

Către: Agenția Medicamentului
și Dispozitivelor Medicale

NOTIFICARE
pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale
nr. 46 din 23.11.2023

Solicitantul „GBG-MLD” SRL, cu sediul în mun. Chișinău, str. Albisoara 64/2, tel./fax: 022 54 73 73, e-mail office@gbg.md, solicit înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii și tipuri de dispozitive medicale pentru introducerea și punerea la dispoziție pe piață a producătorului **SPORTMED SYSTEMS SRL**, cu următoarele poziții:

Product Codes	Product Descriptions	EU Device Classes:	EU DoCs	CE cert
AR-1360P	Peek Interference Screw, 6 mm x 23 mm	IIB	DoC_Plates, Screws, Wedge, Staples _r47	CE 85507
AR-1370P	Peek Interference Screw, 7 mm x 23 mm	IIB	DoC_Plates, Screws, Wedge, Staples _r47	CE 85507
AR-5028P-07	Round Delta Tapered PEEK Screw, 7 X 28mm	IIB	DoC_Plates, Screws, Wedge, Staples _r47	CE 85507
AR-5028P-08	Round Delta Tapered PEEK Screw, 8 X 28mm	IIB	DoC_Plates, Screws, Wedge, Staples _r47	CE 85507
AR-5028P-09	Round Delta Tapered PEEK Screw, 9 X 28mm	IIB	DoC_Plates, Screws, Wedge, Staples _r47	CE 85507
AR-5028P-10	Round Delta Tapered PEEK Screw, 10 X 28mm	IIB	DoC_Plates, Screws, Wedge, Staples _r47	CE 85507
AR-5028P-11	Round Delta Tapered PEEK Screw, 11 X 28mm	IIB	DoC_Plates, Screws, Wedge, Staples _r47	CE 85507
AR-5028P-12	Round Delta Tapered PEEK Screw, 12 X 28mm	IIB	DoC_Plates, Screws, Wedge, Staples _r47	CE 85507
AR-5035P-09	Delta Tapered PEEK Screw 9 X 35mm	IIB	DoC_Plates, Screws, Wedge, Staples _r47	CE 85507
AR-5035P-10	Delta Tapered PEEK Screw 10 X 35mm	IIB	DoC_Plates, Screws, Wedge, Staples _r47	CE 85507
AR-5035P-11	Delta Tapered PEEK Screw 11 X 35mm	IIB	DoC_Plates, Screws, Wedge, Staples _r47	CE 85507
AR-5035P-12	Delta Tapered PEEK Screw 12 X 35mm	IIB	DoC_Plates, Screws, Wedge, Staples _r47	CE 85507
AR-1371T	Full Thread Cannulated Interference Screw, 7 x 25mm	IIB	DoC_Plates, Screws, Wedge, Staples _r48	CE 85508
AR-1372T	Full Thread Cannulated Interference Screw, 7 x 30 mm	IIB	DoC_Plates, Screws, Wedge, Staples _r49	CE 85509
AR-1381T	Full Thread Cannulated Interference crew 8 x 25 mm	IIB	DoC_Plates, Screws, Wedge, Staples _r50	CE 85510
AR-1382T	Full Thread Cannulated Interference Screw, 8 x 30 mm	IIB	DoC_Plates, Screws, Wedge, Staples _r51	CE 85511
AR-1391T	Full Thread Cannulated Interference Screw, 9 x 25 mm	IIB	DoC_Plates, Screws, Wedge, Staples _r52	CE 85512
AR-1392T	Full Thread Cannulated Interference Screw 9 x 30 mm	IIB	DoC_Plates, Screws, Wedge, Staples _r53	CE 85513
AR-1401T	Full Thread Cannulated Interference Screw, 10 x 25 mm	IIB	DoC_Plates, Screws, Wedge, Staples _r54	CE 85514
AR-1402T	Full Thread Cannulated Interference Screw 10 x 30 mm	IIB	DoC_Plates, Screws, Wedge, Staples _r55	CE 85515
AR-1588RT-2J	ACL TightRope® II RT, Double Loaded Passing Sutures	IIB	DoC Buttons; Suture_r43	CE 85507
AR-1324HF-1	Suture Anchor, FASTak II with #2 FiberWireand Handled Inserter, 2.8 x 11.7 mm	IIB	DoC Anchors	CE 85507
AR-1322-752SF	Small Bone FASTak Suture Anchor with 2-0 FiberWire, 2.4 x 7.5 mm	IIB	DoC Anchors	CE 85507

Se anexează următoarele acte:

Notificarea pentru înregistrarea dispozitivelor medicale

Declaratia pe proprie raspundere

Declaratii de conformitate.

Scrisoarea de Autorizare

Certificat CE

Data _____

Semnătura _____

Tabelul de recepționare a notificării

(se completează de către Agenție în momentul depunerii notificării de către solicitant)

Comentarii cu privire la acceptul/refuzul recepționării notificării, inclusiv motivul refuzului	
Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării)	
Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului	
Semnătura persoanei responsabile	

DECLARAȚIE PE PROPRIE RĂSPUNDERE

Solicitant: „GBG-MLD” SRL, cu sediul în mun. Chișinău, str. Albisoara 64/2,

declar pe proprie răspundere, cunoscând prevederile art. 352¹, Codul Penal al Republicii Moldova cu privire la falsul în declarații, că documentele și datele furnizate pentru înregistrarea dispozitivelor producătorului **SPORTMED SYSTEMS SRL** pentru introducerea și punerea la dispoziție pe piață a următoarelor produse:

Product Codes	Product Descriptions	EU Device Classes:	EU DoCs	CE cert
AR-1360P	Peek Interference Screw, 6 mm x 23 mm	IIB	DoC_Plates, Screws, Wedge, Staples_r47	CE 85507
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AR-5028P-07	Round Delta Tapered PEEK Screw, 7 X 28mm	IIB	DoC_Plates, Screws, Wedge, Staples_r47	CE 85507
AR-5028P-08	Round Delta Tapered PEEK Screw, 8 X 28mm	IIB	DoC_Plates, Screws, Wedge, Staples_r47	CE 85507
AR-5028P-09	Round Delta Tapered PEEK Screw, 9 X 28mm	IIB	DoC_Plates, Screws, Wedge, Staples_r47	CE 85507
AR-5028P-10	Round Delta Tapered PEEK Screw, 10 X 28mm	IIB	DoC_Plates, Screws, Wedge, Staples_r47	CE 85507
AR-5028P-11	Round Delta Tapered PEEK Screw, 11 X 28mm	IIB	DoC_Plates, Screws, Wedge, Staples_r47	CE 85507
AR-5028P-12	Round Delta Tapered PEEK Screw, 12 X 28mm	IIB	DoC_Plates, Screws, Wedge, Staples_r47	CE 85507
AR-5035P-09	Delta Tapered PEEK Screw 9 X 35mm	IIB	DoC_Plates, Screws, Wedge, Staples_r47	CE 85507
AR-5035P-10	Delta Tapered PEEK Screw 10 X 35mm	IIB	DoC_Plates, Screws, Wedge, Staples_r47	CE 85507
AR-5035P-11	Delta Tapered PEEK Screw 11 X 35mm	IIB	DoC_Plates, Screws, Wedge, Staples_r47	CE 85507
AR-5035P-12	Delta Tapered PEEK Screw 12 X 35mm	IIB	DoC_Plates, Screws, Wedge, Staples_r47	CE 85507
AR-1371T	Full Thread Cannulated Interference Screw, 7 x 25mm	IIB	DoC_Plates, Screws, Wedge, Staples_r48	CE 85508
AR-1372T	Full Thread Cannulated Interference Screw, 7 x 30 mm	IIB	DoC_Plates, Screws, Wedge, Staples_r49	CE 85509
AR-1381T	Full Thread Cannulated Interference crew 8 x 25 mm	IIB	DoC_Plates, Screws, Wedge, Staples_r50	CE 85510
AR-1382T	Full Thread Cannulated Interference Screw, 8 x 30 mm	IIB	DoC_Plates, Screws, Wedge, Staples_r51	CE 85511
AR-1391T	Full Thread Cannulated Interference Screw, 9 x 25 mm	IIB	DoC_Plates, Screws, Wedge, Staples_r52	CE 85512
AR-1392T	Full Thread Cannulated Interference Screw 9 x 30 mm	IIB	DoC_Plates, Screws, Wedge, Staples_r53	CE 85513
AR-1401T	Full Thread Cannulated Interference Screw, 10 x 25 mm	IIB	DoC_Plates, Screws, Wedge, Staples_r54	CE 85514
AR-1402T	Full Thread Cannulated Interference Screw 10 x 30 mm	IIB	DoC_Plates, Screws, Wedge, Staples_r55	CE 85515
AR-1588RT-2J	ACL TightRope® II RT, Double Loaded Passing Sutures	IIB	DoC Buttons; Suture_r43	CE 85507
AR-1324HF-1	Suture Anchor, FASTak II with #2 FiberWireand Handled Inserter, 2.8 x 11.7 mm	IIB	DoC Anchors	CE 85507
AR-1322-752SF	Small Bone FASTak Suture Anchor with 2-0 FiberWire,2.4 x 7.5 mm	IIB	DoC Anchors	CE 85507

Sunt autentice și corespund realității.

Cristina GUȚU, Șef Secție „GBG-MLD” SRL

Semnătura _____

Data _____

Section

1

1. Declaration of Conformity

Technical File Plates, Screws, Wedges, and Staples

GMDN Codes Refer to Parts List, Rev. 47 for a complete list of all GMDN Codes subject of this Technical File

Revision 47

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.



