchor, PEEK SutureTak®, Knotless With #2 Suture, 3 x 12.7 mm	IIb	ANCHORS	8	II	8/15/2013
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1938PS-1	Suture Anchor, PEEK SutureTak®, Knotless With #2 Suture, 3 x 12.7 mm (1 pack)	IIb	ANCHORS	8	II	12/22/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1938PSS	PEEK Knotless SutureTak® Anchor, Open Repair With #2 Suture, 3 x 12.7 mm	IIb	ANCHORS	8	II	2/16/2018
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1938PSS-1	PEEK Knotless SutureTak® Anchor, Open Repair With #2 Suture, 3 x 12.7 mm (1 pack)	IIb	ANCHORS	8	II	2/16/2018
SwivelLock									
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1662PSL-7	Suture Anchor, SwivelLock® Tenodesis, PEEK with Fork Tip PEEK Eyelet and #2 FiberWire®, 7 x 19.5 mm	IIb	ANCHORS	8	II	9/15/2011
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1662PSL-7-1	Suture Anchor, SwivelLock® Tenodesis, PEEK with Fork Tip PEEK Eyelet and #2 FiberWire®, 7 x 19.5 mm (1 pack)	IIb	ANCHORS	8	II	11/30/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1662PSL-8	Suture Anchor, SwivelLock® Tenodesis, PEEK with Fork Tip PEEK Eyelet and #2 FiberWire®, 8 x 19.5 mm	IIb	ANCHORS	8	II	9/15/2011
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1662PSL-8-1	Suture Anchor, SwivelLock® Tenodesis, PEEK with Fork Tip PEEK Eyelet and #2 FiberWire®, 8 x 19.5 mm (1 pack)	IIb	ANCHORS	8	II	8/23/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1662PSL-9	Suture Anchor, SwivelLock® Tenodesis, PEEK with Fork Tip PEEK Eyelet and #2 FiberWire®, 9 x 19.5 mm	IIb	ANCHORS	8	II	9/15/2011
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1662PSL-9-1	Suture Anchor, SwivelLock® Tenodesis, PEEK with Fork Tip PEEK Eyelet and #2 FiberWire®, 9 x 19.5 mm (1 pack)	IIb	ANCHORS	8	II	11/17/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-2323KPSLC	PEEK Knotless SwivelLock® Suture Anchor, 5.5 x 19.1 mm With Blue #2 Suture	IIb	ANCHORS	8	II	3/23/2020
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-2323KPSLC-1	PEEK Knotless SwivelLock® Suture Anchor, 5.5 x 19.1 mm With Blue #2 Suture (1 pack)	IIb	ANCHORS	8	II	3/23/2020
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-2323PSL	Suture Anchor, PEEK SwivelLock® With PEEK Eyelet and #2 FiberWire®, 5.5 x 20 mm	IIb	ANCHORS	8	II	12/8/2006
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-2323PSLC	Suture Anchor, PEEK SwivelLock® C With Closed PEEK Eyelet and #2 FiberWire®, 5.5 x 19.1 mm	IIb	ANCHORS	8	II	9/19/2008
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-2323PSLC-1	Suture Anchor, PEEK SwivelLock® C With Closed PEEK Eyelet and #2 FiberWire®, 5.5 x 19.1 mm (1 pack)	IIb	ANCHORS	8	II	8/23/2017

Manufacturer Name	Manufacturing Location	EC QA Cert. Number	Product Code	Product Name	Class	TF	Rule	Annex	First DoC
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-2323PSLC-2	PEEK Swivelock® Suture Anchor, Double Loaded With PEEK Eyelet and two #2 TigerTail® Sutures, 5.5 x 22 mm	IIb	ANCHORS	8	II	2/17/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-2323PSLC-2-1	PEEK Swivelock® Suture Anchor, Double Loaded With PEEK Eyelet and two #2 TigerTail® Sutures, 5.5 x 22 mm (1 pack)	IIb	ANCHORS	8	II	2/17/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-2323PSLM	Suture Anchor, PEEK Swivelock® SP Self Punching With Titanium Eyelet and #2 FiberWire®	IIb	ANCHORS	8	II	12/11/2008
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-2323PSLM-1	Suture Anchor, PEEK Swivelock® SP Self Punching With Titanium Eyelet and #2 FiberWire® (1 pack)	IIb	ANCHORS	8	II	8/23/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-2324KPCT	PEEK Knotless Swivelock® Suture Anchor With Blue FiberTape® Loop and White/Black #2 Suture, 4.75 x 19.1 mm	IIb	ANCHORS	8	II	3/23/2020
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-2324KPCT-1	PEEK Knotless Swivelock® Suture Anchor With Blue FiberTape® Loop and White/Black #2 Suture, 4.75 x 19.1 mm (1 pack)	IIb	ANCHORS	8	II	3/23/2020
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-2324KPCTT	PEEK Knotless Swivelock® Suture Anchor With White/Black TigerTape™ Loop and Blue # 2 Suture, 4.75 x 19.1 mm	IIb	ANCHORS	8	II	3/23/2020