David Rogers
Director, Regulatory Affairs

2/25/22
Date

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	GMDN code	Technical File	Rule	Annex	First DoC
BI-CORTICAL POST Family										
Arthrex, Inc.	Naples, FL	CE 85507	AR-1365-275	Bi-Cortical Post 27.5mm	IIB	46646	PLATE, SCREWS, WEDGE and STAPLES	8	II	11/25/2002
Arthrex, Inc.	Naples, FL	CE 85507	AR-1365-30	Bi-Cortical Post 30mm	IIB	46646	PLATE, SCREWS, WEDGE and STAPLES	8	II	11/25/2002
Arthrex, Inc.	Naples, FL	CE 85507	AR-1365-325	Bi-Cortical Post 32.5mm	IIB	46646	PLATE, SCREWS, WEDGE and STAPLES	8	II	11/25/2002
Arthrex, Inc.	Naples, FL	CE 85507	AR-1365-35	Bi-Cortical Post 35mm	IIB	46646	PLATE, SCREWS, WEDGE and STAPLES	8	II	11/25/2002
Arthrex, Inc.	Naples, FL	CE 85507	AR-1365-375	Bi-Cortical Post 37.5mm	IIB	46646	PLATE, SCREWS, WEDGE and STAPLES	8	II	11/25/2002
Arthrex, Inc.	Naples, FL	CE 85507	AR-1365-40	Bi-Cortical Post 40mm	IIB	46646	PLATE, SCREWS, WEDGE and STAPLES	8	II	11/25/2002
Arthrex, Inc.	Naples, FL	CE 85507	AR-1365-425	Bi-Cortical Post 42.5mm	IIB	46646	PLATE, SCREWS, WEDGE and STAPLES	8	II	11/25/2002
Arthrex, Inc.	Naples, FL	CE 85507	AR-1365-45	Bi-Cortical Post 45mm	IIB	46646	PLATE, SCREWS, WEDGE and STAPLES	8	II	11/25/2002
Arthrex, Inc.	Naples, FL	CE 85507	AR-1365-475	Bi-Cortical Post 47.5mm	IIB	46646	PLATE, SCREWS, WEDGE and STAPLES	8	II	11/25/2002
Arthrex, Inc.	Naples, FL	CE 85507	AR-1365-50	Bi-Cortical Post 50mm	IIB	46646	PLATE, SCREWS, WEDGE and STAPLES	8	II	11/25/2002
CLAVICLE PLATE Family										
Arthrex, Inc.	Naples, FL	CE 85507	AR-2622DL	Distal Clavicle Plate, 22 Degree, Left	IIB	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	7/24/2015
Arthrex, Inc.	Naples, FL	CE 85507	AR-2622DR	Distal Clavicle Plate, 22 Degree, Right	IIB	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	7/24/2015
Arthrex, Inc.	Naples, FL	CE 85507	AR-2650CL	CLAVICLE FRACTURE PLATE, CENTRAL THIRD, LEFT, SS	IIB	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	9/10/2010
Arthrex, Inc.	Naples, FL	CE 85507	AR-2650CLS	Clav Frac Plt, Central Third, Lft, SS, Strl	IIB	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	5/9/2016
Arthrex, Inc.	Naples, FL	CE 85507	AR-2650CR	CLAVICLE FRACTURE PLATE, CENTRAL THIRD, RIGHT, SS	IIB	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	9/10/2010
Arthrex, Inc.	Naples, FL	CE 85507	AR-2650CRS	Clav Frac Plt, Central Third, RT, SS, STRL	IIB	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	5/9/2016
Arthrex, Inc.	Naples, FL	CE 85507	AR-2651CL	CLAVICLE FRACTURE PLATE, CENTRAL THIRD, LEFT, SS	IIB	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	9/10/2010
Arthrex, Inc.	Naples, FL	CE 85507	AR-2651CLS	Clav Frac Plt, Central Third, Lft, SS, Strl	IIB	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	5/9/2016
Arthrex, Inc.	Naples, FL	CE 85507	AR-2651CR	CLAVICLE FRACTURE PLATE, CENTRAL THIRD, RIGHT, SS	IIB	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	9/10/2010
Arthrex, Inc.	Naples, FL	CE 85507	AR-2651CRS	Clavicle Fracture Plate, Central Third, Right, Stainless Steel, Sterile	IIB	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	5/25/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-2652CL	CLAVICLE FRACTURE PLATE, CENTRAL THIRD, LEFT, SS	IIB	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	9/10/2010
Arthrex, Inc.	Naples, FL	CE 85507	AR-2652CLS	Clav Frac Plt, Central Third, Lft, SS, Strl	IIB	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	5/9/2016
Arthrex, Inc.	Naples, FL	CE 85507	AR-2652CR	CLAVICLE FRACTURE PLATE, CENTRAL THIRD, RIGHT, SS	IIB	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	9/10/2010
Arthrex, Inc.	Naples, FL	CE 85507	AR-2652CRS	Clav Frac Plt, Central Third, RT, SS, STRL	IIB	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	5/9/2016
Arthrex, Inc.	Naples, FL	CE 85507	AR-2653CL	CLAVICLE FRACTURE PLATE, CENTRAL THIRD, LEFT, SS	IIB	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	9/10/2010
Arthrex, Inc.	Naples, FL	CE 85507	AR-2653CLS	Clav Frac Plt, Central Third, Lft, SS, Strl	IIB	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	5/9/2016
Arthrex, Inc.	Naples, FL	CE 85507	AR-2653CR	CLAVICLE FRACTURE PLATE, CENTRAL THIRD, RIGHT, SS	IIB	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	9/10/2010
Arthrex, Inc.	Naples, FL	CE 85507	AR-2653CRS	Clav Frac Plt, Central Third, RT, SS, STRL	IIB	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	5/9/2016
Arthrex, Inc.	Naples, FL	CE 85507	AR-2654CL	CLAVICLE FRACTURE PLATE, CENTRAL THIRD, LEFT, SS	IIB	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	9/10/2010
Arthrex, Inc.	Naples, FL	CE 85507	AR-2654CLS	Clav Frac Plt, Central Third, Lft, SS, Strl	IIB	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	5/9/2016
Arthrex, Inc.	Naples, FL	CE 85507	AR-2654CR	CLAVICLE FRACTURE PLATE, CENTRAL THIRD, RIGHT, SS	IIB	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	9/10/2010
Arthrex, Inc.	Naples, FL	CE 85507	AR-2654CRS	Clav Frac Plt, Central Third, RT, SS, STRL	IIB	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	5/9/2016
Arthrex, Inc.	Naples, FL	CE 85507	AR-2655CL	CLAVICLE FRACTURE PLATE, CENTRAL THIRD, LEFT, SS	IIB	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	9/10/2010
Arthrex, Inc.	Naples, FL	CE 85507	AR-2655CLS	Clavicle Fracture Plate, Central Third, Left, Stainless Steel, Sterile	IIB	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	5/25/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-2655CR	CLAVICLE FRACTURE PLATE, CENTRAL THIRD, RIGHT, SS	IIB	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	9/10/2010
Arthrex, Inc.	Naples, FL	CE 85507	AR-2655CRS	Clav Frac Plt, Central Third, RT, SS, STRL	IIB	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	5/9/2016
Arthrex, Inc.	Naples, FL	CE 85507	AR-2656DL	DISTAL CLAVICLE PLATE, SHORT, LEFT, SS	IIB	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	11/3/2010
Arthrex, Inc.	Naples, FL	CE 85507	AR-2656DLS	Distal Clav Plate, Short, Left, SS, STRL	IIB	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	5/9/2016
Arthrex, Inc.	Naples, FL	CE 85507	AR-2656DR	DISTAL CLAVICLE PLATE, SHORT, RIGHT, SS	IIB	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	11/3/2010
Arthrex, Inc.	Naples, FL	CE 85507	AR-2656DRS	Distal Clav Plate, Short, Right, SS, STRL	IIB	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	5/9/2016
Arthrex, Inc.	Naples, FL	CE 85507	AR-2657DL	DISTAL CLAVICLE PLATE, LONG, LEFT, SS	IIB	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	11/3/2010
Arthrex, Inc.	Naples, FL	CE 85507	AR-2657DLS	Distal Clav Plate, 8 Hole, Left, SS, STRL	IIB	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	5/9/2016
Arthrex, Inc.	Naples, FL	CE 85507	AR-2657DR	DISTAL CLAVICLE PLATE, LONG, RIGHT, SS	IIB	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	11/3/2010
Arthrex, Inc.	Naples, FL	CE 85507	AR-2657DRS	Distal Clav Plate, 8 Hole, Left, SS, STRL	IIB	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	5/9/2016
Arthrex, Inc.	Naples, FL	CE 85507	AR-2658	Button, Distal Clavicle Plate, Stainless Steel	IIB	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	4/5/2019
Arthrex, Inc.	Naples, FL	CE 85507	AR-2658S	Button, Distal Clavicle Plate, Stainless Steel, Sterile	IIB	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	5/25/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-2658T	Knotless Distal Clavicle Plate Button Assembly	IIB	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	4/5/2019
Arthrex, Inc.	Naples, FL	CE 85507	AR-2680ST	Clavicle Fracture Plate, 7 Hole, Straight	IIB	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	7/24/2015
Arthrex, Inc.	Naples, FL	CE 85507	AR-2685DL-10	Distal Clavicle Plate, 10 Hole, Left	IIB	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	7/24/2015
Arthrex, Inc.	Naples, FL	CE 85507	AR-2685DR-10	Distal Clavicle Plate, 10 Hole, Right	IIB	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	7/24/2015
COMPRESSION SCREW Family										
Arthrex, Inc.	Naples, FL	CE 85507	AR-8625-08	Headless Compression Screw, 2.5 x 8 mm, cannulated	IIB	56642	PLATE, SCREWS, WEDGE and STAPLES	8	II	10/1/2015
Arthrex, Inc.	Naples, FL	CE 85507	AR-8625-08S	Headless Compression Screw, 2.5 x 8 mm, cannulated, sterile	IIB	56642	PLATE, SCREWS, WEDGE and STAPLES	8	II	10/1/2015
Arthrex, Inc.	Naples, FL	CE 85507	AR-8625-10	Headless Compression Screw, 2.5 x 10 mm, cannulated	IIB	56642	PLATE, SCREWS, WEDGE and STAPLES	8	II	10/1/2015
Arthrex, Inc.	Naples, FL	CE 85507	AR-8625-10S	Headless Compression Screw, 2.5 x 10 mm, cannulated, sterile	IIB	56642	PLATE, SCREWS, WEDGE and STAPLES	8	II	10/1/2015
Arthrex, Inc.	Naples, FL	CE 85507	AR-8625-12	Headless Compression Screw, 2.5 x 12 mm, cannulated	IIB	56642	PLATE, SCREWS, WEDGE and STAPLES	8	II	10/1/2015
Arthrex, Inc.	Naples, FL	CE 85507	AR-8625-12S	Headless Compression Screw, 2.5 x 12 mm, cannulated, sterile	IIB	56642	PLATE, SCREWS, WEDGE and STAPLES	8	II	10/1/2015
Arthrex, Inc.	Naples, FL	CE 85507	AR-8625-14	Headless Compression Screw, 2.5 x 14 mm, cannulated	IIB	56642	PLATE, SCREWS, WEDGE and STAPLES	8	II	10/1/2015
Arthrex, Inc.	Naples, FL	CE 85507	AR-8625-14S	Headless Compression Screw, 2.5 x 14 mm, cannulated, sterile	IIB	56642	PLATE, SCREWS, WEDGE and STAPLES	8	II	10/1/2015
Arthrex, Inc.	Naples, FL	CE 85507	AR-8625-16	Headless Compression Screw, 2.5 x 16 mm, cannulated	IIB	56642	PLATE, SCREWS, WEDGE and STAPLES	8	II	10/1/2015

Manufacturer Name	Manufacturing Location	EC QA Cert. Number	Product Code	Product Name	Class	GMDN code	Technical File	Rule	Annex	First DoC
Arthrex, Inc.	Naples, FL	CE 85507	AR-1400	Cannulated Interference Screw, 10 x 20mm	IIb	46646	PLATE, SCREWS, WEDGE and STAPLES	8	II	1/2/2002
Arthrex, Inc.	Naples, FL	CE 85507	AR-1400H-25	Soft Screw, 10 x 25mm	IIb	46646	PLATE, SCREWS, WEDGE and STAPLES	8	II	1/2/2002
Arthrex, Inc.	Naples, FL	CE 85507	AR-1400H-30	Soft Screw, 10 x 30mm	IIb	46646	PLATE, SCREWS, WEDGE and STAPLES	8	II	1/2/2002
Arthrex, Inc.	Naples, FL	CE 85507	AR-1400H-35	Soft Screw, 10 x 35mm	IIb	46646	PLATE, SCREWS, WEDGE and STAPLES	8	II	1/2/2002
Arthrex, Inc.	Naples, FL	CE 85507	AR-1400P	Peek Inteference Screw, 10 x 23 mm	IIb	46646	PLATE, SCREWS, WEDGE and STAPLES	8	II	9/19/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-1400T	Full Threaded Cannulated Interference Screw, 10 x 20mm	IIb	46646	PLATE, SCREWS, WEDGE and STAPLES	8	II	1/2/2002
Arthrex, Inc.	Naples, FL	CE 85507	AR-1401	Cannulated Interference Screw, 10 x 25mm	IIb	46646	PLATE, SCREWS, WEDGE and STAPLES	8	II	1/2/2002
Arthrex, Inc.	Naples, FL	CE 85507	AR-1401T	Full Threaded Cannulated Interference Screw, 10 x 25mm	IIb	46646	PLATE, SCREWS, WEDGE and STAPLES	8	II	1/2/2002
Arthrex, Inc.	Naples, FL	CE 85507	AR-1402T	Full Threaded Cannulated Interference Screw, 10 x 30mm	IIb	46646	PLATE, SCREWS, WEDGE and STAPLES	8	II	1/2/2002
Arthrex, Inc.	Naples, FL	CE 85507	AR-1525PS	Tenodesis Screw, PEEK, 2.5 x 6 mm	IIb	46646	PLATE, SCREWS, WEDGE AND STAPLES	8	II	5/7/2019
Arthrex, Inc.	Naples, FL	CE 85507	AR-1525PS-1	Tenodesis Screw, PEEK, 2.5 x 6 mm	IIb	46646	PLATE, SCREWS, WEDGE AND STAPLES	8	II	5/7/2019
Arthrex, Inc.	Naples, FL	CE 85507	AR-1530PS	PEEK-Tenodesis Screw w/Handled Inserter, 3 x 8 mm	IIb	46646	PLATE, SCREWS, WEDGE and STAPLES	8	II	9/19/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-1540PS	PEEK Tenodesis Screw, 4 mm x 10 mm	IIb	46646	PLATE, SCREWS, WEDGE and STAPLES	8	II	4/4/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-1547PS	PEEK Tenodesis Screw, 4.75 mm x 15 mm	IIb	46646	PLATE, SCREWS, WEDGE and STAPLES	8	II	4/4/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-1555PS	PEEK Tenodesis Screw, 5.5 mm x 15 mm	IIb	46646	PLATE, SCREWS, WEDGE and STAPLES	8	II	1/18/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-1562PS	PEEK Tenodesis Screw, 6.25 mm x 15 mm	IIb	46646	PLATE, SCREWS, WEDGE and STAPLES	8	II	4/4/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-1570PS	Peek Tenodesis Screw, 7 X 23mm	IIb	46646	PLATE, SCREWS, WEDGE and STAPLES	8	II	2/5/2009
Arthrex, Inc.	Naples, FL	CE 85507	AR-1580PS	Peek Tenodesis Screw, 8 X 23mm	IIb	46646	PLATE, SCREWS, WEDGE and STAPLES	8	II	2/5/2009
Arthrex, Inc.	Naples, FL	CE 85507	AR-1590PS	Peek Tenodesis Screw, 9 X 23mm	IIb	46646	PLATE, SCREWS, WEDGE and STAPLES	8	II	2/5/2009
Arthrex, Inc.	Naples, FL	CE 85507	AR-1655PS	PEEK Tenodesis Screw, 5.5 x 8 mm, sterile	IIb	46646	PLATE, SCREWS, WEDGE and STAPLES	8	II	7/25/2005
Arthrex, Inc.	Naples, FL	CE 85507	AR-1655PS-10	PEEK Tenodesis Screw, 5.5 mm x 10 mm	IIb	46646	PLATE, SCREWS, WEDGE and STAPLES	8	II	1/18/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-1655PS-12	PEEK Tenodesis Screw, 5.5 mm x 12 mm	IIb	46646	PLATE, SCREWS, WEDGE and STAPLES	8	II	1/18/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-1662PSL-710	PEEK SwiveLock Biceps Tenodesis Screw, 7 x 10 mm	IIb	46646	PLATE, SCREWS, WEDGE and STAPLES	8	II	4/5/2019
Arthrex, Inc.	Naples, FL	CE 85507	AR-1662PSL-710-1	PEEK SwiveLock Biceps Tenodesis Screw, 7 x 10 mm	IIb	46646	PLATE, SCREWS, WEDGE and STAPLES	8	II	4/5/2019
Arthrex, Inc.	Naples, FL	CE 85507	AR-1662PSL-723	PEEK SwiveLock Biceps Tenodesis Screw, 7 x 23 mm	IIb	46646	PLATE, SCREWS, WEDGE and STAPLES	8	II	4/5/2019
Arthrex, Inc.	Naples, FL	CE 85507	AR-1662PSL-723-1	PEEK SwiveLock Biceps Tenodesis Screw, 7 x 23 mm	IIb	46646	PLATE, SCREWS, WEDGE and STAPLES	8	II	4/5/2019
Arthrex, Inc.	Naples, FL	CE 85507	AR-1662PSL-812	PEEK SwiveLock Biceps Tenodesis Screw, 8 x 12 mm	IIb	46646	PLATE, SCREWS, WEDGE and STAPLES	8	II	4/5/2019
Arthrex, Inc.	Naples, FL	CE 85507	AR-1662PSL-812-1	PEEK SwiveLock Biceps Tenodesis Screw, 8 x 12 mm	IIb	46646	PLATE, SCREWS, WEDGE and STAPLES	8	II	4/5/2019
Arthrex, Inc.	Naples, FL	CE 85507	AR-1662PSL-823	PEEK SwiveLock Biceps Tenodesis Screw, 8 x 23 mm	IIb	46646	PLATE, SCREWS, WEDGE and STAPLES	8	II	4/5/2019
Arthrex, Inc.	Naples, FL	CE 85507	AR-1662PSL-823-1	PEEK SwiveLock Biceps Tenodesis Screw, 8 x 23 mm	IIb	46646	PLATE, SCREWS, WEDGE and STAPLES	8	II	4/5/2019
Arthrex, Inc.	Naples, FL	CE 85507	AR-1662PSL-923	PEEK SwiveLock Biceps Tenodesis Screw, 9 x 23 mm	IIb	46646	PLATE, SCREWS, WEDGE and STAPLES	8	II	4/5/2019
Arthrex, Inc.	Naples, FL	CE 85507	AR-1662PSL-923-1	PEEK SwiveLock Biceps Tenodesis Screw, 9 x 23 mm	IIb	46646	PLATE, SCREWS, WEDGE and STAPLES	8	II	4/5/2019
Arthrex, Inc.	Naples, FL	CE 85507	AR-1670PS	PEEK Tenodesis Screw, 7 mm x 10 mm	IIb	46646	PLATE, SCREWS, WEDGE and STAPLES	8	II	4/4/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-1680PS	PEEK Tenodesis Screw, 8 mm x 12 mm	IIb	46646	PLATE, SCREWS, WEDGE and STAPLES	8	II	1/18/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-4020P-06	FastThread™ PEEK Interference Screws With Disposable Sheath, 6 X 20mm	IIb	46646	PLATE, SCREWS, WEDGE and STAPLES	8	II	6/8/2020
Arthrex, Inc.	Naples, FL	CE 85507	AR-4020P-07	FastThread™ PEEK Interference Screws With Disposable Sheath, 7 X 20mm	IIb	46646	PLATE, SCREWS, WEDGE and STAPLES	8	II	6/8/2020
Arthrex, Inc.	Naples, FL	CE 85507	AR-4020P-08	FastThread™ PEEK Interference Screws With Disposable Sheath, 8 X 20mm	IIb	46646	PLATE, SCREWS, WEDGE and STAPLES	8	II	6/8/2020
Arthrex, Inc.	Naples, FL	CE 85507	AR-4020P-09	FastThread™ PEEK Interference Screws With Disposable Sheath, 9 X 20mm	IIb	46646	PLATE, SCREWS, WEDGE and STAPLES	8	II	6/8/2020
Arthrex, Inc.	Naples, FL	CE 85507	AR-4020P-10	FastThread™ PEEK Interference Screws With Disposable Sheath, 10 X 20mm	IIb	46646	PLATE, SCREWS, WEDGE and STAPLES	8	II	6/8/2020
Arthrex, Inc.	Naples, FL	CE 85507	AR-4030P-07	FastThread™ PEEK Interference Screws, 7mm X 30mm	IIb	46646	PLATE, SCREWS, WEDGE and STAPLES	8	II	6/8/2020
Arthrex, Inc.	Naples, FL	CE 85507	AR-4030P-08	FastThread™ PEEK Interference Screws, 8mm X 30mm	IIb	46646	PLATE, SCREWS, WEDGE and STAPLES	8	II	6/8/2020
Arthrex, Inc.	Naples, FL	CE 85507	AR-4030P-09	FastThread™ PEEK Interference Screws, 9mm X 30mm	IIb	46646	PLATE, SCREWS, WEDGE and STAPLES	8	II	6/8/2020
Arthrex, Inc.	Naples, FL	CE 85507	AR-4030P-10	FastThread™ PEEK Interference Screws, 10mm X 30mm	IIb	46646	PLATE, SCREWS, WEDGE and STAPLES	8	II	6/8/2020
Arthrex, Inc.	Naples, FL	CE 85507	AR-4030P-11	FastThread™ PEEK Interference Screws, 11mm X 30mm	IIb	46646	PLATE, SCREWS, WEDGE and STAPLES	8	II	6/8/2020
Arthrex, Inc.	Naples, FL	CE 85507	AR-4030P-12	FastThread™ PEEK Interference Screws, 12mm X 30mm	IIb	46646	PLATE, SCREWS, WEDGE and STAPLES	8	II	6/8/2020
Arthrex, Inc.	Naples, FL	CE 85507	AR-5028P-07	Round Delta Tapered PEEK Screw, 7 X 28mm	IIb	46646	PLATE, SCREWS, WEDGE and STAPLES	8	II	12/14/2009
Arthrex, Inc.	Naples, FL	CE 85507	AR-5028P-08	Round Delta Tapered PEEK Screw, 8 X 28mm	IIb	46646	PLATE, SCREWS, WEDGE and STAPLES	8	II	12/14/2009
Arthrex, Inc.	Naples, FL	CE 85507	AR-5028P-09	Round Delta Tapered PEEK Screw, 9 X 28mm	IIb	46646	PLATE, SCREWS, WEDGE and STAPLES	8	II	12/14/2009
Arthrex, Inc.	Naples, FL	CE 85507	AR-5028P-10	Round Delta Tapered PEEK Screw, 10 X 28mm	IIb	46646	PLATE, SCREWS, WEDGE and STAPLES	8	II	12/14/2009
Arthrex, Inc.	Naples, FL	CE 85507	AR-5028P-11	Round Delta Tapered PEEK Screw, 11 X 28mm	IIb	46646	PLATE, SCREWS, WEDGE and STAPLES	8	II	12/14/2009
Arthrex, Inc.	Naples, FL	CE 85507	AR-5028P-12	Round Delta Tapered PEEK Screw, 12 X 28mm	IIb	46646	PLATE, SCREWS, WEDGE and STAPLES	8	II	12/14/2009
Arthrex, Inc.	Naples, FL	CE 85507	AR-5035P-09	Delta Tapered PEEK Screw 9 X 35mm	IIb	46646	PLATE, SCREWS, WEDGE and STAPLES	8	II	12/14/2009
Arthrex, Inc.	Naples, FL	CE 85507	AR-5035P-10	Delta Tapered PEEK Screw 10 X 35mm	IIb	46646	PLATE, SCREWS, WEDGE and STAPLES	8	II	12/14/2009
Arthrex, Inc.	Naples, FL	CE 85507	AR-5035P-11	Delta Tapered PEEK Screw 11 X 35mm	IIb	46646	PLATE, SCREWS, WEDGE and STAPLES	8	II	12/14/2009
Arthrex, Inc.	Naples, FL	CE 85507	AR-5035P-12	Delta Tapered PEEK Screw 12 X 35mm	IIb	46646	PLATE, SCREWS, WEDGE and STAPLES	8	II	12/14/2009
K-WIRE Family										
Arthrex, Inc.	Naples, FL	CE 85507	AR-2521	Percutaneous Pinning, Term Threaded Pin, 2.8mm	IIb	32854	PLATE, SCREWS, WEDGE and STAPLES	8	II	12/11/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-5050K-1	K-WIRE, 1.6 X 200 MM	IIb	32854	PLATE, SCREWS, WEDGE and STAPLES	8	II	7/24/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-5050K-2	K-WIRE, 2.0 X 200 MM	IIb	32854	PLATE, SCREWS, WEDGE and STAPLES	8	II	7/24/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-5050K-1S	K-Wire, 1.6 x 200 mm, SS, Sterile	IIb	32854	PLATE, SCREWS, WEDGE and STAPLES	8	II	2/24/2020
Arthrex, Inc.	Naples, FL	CE 85507	AR-5050K-2S	K-Wire, 2.0 x 200 mm, SS, Sterile	IIb	32854	PLATE, SCREWS, WEDGE and STAPLES	8	II	2/24/2020
OPENING and CLOSING WEDGE OSTEOTOMY SYSTEM Family										