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-2324KPCTT-1	PEEK Knotless Swivelock® Suture Anchor With White/Black TigerTape™ Loop and Blue # 2 Suture, 4.75 x 19.1 mm (1 pack)	IIb	ANCHORS	8	II	3/23/2020
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-2324KPSLC	PEEK Knotless Swivelock® Suture Anchor With Blue #2 Suture, 4.75 x 19.1 mm	IIb	ANCHORS	8	II	3/23/2020
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-2324KPSLC-1	PEEK Knotless Swivelock® Suture Anchor With Blue #2 Suture, 4.75 x 19.1 mm (1 pack)	IIb	ANCHORS	8	II	3/23/2020
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-2324PCT	Suture Anchor, PEEK Swivelock® With Closed Eyelet and Blue FiberTape® Loop, 4.75 x 19.1 mm	IIb	ANCHORS	8	II	2/5/2014
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-2324PCT-1	Suture Anchor, PEEK Swivelock® With Closed PEEK Eyelet and Blue FiberTape® Loop, 4.75 x 19.1 mm (1 pack)	IIb	ANCHORS	8	II	8/23/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-2324PCTT	Suture Anchor, PEEK Swivelock® With Closed PEEK Eyelet and White/Black TigerTape™ Loop, 4.75 x 19.1 mm	IIb	ANCHORS	8	II	2/5/2014
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-2324PCTT-1	Suture Anchor, PEEK Swivelock® With Closed PEEK Eyelet and White/Black TigerTape™ Loop, 4.75 x 19.1 mm (1 pack)	IIb	ANCHORS	8	II	8/23/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-2324PSLC	Suture Anchor, PEEK Swivelock® C With Closed PEEK Eyelet and #2 FiberWire®, 4.75 x 19.1 mm	IIb	ANCHORS	8	II	12/14/2009
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-2324PSLC-1	Suture Anchor, PEEK Swivelock® C With Closed PEEK Eyelet and #2 FiberWire®, 4.75 x 19.1 mm (1 pack)	IIb	ANCHORS	8	II	8/23/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-2324PSLC-2	PEEK Swivelock Suture Anchor, Double Loaded With PEEK Eyelet and two #2 TigerTail® Sutures, 4.75 x 22 mm	IIb	ANCHORS	8	II	2/17/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-2324PSLC-2-1	PEEK Swivelock Suture Anchor, Double Loaded With PEEK Eyelet and two #2 TigerTail® Sutures, 4.75 x 22 mm (1 pack)	IIb	ANCHORS	8	II	2/17/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-2324PSLM	Suture Anchor, PEEK Swivelock® SP Self Punching With Titanium Eyelet and #2 FiberWire®, 4.75 x 24.5 mm	IIb	ANCHORS	8	II	12/11/2008
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-2324PSLM-1	Suture Anchor, PEEK Swivelock® SP Self Punching With Titanium Eyelet and #2 FiberWire®, 4.75 x 24.5 mm (1 pack)	IIb	ANCHORS	8	II	8/23/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-2324SLM	Suture Anchor, Swivelock® SP Self Punching With #2 FiberWire® and Metal Tip Eyelet,, 4.75 x 24.5 mm	IIb	ANCHORS	8	II	12/11/2008
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-2325PSLC	Suture Anchor, PEEK Swivelock®, 3.5 x 15.8 mm	IIb	ANCHORS	8	II	4/14/2009
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-2325PSLC-1	Suture Anchor, PEEK Swivelock®, 3.5 x 15.8 mm (1 pack)	IIb	ANCHORS	8	II	11/17/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-2326PSLC	PEEK Swivelock® Suture Anchor, 3.9 x 17.9 mm	IIb	ANCHORS	8	II	5/17/2018
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-2326PSLC-1	PEEK Swivelock® Suture Anchor, 3.9 x 17.9mm (1 pack)	IIb	ANCHORS	8	II	8/23/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7324PSL	Suture Anchor, Swivelock® Tenodesis, PEEK With Forked Tip PEEK Eyelet, 4.75 x 14 mm	IIb	ANCHORS	8	II	11/12/2012
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-8978P	DX Swivelock® SL, with Forked Eyelet 3.5 x 8.5mm	IIb	ANCHORS	8	II	3/27/2015
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-8978P-1	DX Swivelock® SL, with Forked Eyelet 3.5 x 8.5mm (1 pack)	IIb	ANCHORS	8	II	10/2/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-8979P	DX Swivelock® 3.5 x 13.5mm	IIb	ANCHORS	8	II	3/27/2015
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-8979P-1	DX Swivelock® 3.5 x 13.5mm (1 pack)	IIb	ANCHORS	8	II	10/2/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-8980P-1	Suture Anchor, DX Swivelock®, PEEK-OPTIMA®, 1-Pack, 4.75 mm With #2 FiberWire®	IIb	ANCHORS	8	II	10/15/2020