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Manufacturer Name	Manufacturing Location	EC QA Cert. Number	Product Code	Product Name	Class	GMDN code	Technical File	Rule	Annex	First DoC
Arthrex, Inc.	Naples, FL	CE 85507	AR-13715-05.0	CONTOURLOCK HTO PLATE, STRAIGHT WEDGE 5MM RGT	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	9/19/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-13715-07.5	CONTOURLOCK HTO PLATE, STRAIGHT WEDGE 7.5MM RGT	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	9/19/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-13715-09.0	CONTOURLOCK HTO PLATE, STRAIGHT WEDGE 9MM RGT	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	9/19/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-13715-10.0	CONTOURLOCK HTO PLATE, STRAIGHT WEDGE 10MM RGT	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	9/19/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-13715-11.0	CONTOURLOCK HTO PLATE, STRAIGHT WEDGE 11MM RGT	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	9/19/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-13715-12.5	CONTOURLOCK HTO PLATE, STRGT WEDGE 12.5MM RGT	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	9/19/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-13715-15.0	CONTOURLOCK HTO PLATE, STRAIGHT WEDGE 15MM RGT	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	9/19/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-13715-17.5	CONTOURLOCK HTO PLATE, STRGT WEDGE 17.5MM RGT	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	9/19/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-13720-05.0	CONTOURLOCK HTO PLATE, A/P SLOPED WEDGE 5MM LF	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	9/19/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-13720-07.5	CONTOURLOCK HTO PLATE, A/P SLOPED WEDGE 7.5MM LF	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	9/19/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-13720-09.0	CONTOURLOCK HTO PLATE, A/P SLOPED WEDGE 9MM LF	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	9/19/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-13720-10.0	CONTOURLOCK HTO PLATE, A/P SLOPED WEDGE 10MM LF	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	9/19/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-13720-11.0	CONTOURLOCK HTO PLATE, A/P SLOPED WEDGE 11MM LF	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	9/19/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-13720-12.5	CONTOURLOCK HTO PLATE, A/P SLOPED WEDGE 12.5MM LF	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	9/19/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-13720-15.0	CONTOURLOCK HTO PLATE, A/P SLOPED WEDGE 15MM LF	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	9/19/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-13720-17.5	CONTOURLOCK HTO PLATE, A/P SLOPED WEDGE 17.5MM LF	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	9/19/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-13725-05.0	CONTOURLOCK HTO PLATE, A/P SLOPED WEDGE 5MM RGT	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	9/19/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-13725-07.5	CONTOURLOCK HTO PLATE, A/P SLOPED WEDGE 7.5MM R	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	9/19/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-13725-09.0	CONTOURLOCK HTO PLATE, A/P SLOPED WEDGE 9MM RGT	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	9/19/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-13725-10.0	CONTOURLOCK HTO PLATE, A/P SLOPED WEDGE 10MM R	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	9/19/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-13725-11.0	CONTOURLOCK HTO PLATE, A/P SLOPED WEDGE 11MM R	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	9/19/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-13725-12.5	CONTOURLOCK HTO PLATE, A/P SLPD W, SD-R, 12.5MM	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	9/19/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-13725-15.0	CONTOURLOCK HTO PLATE, A/P SLOPED WEDGE 15MM R	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	9/19/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-13725-17.5	CONTOURLOCK HTO PLATE, A/P SLOPED WEDGE 17.5MM R	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	9/19/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-13730-01	CONTOURLOCK HTO PLATE, FLAT, LEFT, 67MM	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	9/19/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-13730-02	CONTOURLOCK HTO PLATE, FLAT, LEFT, 71MM	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	9/19/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-13730-03	CONTOURLOCK HTO PLATE, FLAT, LEFT, 84MM	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	9/19/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-13735-01	CONTOURLOCK HTO PLATE, FLAT, RIGHT, 67MM	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	9/19/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-13735-02	CONTOURLOCK HTO PLATE, FLAT, RIGHT, 71MM	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	9/19/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-13735-03	CONTOURLOCK HTO PLATE, FLAT, RIGHT, 84MM	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	9/19/2008
				PATELLA SUTUREPLATE Family						
Arthrex, Inc.	Naples, FL	CE 85507	AR-13059S	Patella SuturePlate™ Star Small	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	2/24/2012
Arthrex, Inc.	Naples, FL	CE 85507	AR-13059S-S	Patella SuturePlate™, Star, Small, Sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	7/5/2018
Arthrex, Inc.	Naples, FL	CE 85507	AR-13060A	Patella SuturePlate™ Arrow	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	3/21/2011
Arthrex, Inc.	Naples, FL	CE 85507	AR-13060A-S	Patella SuturePlate™, Arrow, Sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	7/5/2018
Arthrex, Inc.	Naples, FL	CE 85507	AR-13060S	Patella SuturePlate™ Star	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	3/21/2011
Arthrex, Inc.	Naples, FL	CE 85507	AR-13060S-S	Patella SuturePlate™, Star, Medium, Sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	7/5/2018
Arthrex, Inc.	Naples, FL	CE 85507	AR-13061S	Patella SuturePlate™ Star Large	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	2/24/2012
Arthrex, Inc.	Naples, FL	CE 85507	AR-13061S-S	Patella SuturePlate™, Star, Large, Sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	7/5/2018
Arthrex, Inc.	Naples, FL	CE 85507	AR-13070A	Patella SuturePlate™ II, Arrow	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	6/1/2018
Arthrex, Inc.	Naples, FL	CE 85507	AR-13070A-S	Patella SuturePlate™ II, Arrow, 3 mm, Sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	7/5/2018
Arthrex, Inc.	Naples, FL	CE 85507	AR-13070L	Patella SuturePlate™ II, Star, Large	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	6/1/2018
Arthrex, Inc.	Naples, FL	CE 85507	AR-13070L-P	Patella SuturePlate™ II, Star, Pole Fracture, Large	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	6/1/2018
Arthrex, Inc.	Naples, FL	CE 85507	AR-13070L-P-S	Patella SuturePlate™ II, Star, Pole Fracture, Large, Sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	7/5/2018
Arthrex, Inc.	Naples, FL	CE 85507	AR-13070L-S	Patella SuturePlate™ II, Star, 3 mm, Large, Sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	7/5/2018
Arthrex, Inc.	Naples, FL	CE 85507	AR-13070M	Patella SuturePlate™ II, Star, Medium	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	6/1/2018
Arthrex, Inc.	Naples, FL	CE 85507	AR-13070M-P	Patella SuturePlate™ II, Star, Pole Fracture, Medium	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	7/5/2018
Arthrex, Inc.	Naples, FL	CE 85507	AR-13070M-P-S	Patella SuturePlate™ II, Star, Pole Fracture, Medium, Sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	7/5/2018
Arthrex, Inc.	Naples, FL	CE 85507	AR-13070M-S	Patella SuturePlate™ II, Star, 3 mm, Medium, Sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	7/5/2018
Arthrex, Inc.	Naples, FL	CE 85507	AR-13070S	Patella SuturePlate™ II, Star, Small	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	6/1/2018
Arthrex, Inc.	Naples, FL	CE 85507	AR-13070S-P	Patella SuturePlate™ II, Star, Pole Fracture, Small	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	6/1/2018
Arthrex, Inc.	Naples, FL	CE 85507	AR-13070S-P-S	Patella SuturePlate™ II, Star, Pole Fracture, Small, Sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	7/5/2018
Arthrex, Inc.	Naples, FL	CE 85507	AR-13070S-S	Patella SuturePlate™ II, Star, 3 mm, Small, Sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	7/5/2018
				PEEKPOWER SYSTEMS Family						
Arthrex, Inc.	Naples, FL	CE 85507	AR-13401L	PEEKPower, HTO Plate	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	11/19/2009
Arthrex, Inc.	Naples, FL	CE 85507	AR-13402L	PEEKPower Plate, Lateral Distal Femoral Osteotomy, Left	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	10/28/2015
Arthrex, Inc.	Naples, FL	CE 85507	AR-13402R	PEEKPower Plate, Lateral Distal Femoral Osteotomy, Right	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	10/28/2015
Arthrex, Inc.	Naples, FL	CE 85507	AR-14003P	PEEKPower, Humeral Fracture Plate, proximal 3-hole	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	12/10/2012
Arthrex, Inc.	Naples, FL	CE 85507	AR-14005P	PEEKPower, Humeral Fracture Plate, proximal 5-hole	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	12/10/2012

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Manufacturer Name	Manufacturing Location	EC QA Cert. Number	Product Code	Product Name	Class	GMDN code	Technical File	Rule	Annex	First DoC
Arthrex, Inc.	Naples, FL	CE 85507	AR-8654MR-S	Distal Humerus Fracture Plate, Medial, SS, Right, Short	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	5/25/2021
Arthrex, Inc.	Naples, FL	CE 85507	AR-8654MR-SS	Distal Humerus Fracture Plate, Medial, Ti, Right, Sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	5/25/2021
Arthrex, Inc.	Naples, FL	CE 85507	AR-8654PL-L	Distal Humerus Fracture Plate, Posterolateral, SS, Left, Long	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	5/25/2021
Arthrex, Inc.	Naples, FL	CE 85507	AR-8654PL-LS	Distal Humerus Fracture Plate, Posterolateral, SS, Left, Long, Sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	5/25/2021
Arthrex, Inc.	Naples, FL	CE 85507	AR-8654PL-M	Distal Humerus Fracture Plate, Posterolateral, SS, Left, Medium	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	5/25/2021
Arthrex, Inc.	Naples, FL	CE 85507	AR-8654PL-MS	Distal Humerus Fracture Plate, Posterolateral, SS, Left, Medium, Sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	5/25/2021
Arthrex, Inc.	Naples, FL	CE 85507	AR-8654PL-S	Distal Humerus Fracture Plate, Posterolateral, SS, Left, Short	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	5/25/2021
Arthrex, Inc.	Naples, FL	CE 85507	AR-8654PL-SS	Distal Humerus Fracture Plate, Posterolateral, SS, Left, Short, Sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	5/25/2021
Arthrex, Inc.	Naples, FL	CE 85507	AR-8654PR-L	Distal Humerus Fracture Plate, Posterolateral, SS, Right, Long	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	5/25/2021
Arthrex, Inc.	Naples, FL	CE 85507	AR-8654PR-LS	Distal Humerus Fracture Plate, Posterolateral, SS, Right, Long, Sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	5/25/2021
Arthrex, Inc.	Naples, FL	CE 85507	AR-8654PR-M	Distal Humerus Fracture Plate, Posterolateral, SS, Right, Medium	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	5/25/2021
Arthrex, Inc.	Naples, FL	CE 85507	AR-8654PR-MS	Distal Humerus Fracture Plate, Posterolateral, SS, Right, Medium, Sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	5/25/2021
Arthrex, Inc.	Naples, FL	CE 85507	AR-8654PR-S	Distal Humerus Fracture Plate, Posterolateral, SS, Right, Short	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	5/25/2021
Arthrex, Inc.	Naples, FL	CE 85507	AR-8654PR-SS	Distal Humerus Fracture Plate, Posterolateral, SS, Right, Short, Sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	5/25/2021
Arthrex, Inc.	Naples, FL	CE 85507	AR-8724W	WASHER, 6.0MM, TI	IIb	61670	PLATE, SCREWS, WEDGE and STAPLES	8	II	6/12/2013
Arthrex, Inc.	Naples, FL	CE 85507	AR-8724WS	Washer, 6 mm, Sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	7/11/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8730W	WASHER, 6.5MM, TI	IIb	61670	PLATE, SCREWS, WEDGE and STAPLES	8	II	6/12/2013
Arthrex, Inc.	Naples, FL	CE 85507	AR-8730WS	Washer, 6.5 mm, Ti, Sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	7/24/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8740W	WASHER, 7.0MM, TI	IIb	61670	PLATE, SCREWS, WEDGE and STAPLES	8	II	6/12/2013
Arthrex, Inc.	Naples, FL	CE 85507	AR-8740WS	Washer, 7 mm, Sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	7/11/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8870W	WASHER, 7.0 MM STAINLESS STEEL	IIb	61670	PLATE, SCREWS, WEDGE and STAPLES	8	II	4/14/2009
Arthrex, Inc.	Naples, FL	CE 85507	AR-8870WS	Washer, 7.0 mm, SS, Sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	8/24/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8941	LOW PROFILE LAPIDUS PLATE, TITANIUM	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	3/9/2007
Arthrex, Inc.	Naples, FL	CE 85507	AR-8941L	LOW PROFILE LAPIDUS PLATE, LONG	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	6/12/2013
Arthrex, Inc.	Naples, FL	CE 85507	AR-8941LST	Low Profile Lapidus Plate, Long, Ti, Sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	7/24/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8941PL	Plantar Lapidus Plate Left	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	5/20/2014
Arthrex, Inc.	Naples, FL	CE 85507	AR-8941PLS	Plantar Lapidus Plate, Short Left	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	12/20/2016
Arthrex, Inc.	Naples, FL	CE 85507	AR-8941PLS-ST	Plantar Lapidus Plate, Short Left Sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	12/20/2016
Arthrex, Inc.	Naples, FL	CE 85507	AR-8941PL-ST	Plantar Lapidus Plate Left Sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	12/20/2016
Arthrex, Inc.	Naples, FL	CE 85507	AR-8941PR	Plantar Lapidus Plate Right	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	5/20/2014
Arthrex, Inc.	Naples, FL	CE 85507	AR-8941PRS	Plantar Lapidus Plate, Short Right	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	12/20/2016
Arthrex, Inc.	Naples, FL	CE 85507	AR-8941PRS-ST	Plantar Lapidus Plate, Short Right Sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	12/20/2016
Arthrex, Inc.	Naples, FL	CE 85507	AR-8941PR-ST	Plantar Lapidus Plate Right Sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	12/20/2016
Arthrex, Inc.	Naples, FL	CE 85507	AR-8942L-06	H-PLATE, 32 X 16MM, 6MM WEDGE, LEFT	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	3/9/2007
Arthrex, Inc.	Naples, FL	CE 85507	AR-8942L-06S	Low Profile H-Plate™, Ti, 6 mm Wedge, Left, sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	5/19/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-8942L-08	H-PLATE 34 X 16MM, 8MM WEDGE, LEFT	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	3/9/2007
Arthrex, Inc.	Naples, FL	CE 85507	AR-8942L-08S	Low Profile H-Plate™, Ti, 8 mm Wedge, Left, sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	5/19/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-8942L-10	H-PLATE, 36 X 16MM, 10MM WEDGE, LEFT	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	3/9/2007
Arthrex, Inc.	Naples, FL	CE 85507	AR-8942L-10S	Low Profile H-Plate™, Ti, 10 mm Wedge, Left, sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	5/19/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-8942L-L	H-PLATE, 36 X 16MM, LEFT, LARGE	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	3/9/2007
Arthrex, Inc.	Naples, FL	CE 85507	AR-8942L-LS	Low Profile H-Plate™, Large, Left, sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	5/19/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-8942L-M	H-PLATE, 32 X 16MM, LEFT, MEDIUM	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	3/9/2007
Arthrex, Inc.	Naples, FL	CE 85507	AR-8942L-MS	Low Profile H-Plate™, Medium, Left, sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	5/19/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-8942L-S	H-PLATE, 28 X 16MM, LEFT, SMALL	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	3/9/2007
Arthrex, Inc.	Naples, FL	CE 85507	AR-8942L-SS	Low Profile H-Plate™, Small, Left, sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	5/19/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-8942R-06	H-PLATE, 32 X 16MM, 6MM WEDGE, RIGHT	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	3/9/2007
Arthrex, Inc.	Naples, FL	CE 85507	AR-8942R-06S	Low Profile H-Plate™, Ti, 6 mm Wedge, Right, sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	5/19/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-8942R-08	H-PLATE 34 X 16MM, 8MM WEDGE, RIGHT	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	3/9/2007
Arthrex, Inc.	Naples, FL	CE 85507	AR-8942R-08S	Low Profile H-Plate™, Ti, 8 mm Wedge, Right, sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	5/19/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-8942R-10	H-PLATE, 36 X 16MM, 10MM WEDGE, RIGHT	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	3/9/2007
Arthrex, Inc.	Naples, FL	CE 85507	AR-8942R-10S	Low Profile H-Plate™, Ti, 10 mm Wedge, Right, sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	5/19/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-8942R-L	H-PLATE, 36 X 16MM RIGHT, LARGE	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	3/9/2007
Arthrex, Inc.	Naples, FL	CE 85507	AR-8942R-LS	Low Profile H-Plate™, Large, Right, sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	5/19/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-8942R-M	H-PLATE, 32 X 16MM, RIGHT, MEDIUM	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	3/9/2007
Arthrex, Inc.	Naples, FL	CE 85507	AR-8942R-MS	Low Profile H-Plate™, Medium, Right, sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	5/19/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-8942R-S	H-PLATE, 28 X 16MM, RIGHT, SMALL	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	3/9/2007
Arthrex, Inc.	Naples, FL	CE 85507	AR-8942R-SS	Low Profile H-Plate™, Small, Right, sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	5/19/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-8943BL-04	LOCKING DISTAL FIBULA PLATE, SS, LEFT, 4H	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	4/14/2009
Arthrex, Inc.	Naples, FL	CE 85507	AR-8943BL-05	LOCKING DISTAL FIBULA PLATE, SS, LEFT, 5H	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	4/14/2009
Arthrex, Inc.	Naples, FL	CE 85507	AR-8943BL-06	LOCKING DISTAL FIBULA PLATE, SS, LEFT, 6H	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	4/14/2009
Arthrex, Inc.	Naples, FL	CE 85507	AR-8943BL-08	LOCKING DISTAL FIBULA PLATE, SS, LEFT, 8H	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	4/14/2009
Arthrex, Inc.	Naples, FL	CE 85507	AR-8943BLS-03	Locking Distal Fibula Plate, Left, 3 Hole, SS, Sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	11/10/2017

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Manufacturer Name	Manufacturing Location	EC QA Cert. Number	Product Code	Product Name	Class	GMDN code	Technical File	Rule	Annex	First DoC
Arthrex, Inc.	Naples, FL	CE 85507	AR-8943DR-145	Distal Fibula Plate, Locking, SS, Right, 14 Hole, Sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	2/2/2021
Arthrex, Inc.	Naples, FL	CE 85507	AR-8943H-03	LOCKING MEDIAL HOOK PLATE, SS, 3H	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	5/18/2009
Arthrex, Inc.	Naples, FL	CE 85507	AR-8943H-03S	LOCKING MEDIAL HOOK PLATE, 3H, STERILE	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	5/25/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8943H-05	LOCKING MEDIAL HOOK PLATE, SS, 5H	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	5/18/2009
Arthrex, Inc.	Naples, FL	CE 85507	AR-8943H-05S	LOCKING MEDIAL HOOK PLATE, 5H, STERILE	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	5/25/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8943H-07	LOCKING MEDIAL HOOK PLATE, SS, 7H	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	5/18/2009
Arthrex, Inc.	Naples, FL	CE 85507	AR-8943H-07S	LOCKING MEDIAL HOOK PLATE, 7H, STERILE	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	5/25/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8943T-04	LOCKING THIRD TUBULAR PLATE, SS, 4H	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	4/14/2009
Arthrex, Inc.	Naples, FL	CE 85507	AR-8943T-04S	Locking Third Tubular Plate, 4 Hole, SS, Sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	8/24/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8943T-05	LOCKING THIRD TUBULAR PLATE, SS, 5H	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	4/14/2009
Arthrex, Inc.	Naples, FL	CE 85507	AR-8943T-05S	Locking Third Tubular Plate, 5 Hole, SS, Sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	11/10/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8943T-06	LOCKING THIRD TUBULAR PLATE, SS, 6H	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	4/14/2009
Arthrex, Inc.	Naples, FL	CE 85507	AR-8943T-06S	Locking Third Tubular Plate 6 Hole, sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	5/22/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8943T-07	LOCKING THIRD TUBULAR PLATE, SS, 7H	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	4/14/2009
Arthrex, Inc.	Naples, FL	CE 85507	AR-8943T-07S	Locking Third Tubular Plate, 7 Hole, Sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	6/6/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8943T-08	LOCKING THIRD TUBULAR PLATE, SS, 8H	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	4/14/2009
Arthrex, Inc.	Naples, FL	CE 85507	AR-8943T-08S	Locking Third Tubular Plate, 8 Hole, Sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	6/6/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8943T-09S	Locking Third Tubular Plate, 9 Hole, SS, Sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	11/10/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8943T-10	LOCKING THIRD TUBULAR PLATE, SS, 10H	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	4/14/2009
Arthrex, Inc.	Naples, FL	CE 85507	AR-8943T-10S	Locking Third Tubular Plate, 10 Hole, Sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	6/6/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8943T-11S	Locking Third Tubular Plate, 11 Hole, SS, Sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	11/10/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8943T-12	LOCKING THIRD TUBULAR PLATE, SS, 12H	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	4/14/2009
Arthrex, Inc.	Naples, FL	CE 85507	AR-8943T-12S	Locking Third Tubular Plate, 12 Hole, SS, Sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	11/10/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8943TH-03	LOCKING LATERAL HOOK PLATE, 3 HOLE, SS	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	9/16/2009
Arthrex, Inc.	Naples, FL	CE 85507	AR-8943TH-03S	Locking Lateral Hook Plate, 3 Hole, SS, Sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	7/24/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8943TH-05	LOCKING LATERAL HOOK PLATE, 5 HOLE, SS	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	9/16/2009
Arthrex, Inc.	Naples, FL	CE 85507	AR-8943TH-05S	Locking Lateral Hook Plate, 5 Hole, SS, Sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	7/24/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8943TH-07	LOCKING LATERAL HOOK PLATE, 7 HOLE, SS	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	9/16/2009
Arthrex, Inc.	Naples, FL	CE 85507	AR-8943TH-07S	Locking Lateral Hook Plate, 7 Hole, SS, Sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	7/24/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8943TNL-05	Non-Locking Third Tubular Plate, SS, 5H	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	7/27/2011
Arthrex, Inc.	Naples, FL	CE 85507	AR-8943TNL-06	Non-Locking Third Tubular Plate, SS, 6H	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	7/27/2011
Arthrex, Inc.	Naples, FL	CE 85507	AR-8943TNL-07	Non-Locking Third Tubular Plate, SS, 7H	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	7/27/2011
Arthrex, Inc.	Naples, FL	CE 85507	AR-8943TNL-08	Non-Locking Third Tubular Plate, SS, 8H	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	7/27/2011
Arthrex, Inc.	Naples, FL	CE 85507	AR-8944-10S	MTP Plate, Standard, 10° Valgus, 0° Dorsiflexion	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	1/11/2016
Arthrex, Inc.	Naples, FL	CE 85507	AR-8944C-10S	MTP Plate, Standard, 10° Valgus, 8° Dorsiflexion	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	1/11/2016
Arthrex, Inc.	Naples, FL	CE 85507	AR-8944CL-L	LOW PROFILE MTP PLATE, CONTOURED, LONG, L, TI	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	7/24/2007
Arthrex, Inc.	Naples, FL	CE 85507	AR-8944CL-LS	Low Profile MTP Plate™, Contoured, Long, Left, Ti, sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	1/27/2009
Arthrex, Inc.	Naples, FL	CE 85507	AR-8944CL-P	LOW PROFILE MTP PLATE TM CONTOURED, SHORT, L, TI	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	9/19/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-8944CL-PS	Low Profile MTP Plate™, Contoured, Short, Left, Ti, sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	3/26/2009
Arthrex, Inc.	Naples, FL	CE 85507	AR-8944CL-S	LOW PROFILE MTP PLATE, CONTOURED, STD, L, TI	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	7/24/2007
Arthrex, Inc.	Naples, FL	CE 85507	AR-8944CL-SS	Low Profile MTP Plate™, Contoured, Standard, Left, Ti, sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	1/27/2009
Arthrex, Inc.	Naples, FL	CE 85507	AR-8944CR-L	LOW PROFILE MTP PLATE, CONTOURED, LONG, R, TI	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	7/24/2007
Arthrex, Inc.	Naples, FL	CE 85507	AR-8944CR-LS	Low Profile MTP Plate™, Contoured, Long, Right, Ti, sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	1/27/2009
Arthrex, Inc.	Naples, FL	CE 85507	AR-8944CR-P	LOW PROFILE MTP PLATE TM CONTOURED, SHORT, R, TI	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	9/19/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-8944CR-PS	Low Profile MTP Plate™, Contoured, Short, Right, Ti, sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	3/26/2009
Arthrex, Inc.	Naples, FL	CE 85507	AR-8944CR-S	LOW PROFILE MTP PLATE, CONTOURED, STD, R, TI	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	7/24/2007
Arthrex, Inc.	Naples, FL	CE 85507	AR-8944CR-SS	Low Profile MTP Plate™, Contoured, Standard, Right, Ti, sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	1/27/2009
Arthrex, Inc.	Naples, FL	CE 85507	AR-8944-L	LOW PROFILE STRAIGHT MTP PLATE, LONG, TITANIUM	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	9/15/2010
Arthrex, Inc.	Naples, FL	CE 85507	AR-8944L-S	Low Profile MTP Plate, Straight, Long, Ti, Sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	11/10/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8944-P	LOW PROFILE STRAIGHT MTP PLATE, SHORT, TITANIUM	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	9/15/2010
Arthrex, Inc.	Naples, FL	CE 85507	AR-8944-PS	Low Profile Straight MTP Plate, Short, Ti, Sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	11/10/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8944-S	LOW PROFILE STRAIGHT MTP PLATE, STANDARD, TITANIUM	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	9/15/2010
Arthrex, Inc.	Naples, FL	CE 85507	AR-8944-SS	Low Profile Straight MTP Plate, Straight, Ti, Sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	11/10/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8945W	WASHER, 10MM, TITANIUM	IIb	61670	PLATE, SCREWS, WEDGE and STAPLES	8	II	12/11/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-8945WS	WASHER, 10MM, TITANIUM, STERILE	IIb	61671	PLATE, SCREWS, WEDGE and STAPLES	8	II	10/2/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8948-00	PLATE, LOW PROFILE, COTTON, TITANIUM, FLAT	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	9/19/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-8948-00S	Plate, Low Profile, Cotton, Titanium, Flat, sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	3/26/2009
Arthrex, Inc.	Naples, FL	CE 85507	AR-8948-02	PLATE, LOW PROFILE, COTTON, TITANIUM, 2 MM	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	9/19/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-8948-02S	Plate, Low Profile, Cotton, Titanium, 2 mm, sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	3/26/2009
Arthrex, Inc.	Naples, FL	CE 85507	AR-8948-04	PLATE, LOW PROFILE, COTTON, TITANIUM, 4 MM	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	9/19/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-8948-04S	Plate, Low Profile, Cotton, Titanium, 4 mm, sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	3/26/2009
Arthrex, Inc.	Naples, FL	CE 85507	AR-8948-06	PLATE, LOW PROFILE, COTTON, TITANIUM, 6 MM	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	9/19/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-8948-06S	Plate, Low Profile, Cotton, Titanium, 6 mm, sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	3/26/2009
Arthrex, Inc.	Naples, FL	CE 85507	AR-8948-08	PLATE, LOW PROFILE, COTTON, TITANIUM, 8 MM	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	9/19/2008

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Manufacturer Name	Manufacturing Location	EC QA Cert. Number	Product Code	Product Name	Class	GMDN code	Technical File	Rule	Annex	First DoC
Arthrex, Inc.	Naples, FL	CE 85507	AR-8948-08S	Plate, Low Profile, Cotton, Titanium, 8 mm, sterile	IIB	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	3/26/2009
Arthrex, Inc.	Naples, FL	CE 85507	AR-8949-050	CALCANEUS STEP PLATE, 5 MM STEP	IIB	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	6/12/2013
Arthrex, Inc.	Naples, FL	CE 85507	AR-8949-050S	Calc Step Plate, 5 mm, Ti, Sterile	IIB	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	7/24/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8949-075	CALCANEUS STEP PLATE, 7.5 MM STEP	IIB	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	6/12/2013
Arthrex, Inc.	Naples, FL	CE 85507	AR-8949-075S	Calc Step Plate, 7.5 mm, Ti, Sterile	IIB	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	7/24/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8949-100	CALCANEUS STEP PLATE, 10 MM STEP	IIB	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	6/12/2013
Arthrex, Inc.	Naples, FL	CE 85507	AR-8949-100S	Calc Step Plate, 10 mm, Ti, Sterile	IIB	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	7/24/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8951LL	LISFRANC PLATE, LARGE, LEFT, TI	IIB	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	6/12/2013
Arthrex, Inc.	Naples, FL	CE 85507	AR-8951LLS	Lisfranc Plate, Large, Left, Ti, Sterile	IIB	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	8/24/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8951LR	LISFRANC PLATE, LARGE, RIGHT, TI	IIB	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	6/12/2013
Arthrex, Inc.	Naples, FL	CE 85507	AR-8951LRS	Lisfranc Plate, Large, Right, Ti, Sterile	IIB	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	8/24/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8951ML	LISFRANC PLATE, MEDIUM, LEFT, TI	IIB	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	6/12/2013
Arthrex, Inc.	Naples, FL	CE 85507	AR-8951MLS	Lisfranc Plate, Medium, Left, Ti, Sterile	IIB	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	8/24/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8951MR	LISFRANC PLATE, MEDIUM, RIGHT, TI	IIB	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	6/12/2013
Arthrex, Inc.	Naples, FL	CE 85507	AR-8951MRS	Lisfranc Plate, Medium, Right, Ti, Sterile	IIB	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	8/24/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8951SL	LISFRANC PLATE, SMALL, LEFT, TI	IIB	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	6/12/2013
Arthrex, Inc.	Naples, FL	CE 85507	AR-8951SLS	Lisfranc Plate, Small, Left, Ti, Sterile	IIB	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	8/24/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8951SR	LISFRANC PLATE, SMALL, RIGHT, TI	IIB	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	6/12/2013
Arthrex, Inc.	Naples, FL	CE 85507	AR-8951SRS	Lisfranc Plate, Small, Right, Ti, Sterile	IIB	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	8/24/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8952DFL	Dorsal Midfoot Fusion Plate, 3mm, Large	IIB	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	3/29/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8952DFL-S	Dorsal Midfoot Fusion Plate, 3mm, Large, Sterile	IIB	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	3/29/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8952DFM	Dorsal Midfoot Fusion Plate, 3mm, Medium	IIB	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	3/29/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8952DFM-S	Dorsal Midfoot Fusion Plate, 3mm, Medium, Sterile	IIB	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	3/29/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8952DFS	Dorsal Midfoot Fusion Plate, 3mm, Small	IIB	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	3/29/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8952DFS-S	Dorsal Midfoot Fusion Plate, 3mm, Small, Sterile	IIB	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	3/29/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8952MC-LL	LP MEDIAL COLUMN PLATE, 3.5MM, LARGE, LEFT	IIB	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	5/23/2013
Arthrex, Inc.	Naples, FL	CE 85507	AR-8952MC-LLS	Low Profile Medial Column Plate, Large, Left, Ti, Sterile	IIB	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	11/10/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8952MC-LR	LP MEDIAL COLUMN PLATE, 3.5MM, LARGE, RIGHT	IIB	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	5/23/2013
Arthrex, Inc.	Naples, FL	CE 85507	AR-8952MC-LRS	Low Profile Medial Column Plate, Large, Right, Ti, Sterile	IIB	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	11/10/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8952MC-ML	LP MEDIAL COLUMN PLATE, 3.5MM, MEDIUM, LEFT	IIB	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	5/23/2013
Arthrex, Inc.	Naples, FL	CE 85507	AR-8952MC-MLS	Low Profile Medial Column Plate, Medium, Left, Ti, Sterile	IIB	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	11/10/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8952MC-MR	LP MEDIAL COLUMN PLATE, 3.5MM, MEDIUM, RIGHT	IIB	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	5/23/2013
Arthrex, Inc.	Naples, FL	CE 85507	AR-8952MC-MRS	Low Profile Medial Column Plate, Medium, Right, Ti, Sterile	IIB	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	11/10/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8952MC-SL	LP MEDIAL COLUMN PLATE, 3.5MM, SMALL, LEFT	IIB	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	5/23/2013
Arthrex, Inc.	Naples, FL	CE 85507	AR-8952MC-SLS	Low Profile Medial Column Plate, Small, Left, Ti, Sterile	IIB	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	11/10/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8952MC-SR	LP MEDIAL COLUMN PLATE, 3.5MM, SMALL, RIGHT	IIB	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	5/23/2013
Arthrex, Inc.	Naples, FL	CE 85507	AR-8952MC-SRS	Low Profile Medial Column Plate, Small, Right, Ti, Sterile	IIB	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	11/10/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8952ML-05L	2.4mm 2H L-Plate, Ti, Left, 5H	IIB	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	2/3/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8952ML-05LST	L-Plate, 5 Hole, Left, 2.4 mm, Sterile	IIB	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	7/11/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8952ML-05R	2.4mm 2H L-Plate, Ti, Right, 5H	IIB	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	2/3/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8952ML-05RST	L-Plate, 5 Hole, Right, 2.4 mm, Sterile	IIB	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	7/11/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8952MS-04	LOW PROFILE STRAIGHT PLATE, 2.4MM, 4 HOLE	IIB	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	6/12/2013
Arthrex, Inc.	Naples, FL	CE 85507	AR-8952MS-04S	Low Profile Straight Plate, 2.4 mm, 4 Hole, Ti, Sterile	IIB	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	8/24/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8952MS-05	LOW PROFILE STRAIGHT PLATE, 2.4MM, 5 HOLE	IIB	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	6/12/2013
Arthrex, Inc.	Naples, FL	CE 85507	AR-8952MS-05S	Low Profile Straight Plate, 2.4 mm, 5 Hole, Ti, Sterile	IIB	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	8/24/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8952MS-06	LOW PROFILE STRAIGHT PLATE, 2.4MM, 6 HOLE	IIB	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	6/12/2013
Arthrex, Inc.	Naples, FL	CE 85507	AR-8952MS-06S	Low Profile Straight Plate, 2.4 mm, 6 Hole, Ti, Sterile	IIB	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	8/24/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8952MS-07	LOW PROFILE STRAIGHT PLATE, 2.4MM, 7 HOLE	IIB	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	6/12/2013
Arthrex, Inc.	Naples, FL	CE 85507	AR-8952MS-07S	Low Profile Straight Plate, 2.4 mm, 7 Hole, Ti, Sterile	IIB	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	11/10/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8952MS-08	LOW PROFILE STRAIGHT PLATE, 2.4MM, 8 HOLE	IIB	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	6/12/2013
Arthrex, Inc.	Naples, FL	CE 85507	AR-8952MS-08S	Low Profile Straight Plate, 2.4 mm, 8 Hole, Ti, Sterile	IIB	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	11/10/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8952MT-03	LOW PROFILE T-PLATE, 2.4MM, 3 HOLE	IIB	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	6/12/2013
Arthrex, Inc.	Naples, FL	CE 85507	AR-8952MT-03S	Low Profile T-Plate, 2.4 mm, 3 Hole, Ti, Sterile	IIB	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	7/24/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8952MT-04	LOW PROFILE T-PLATE, 2.4MM, 4 HOLE	IIB	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	6/12/2013
Arthrex, Inc.	Naples, FL	CE 85507	AR-8952MT-04S	Low Profile T-Plate, 2.4 mm, 4 Hole, Ti, Sterile	IIB	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	8/24/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8952MT-05	LOW PROFILE T-PLATE, 2.4MM, 5 HOLE	IIB	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	6/12/2013
Arthrex, Inc.	Naples, FL	CE 85507	AR-8952MT-05S	Low Profile T-Plate, 2.4 mm, 5 Hole, Ti, Sterile	IIB	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	8/24/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8952MT-06	LOW PROFILE T-PLATE, 2.4MM, 6 HOLE	IIB	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	6/12/2013
Arthrex, Inc.	Naples, FL	CE 85507	AR-8952MT-06S	Low Profile T-Plate, 2.4 mm, 6 Hole, Ti, Sterile	IIB	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	8/24/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8952MT-07	LOW PROFILE T-PLATE, 2.4MM, 7 HOLE	IIB	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	6/12/2013
Arthrex, Inc.	Naples, FL	CE 85507	AR-8952MT-07S	Low Profile T-Plate, 2.4 mm, 7 Hole, Ti, Sterile	IIB	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	8/24/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8952MT-08	LOW PROFILE T-PLATE, 2.4MM, 8 HOLE	IIB	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	6/12/2013
Arthrex, Inc.	Naples, FL	CE 85507	AR-8952MT-08S	Low Profile T-Plate, 2.4 mm, 8 Hole, Ti, Sterile	IIB	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	8/24/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8952MT-09	LOW PROFILE T-PLATE, 2.4MM, 9 HOLE	IIB	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	6/12/2013

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Manufacturer Name	Manufacturing Location	EC QA Cert. Number	Product Code	Product Name	Class	GMDN code	Technical File	Rule	Annex	First DoC
Arthrex, Inc.	Naples, FL	CE 85507	AR-8952MT-09S	Low Profile T-Plate, 2.4 mm, 9 Hole, Ti, Sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	8/24/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8952TS-02	3.0mm TMT Straight Plate, 2H	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	5/23/2013
Arthrex, Inc.	Naples, FL	CE 85507	AR-8952TS-02S	Low Profile Straight Plate, 3 mm, 2 Hole, Ti, Sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	7/24/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8952TS-04	3.0mm TMT Straight Plate, 4H	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	5/23/2013
Arthrex, Inc.	Naples, FL	CE 85507	AR-8952TS-04S	Low Profile Straight Plate, 3 mm, 4 Hole, Ti, Sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	8/24/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8952TS-05	3.0mm TMT Straight Plate, 5H	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	5/23/2013
Arthrex, Inc.	Naples, FL	CE 85507	AR-8952TS-05S	Low Profile Straight Plate, 3 mm, 5 Hole, Ti, Sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	8/24/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8952TT-02	Low Profile T-Plate, 3mm, 2 Hole	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	3/29/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8952TT-02S	Low Profile T-Plate, 3mm, 2 Hole, Sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	3/29/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8952TT-03	LOW PROFILE T-PLATE, 3.0MM, 3 HOLE, TI	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	6/12/2013
Arthrex, Inc.	Naples, FL	CE 85507	AR-8952TT-03S	Low Profile T-Plate, 3 mm, 3 Hole, Ti, Sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	7/24/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8952TT-04	LOW PROFILE T-PLATE, 3.0MM, 4 HOLE, TI	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	6/12/2013
Arthrex, Inc.	Naples, FL	CE 85507	AR-8952TT-04S	Low Profile T-Plate, 3 mm, 4 Hole, Ti, Sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	7/24/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8952XL	X-Plate, 3.0 mm, Large, Titanium	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	5/23/2013
Arthrex, Inc.	Naples, FL	CE 85507	AR-8952XLS	X-Plate, Large, Sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	7/11/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8952XM	X-Plate, 3.0 mm, Medium, Titanium	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	5/23/2013
Arthrex, Inc.	Naples, FL	CE 85507	AR-8952XMS	X-Plate, Medium, Ti, Sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	7/24/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8952XP	X-Plate, 2.4 mm, Small, Titanium	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	5/23/2013
Arthrex, Inc.	Naples, FL	CE 85507	AR-8952XPS	X-Plate, Small, Ti, Sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	7/24/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8953-00	PLATE, POW, LOCKING, TI	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	6/12/2013
Arthrex, Inc.	Naples, FL	CE 85507	AR-8953-00S	Low Profile Opening Wedge Locking Plate, Ti, Sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	11/10/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8953-02	PLATE, POW, LOCKING, TI, 2 MM	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	6/12/2013
Arthrex, Inc.	Naples, FL	CE 85507	AR-8953-02S	PLATE, POW, LOCKING, TI, 2.5 MM	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	6/12/2013
Arthrex, Inc.	Naples, FL	CE 85507	AR-8953-025S	Low Profile Opening Wedge Locking Plate, 2.5 mm, Sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	7/11/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8953-02S	Low Profile Opening Wedge Locking Plate, 2 mm, Sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	7/11/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8953-03	PLATE, POW, LOCKING, TI, 3 MM	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	6/12/2013
Arthrex, Inc.	Naples, FL	CE 85507	AR-8953-03S	PLATE, POW, LOCKING, TI, 3.5 MM	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	6/12/2013
Arthrex, Inc.	Naples, FL	CE 85507	AR-8953-035S	Low Profile Opening Wedge Locking Plate, 3.5 mm, Sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	7/11/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8953-03S	Low Profile Opening Wedge Locking Plate, 3 mm, Sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	7/11/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8953-04	PLATE, POW, LOCKING, TI, 4 MM	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	6/12/2013
Arthrex, Inc.	Naples, FL	CE 85507	AR-8953-04S	PLATE, POW, LOCKING, TI, 4.5 MM	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	6/12/2013
Arthrex, Inc.	Naples, FL	CE 85507	AR-8953-045S	Low Profile Opening Wedge Locking Plate, 4.5 mm, Ti, Sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	7/24/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8953-04S	Low Profile Opening Wedge Locking Plate, 4 mm, Ti, Sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	7/24/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8953-05	PLATE, POW, LOCKING, TI, 5 MM	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	6/12/2013
Arthrex, Inc.	Naples, FL	CE 85507	AR-8953-05S	PLATE, POW, LOCKING, TI, 5.5 MM	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	6/12/2013
Arthrex, Inc.	Naples, FL	CE 85507	AR-8953-055S	Low Profile Opening Wedge Locking Plate, 5.5 mm, Ti, Sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	7/24/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8953-05S	Low Profile Opening Wedge Locking Plate, 5 mm, Ti, Sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	7/24/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8953-06	PLATE, POW, LOCKING, TI, 6 MM	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	6/12/2013
Arthrex, Inc.	Naples, FL	CE 85507	AR-8953-06S	PLATE, POW, LOCKING, TI, 6.5 MM	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	6/12/2013
Arthrex, Inc.	Naples, FL	CE 85507	AR-8953-065S	Low Profile Opening Wedge Locking Plate, 6.5 mm, Ti, Sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	7/24/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8953-06S	Low Profile Opening Wedge Locking Plate, 6 mm, Ti, Sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	7/24/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8953-07	PLATE, POW, LOCKING, TI, 7 MM	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	6/12/2013
Arthrex, Inc.	Naples, FL	CE 85507	AR-8953-07S	Low Profile Opening Wedge Locking Plate, 7 mm, Sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	7/11/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8954ML-L	CALC FX PERC PLATE, Anterior Process, LONG	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	11/5/2013
Arthrex, Inc.	Naples, FL	CE 85507	AR-8954ML-LS	Calc Fx Perc Plate, Anterior Process, Left, Long, Ti, Sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	8/24/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8954ML-S	CALC FX PERC PLATE, Anterior Process, Standard	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	11/5/2013
Arthrex, Inc.	Naples, FL	CE 85507	AR-8954ML-SS	Calc Fx Perc Plate, Anterior Process, Left, Standard, Ti, Sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	8/24/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8954MR-L	CALC FX PERC PLATE, Anterior Process, LONG	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	11/5/2013
Arthrex, Inc.	Naples, FL	CE 85507	AR-8954MR-LS	Calc Fx Perc Plate, Anterior Process, Right, Long, Ti, Sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	11/10/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8954MR-S	CALC FX PERC PLATE, Anterior Process, Standard	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	11/5/2013
Arthrex, Inc.	Naples, FL	CE 85507	AR-8954MR-SS	Calc Fx Perc Plate, Anterior Process, Right, Standard, Ti, Sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	8/24/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8954MT	Low Profile T-Plate	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	11/5/2013
Arthrex, Inc.	Naples, FL	CE 85507	AR-8954MTS	Low Profile T-Plate, 3.5 mm, 4 Hole, Ti, Sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	3/9/2018
Arthrex, Inc.	Naples, FL	CE 85507	AR-8954PL-L	Calcaneal fracture perimeter plate, large, left	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	7/1/2013
Arthrex, Inc.	Naples, FL	CE 85507	AR-8954PL-LS	Calcaneal Fracture Perimeter Plate, Large, Left, Ti, Sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	8/24/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8954PL-M	Calcaneal fracture perimeter plate, medium, left	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	7/1/2013
Arthrex, Inc.	Naples, FL	CE 85507	AR-8954PL-MS	Calcaneal Fracture Perimeter Plate, Medium, Left, Ti, Sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	8/24/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8954PL-S	Calcaneal fracture perimeter plate, small, left	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	7/1/2013
Arthrex, Inc.	Naples, FL	CE 85507	AR-8954PL-SS	Calcaneal Fracture Perimeter Plate, Small, Left, Ti, Sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	8/24/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8954PL-XS	Calcaneal fracture perimeter plate, x-small, left	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	7/1/2013
Arthrex, Inc.	Naples, FL	CE 85507	AR-8954PL-XSS	Calcaneal Fracture Perimeter Plate, X-Small, Left, Sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	7/11/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8954PR-L	Calcaneal fracture perimeter plate, large, right	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	7/1/2013
Arthrex, Inc.	Naples, FL	CE 85507	AR-8954PR-LS	Calcaneal Fracture Perimeter Plate, Large, Right, Ti, Sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	8/24/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8954PR-M	Calcaneal fracture perimeter plate, medium, right	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	7/1/2013

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Manufacturer Name	Manufacturing Location	EC QA Cert. Number	Product Code	Product Name	Class	GMDN code	Technical File	Rule	Annex	First DoC
Arthrex, Inc.	Naples, FL	CE 85507	AR-8963PF-07S	Posterior Pilon Fusion Plate, 7 Hole, Sterile	IIB	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	5/25/2021
Arthrex, Inc.	Naples, FL	CE 85507	AR-8963PF-08S	Posterior Pilon Fusion Plate, 8 Hole, Sterile	IIB	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	5/25/2021
Arthrex, Inc.	Naples, FL	CE 85507	AR-8963PF-09S	Posterior Pilon Fusion Plate, 9 Hole, Sterile	IIB	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	5/25/2021
Arthrex, Inc.	Naples, FL	CE 85507	AR-8963PF-10S	Posterior Pilon Fusion Plate, 10 Hole, Sterile	IIB	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	5/25/2021
Arthrex, Inc.	Naples, FL	CE 85507	AR-8963PF-11S	Posterior Pilon Fusion Plate, 11 Hole, Sterile	IIB	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	5/25/2021
Arthrex, Inc.	Naples, FL	CE 85507	AR-8963PF-12S	Posterior Pilon Fusion Plate, 12 Hole, Sterile	IIB	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	5/25/2021
Arthrex, Inc.	Naples, FL	CE 85507	AR-8963PF-13S	Posterior Pilon Fusion Plate, 13 Hole, Sterile	IIB	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	5/25/2021
Arthrex, Inc.	Naples, FL	CE 85507	AR-8963PF-14S	Posterior Pilon Fusion Plate, 14 Hole, Sterile	IIB	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	5/25/2021
Arthrex, Inc.	Naples, FL	CE 85507	AR-8963PF-15S	Posterior Pilon Fusion Plate, 15 Hole, Sterile	IIB	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	5/25/2021
Arthrex, Inc.	Naples, FL	CE 85507	AR-8963PLL-04	Postero Dist Fib Plt, SS, 4H	IIB	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	4/6/2016
Arthrex, Inc.	Naples, FL	CE 85507	AR-8963PLL-04S	Posterolateral Distal Fibula Plate, 4 Hole	IIB	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	12/31/2020
Arthrex, Inc.	Naples, FL	CE 85507	AR-8963PLL-05	Postero Dist Fib Plt, SS, 5H	IIB	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	4/6/2016
Arthrex, Inc.	Naples, FL	CE 85507	AR-8963PLL-05S	Posterolateral Distal Fibula Plate, 5 Hole	IIB	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	12/31/2020
Arthrex, Inc.	Naples, FL	CE 85507	AR-8963PLL-06	Postero Dist Fib Plt, SS, 6H	IIB	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	4/6/2016
Arthrex, Inc.	Naples, FL	CE 85507	AR-8963PLL-06S	Posterolateral Distal Fibula Plate, 6 Hole	IIB	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	12/31/2020
Arthrex, Inc.	Naples, FL	CE 85507	AR-8963PLL-07	Postero Dist Fib Plt, SS, 7H	IIB	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	4/6/2016
Arthrex, Inc.	Naples, FL	CE 85507	AR-8963PLL-08	Postero Dist Fib Plt, SS, 8H	IIB	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	4/6/2016
Arthrex, Inc.	Naples, FL	CE 85507	AR-8963PLL-08S	Posterolateral Distal Fibula Plate, 8 Hole	IIB	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	12/31/2020
Arthrex, Inc.	Naples, FL	CE 85507	AR-8963PLL-09	Postero Dist Fib Plt, SS, 9H	IIB	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	4/6/2016
Arthrex, Inc.	Naples, FL	CE 85507	AR-8963PLL-10	Postero Dist Fib Plt, SS, 10H	IIB	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	4/6/2016
Arthrex, Inc.	Naples, FL	CE 85507	AR-8963RM-02	2.7mm Straight Plate, SS, 2H	IIB	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	4/6/2016
Arthrex, Inc.	Naples, FL	CE 85507	AR-8963RM-02S	2.7 mm Straight Plate, 2 Hole	IIB	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	12/31/2020
Arthrex, Inc.	Naples, FL	CE 85507	AR-8963RM-03	2.7mm Straight Plate, SS, 3H	IIB	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	4/6/2016
Arthrex, Inc.	Naples, FL	CE 85507	AR-8963RM-03S	2.7 mm Straight Plate, 3 Hole	IIB	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	12/31/2020
Arthrex, Inc.	Naples, FL	CE 85507	AR-8963RM-04	2.7mm Straight Plate, SS, 4H	IIB	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	4/6/2016
Arthrex, Inc.	Naples, FL	CE 85507	AR-8963RM-04S	2.7 mm Straight Plate, 4 Hole	IIB	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	12/31/2020
Arthrex, Inc.	Naples, FL	CE 85507	AR-8963RM-05	2.7mm Straight Plate, SS, 5H	IIB	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	4/6/2016
Arthrex, Inc.	Naples, FL	CE 85507	AR-8963RM-05S	2.7 mm Straight Plate, 5 Hole	IIB	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	12/31/2020
Arthrex, Inc.	Naples, FL	CE 85507	AR-8963RM-06	2.7mm Straight Plate, SS, 6H	IIB	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	4/6/2016
Arthrex, Inc.	Naples, FL	CE 85507	AR-8963RM-07	2.7mm Straight Plate, SS, 7H	IIB	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	4/6/2016
Arthrex, Inc.	Naples, FL	CE 85507	AR-8963RM-08	2.7mm Straight Plate, SS, 8H	IIB	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	4/6/2016
Arthrex, Inc.	Naples, FL	CE 85507	AR-8963RM-09	2.7mm Straight Plate, SS, 9H	IIB	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	4/6/2016
Arthrex, Inc.	Naples, FL	CE 85507	AR-8963RM-10	2.7mm Straight Plate, SS, 10H	IIB	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	4/6/2016
Arthrex, Inc.	Naples, FL	CE 85507	AR-8967W	WASHER, 13MM, TITANIUM	IIB	61670	PLATE, SCREWS, WEDGE and STAPLES	8	II	1/13/2009
Arthrex, Inc.	Naples, FL	CE 85507	AR-8967WS	Washer, 13 mm, Titanium, Sterile	IIB	61671	PLATE, SCREWS, WEDGE and STAPLES	8	II	1/5/2018
Arthrex, Inc.	Naples, FL	CE 85507	AR-8970AL	Anetrior TT Ankle Fusion Plate, Left	IIB	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	8/15/2014
Arthrex, Inc.	Naples, FL	CE 85507	AR-8970AL-04	Ankle Fusion Plate, Anterior TT, Left, 4-Hole	IIB	61689	PLATE, SCREWS, WEDGE AND STAPLES	8	II	6/7/2019
Arthrex, Inc.	Naples, FL	CE 85507	AR-8970AL-04S	Ankle Fusion Plate, Anterior TT, Left, 4-Hole, Sterile	IIB	61688	PLATE, SCREWS, WEDGE AND STAPLES	8	II	6/7/2019
Arthrex, Inc.	Naples, FL	CE 85507	AR-8970AL-05	Ankle Fusion Plate, Anterior TT, Left, 5-Hole	IIB	61689	PLATE, SCREWS, WEDGE AND STAPLES	8	II	6/7/2019
Arthrex, Inc.	Naples, FL	CE 85507	AR-8970AL-05S	Ankle Fusion Plate, Anterior TT, Left, 5-Hole, Sterile	IIB	61688	PLATE, SCREWS, WEDGE AND STAPLES	8	II	6/7/2019
Arthrex, Inc.	Naples, FL	CE 85507	AR-8970AL-06	Ankle Fusion Plate, Anterior TT, Left, 6-Hole	IIB	61689	PLATE, SCREWS, WEDGE AND STAPLES	8	II	6/7/2019
Arthrex, Inc.	Naples, FL	CE 85507	AR-8970AL-06S	Ankle Fusion Plate, Anterior TT, Left, 6-Hole, Sterile	IIB	61688	PLATE, SCREWS, WEDGE AND STAPLES	8	II	6/7/2019
Arthrex, Inc.	Naples, FL	CE 85507	AR-8970ALS	Ankle Fusion Plate, Anterior TT, Left, Ti, Sterile	IIB	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	12/8/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8970AR	Anetrior TT Ankle Fusion Plate, Right	IIB	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	8/15/2014
Arthrex, Inc.	Naples, FL	CE 85507	AR-8970AR-04	Ankle Fusion Plate, Anterior TT, Right, 4-Hole	IIB	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	6/7/2019
Arthrex, Inc.	Naples, FL	CE 85507	AR-8970AR-04S	Ankle Fusion Plate, Anterior TT, Right, 4-Hole, Sterile	IIB	61688	PLATE, SCREWS, WEDGE AND STAPLES	8	II	6/7/2019
Arthrex, Inc.	Naples, FL	CE 85507	AR-8970AR-05	Ankle Fusion Plate, Anterior TT, Right, 5-Hole	IIB	61689	PLATE, SCREWS, WEDGE AND STAPLES	8	II	6/7/2019
Arthrex, Inc.	Naples, FL	CE 85507	AR-8970AR-05S	Ankle Fusion Plate, Anterior TT, Right, 5-Hole, Sterile	IIB	61688	PLATE, SCREWS, WEDGE AND STAPLES	8	II	6/7/2019
Arthrex, Inc.	Naples, FL	CE 85507	AR-8970AR-06	Ankle Fusion Plate, Anterior TT, Right, 6-Hole	IIB	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	6/7/2019
Arthrex, Inc.	Naples, FL	CE 85507	AR-8970AR-06S	Ankle Fusion Plate, Anterior TT, Right, 6-Hole, Sterile	IIB	61688	PLATE, SCREWS, WEDGE AND STAPLES	8	II	6/7/2019
Arthrex, Inc.	Naples, FL	CE 85507	AR-8970ARS	Ankle Fusion Plate, Anterior TT, Right, Ti, Sterile	IIB	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	1/5/2018
Arthrex, Inc.	Naples, FL	CE 85507	AR-8970AS-03	Ankle Fusion Plate, Short Anterior TT, 3-Hole	IIB	61689	PLATE, SCREWS, WEDGE AND STAPLES	8	II	6/7/2019
Arthrex, Inc.	Naples, FL	CE 85507	AR-8970AS-03S	Ankle Fusion Plate, Short Anterior TT, 4-Hole	IIB	61688	PLATE, SCREWS, WEDGE AND STAPLES	8	II	6/7/2019
Arthrex, Inc.	Naples, FL	CE 85507	AR-8970AS-04	Ankle Fusion Plate, Anterior TT, Short Talar Neck, 4H	IIB	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	6/7/2019
Arthrex, Inc.	Naples, FL	CE 85507	AR-8970AS-04S	Ankle Fusion Plate, Short Anterior TT, 4-Hole, Sterile	IIB	61688	PLATE, SCREWS, WEDGE AND STAPLES	8	II	6/7/2019
Arthrex, Inc.	Naples, FL	CE 85507	AR-8970MA	Ankle Fusion Plate, Minimally Invasive Anterior TT	IIB	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	6/7/2019
Arthrex, Inc.	Naples, FL	CE 85507	AR-8970MAS	Ankle Fusion Plate, Minimally Invasive Anterior TT, Sterile	IIB	61688	PLATE, SCREWS, WEDGE AND STAPLES	8	II	6/7/2019
Arthrex, Inc.	Naples, FL	CE 85507	AR-8970PL	Later Tibiotalocalcaneal Plate, Left	IIB	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	8/15/2014
Arthrex, Inc.	Naples, FL	CE 85507	AR-8970PLS	Ankle Fusion Plate, Posterior TTC, Left, Ti, Sterile	IIB	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	12/8/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8970PR	Posterior Tibiotalocalcaneal Plate, Right	IIB	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	8/15/2014
Arthrex, Inc.	Naples, FL	CE 85507	AR-8970PRS	Ankle Fusion Plate, Posterior TTC, Right, Ti Sterile	IIB	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	12/8/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8970TT	Lateral Tibiotalar Plate (TT)	IIB	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	8/15/2014
Arthrex, Inc.	Naples, FL	CE 85507	AR-8970TT-04	Ankle Fusion Plate, Lateral TT, 4-Hole	IIB	61689	PLATE, SCREWS, WEDGE AND STAPLES	8	II	6/7/2019

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Manufacturer Name	Manufacturing Location	EC QA Cert. Number	Product Code	Product Name	Class	GMDN code	Technical File	Rule	Annex	First DoC
Arthrex, Inc.	Naples, FL	CE 85507	AR-9944L-5R	MaxForce™ MTP Compression Plate, Long, 5° Valgus, 5° Dorsiflex, Right	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	8/20/2020
Arthrex, Inc.	Naples, FL	CE 85507	AR-9944X-5L	MaxForce™ MTP Compression Plate, X-Long, 5° Valgus, 5° Dorsiflex, Left	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	8/20/2020
Arthrex, Inc.	Naples, FL	CE 85507	AR-9944X-5R	MaxForce™ MTP Compression Plate, X-Long, 5° Valgus, 5° Dorsiflex, Right	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	8/20/2020
Arthrex, Inc.	Naples, FL	CE 85507	AR-9944X-LS	MaxForce™ MTP Compression Plate, Revision, Straight	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	8/20/2020
Arthrex, Inc.	Naples, FL	CE 85507	AR-9944X-LD	MaxForce™ MTP Compression Plate, Revision, Straight 5° Dorsiflex	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	8/20/2020
Arthrex, Inc.	Naples, FL	CE 85507	AR-9963APLL-04	Posterolateral Anatomic Distal Fibula Plate, Left, Ti, 4 Hole	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	2/2/2021
Arthrex, Inc.	Naples, FL	CE 85507	AR-9963APLL-06	Posterolateral Anatomic Distal Fibula Plate, Left, Ti, 6 Hole	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	2/2/2021
Arthrex, Inc.	Naples, FL	CE 85507	AR-9963APLL-08	Posterolateral Anatomic Distal Fibula Plate, Left, Ti, 8 Hole	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	2/2/2021
Arthrex, Inc.	Naples, FL	CE 85507	AR-9963APLL-10	Posterolateral Anatomic Distal Fibula Plate, Left, Ti, 10 Hole	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	2/2/2021
Arthrex, Inc.	Naples, FL	CE 85507	AR-9963APLL-04S	Posterolateral Anatomic Distal Fibula Plate, Right, Ti, 4 Hole, Sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	2/2/2021
Arthrex, Inc.	Naples, FL	CE 85507	AR-9963APLL-06S	Posterolateral Anatomic Distal Fibula Plate, Left, Ti, 6 Hole, Sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	2/2/2021
Arthrex, Inc.	Naples, FL	CE 85507	AR-9963APLL-08S	Posterolateral Anatomic Distal Fibula Plate, Left, Ti, 8 Hole, Sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	2/2/2021
Arthrex, Inc.	Naples, FL	CE 85507	AR-9963APLL-10S	Posterolateral Anatomic Distal Fibula Plate, Left, Ti, 10 Hole, Sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	2/2/2021
Arthrex, Inc.	Naples, FL	CE 85507	AR-9963APLR-04	Posterolateral Anatomic Distal Fibula Plate, Right, Ti, 4 Hole	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	2/2/2021
Arthrex, Inc.	Naples, FL	CE 85507	AR-9963APLR-06	Posterolateral Anatomic Distal Fibula Plate, Right, Ti, 6 Hole	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	2/2/2021
Arthrex, Inc.	Naples, FL	CE 85507	AR-9963APLR-08	Posterolateral Anatomic Distal Fibula Plate, Right, Ti, 8 Hole	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	2/2/2021
Arthrex, Inc.	Naples, FL	CE 85507	AR-9963APLR-10	Posterolateral Anatomic Distal Fibula Plate, Right, Ti, 10 Hole	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	2/2/2021
Arthrex, Inc.	Naples, FL	CE 85507	AR-9963APLR-04S	Posterolateral Anatomic Distal Fibula Plate, Right, Ti, 4 Hole, Sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	2/2/2021
Arthrex, Inc.	Naples, FL	CE 85507	AR-9963APLR-06S	Posterolateral Anatomic Distal Fibula Plate, Right, Ti, 6 Hole, Sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	2/2/2021
Arthrex, Inc.	Naples, FL	CE 85507	AR-9963APLR-08S	Posterolateral Anatomic Distal Fibula Plate, Right, Ti, 8 Hole, Sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	2/2/2021
Arthrex, Inc.	Naples, FL	CE 85507	AR-9963APLR-10S	Posterolateral Anatomic Distal Fibula Plate, Right, Ti, 10 Hole, Sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	2/2/2021
Arthrex, Inc.	Naples, FL	CE 85507	AR-9963PLL-04	Posterolateral Distal Fibula Plate, Locking, Ti, 4 Hole	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	2/2/2021
Arthrex, Inc.	Naples, FL	CE 85507	AR-9963PLL-05	Posterolateral Distal Fibula Plate, Locking, Ti, 5 Hole	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	2/2/2021
Arthrex, Inc.	Naples, FL	CE 85507	AR-9963PLL-06	Posterolateral Distal Fibula Plate, Locking, Ti, 6 Hole	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	2/2/2021
Arthrex, Inc.	Naples, FL	CE 85507	AR-9963PLL-08	Posterolateral Distal Fibula Plate, Locking, Ti, 8 Hole	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	2/2/2021
Arthrex, Inc.	Naples, FL	CE 85507	AR-9963PLL-10	Posterolateral Distal Fibula Plate, Locking, Ti, 10 Hole	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	2/2/2021
Arthrex, Inc.	Naples, FL	CE 85507	AR-9963PLL-04S	Posterolateral Distal Fibula Plate, Locking, Ti, 4 Hole, Sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	2/2/2021
Arthrex, Inc.	Naples, FL	CE 85507	AR-9963PLL-05S	Posterolateral Distal Fibula Plate, Locking, Ti, 5 Hole, Sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	2/2/2021
Arthrex, Inc.	Naples, FL	CE 85507	AR-9963PLL-06S	Posterolateral Distal Fibula Plate, Locking, Ti, 6 Hole, Sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	2/2/2021
Arthrex, Inc.	Naples, FL	CE 85507	AR-9963PLL-08S	Posterolateral Distal Fibula Plate, Locking, Ti, 8 Hole, Sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	2/2/2021
Arthrex, Inc.	Naples, FL	CE 85507	AR-9963PLL-10S	Posterolateral Distal Fibula Plate, Locking, Ti, 10 Hole, Sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	2/2/2021
				PROSTOP Family						
Arthrex, Inc.	Naples, FL	CE 85507	AR-4207-12	ProStop Arthroeresis Subtalar Implant, 7 x 12 mm	IIb	46646	PLATE, SCREWS, WEDGE and STAPLES	8	II	6/2/2006
Arthrex, Inc.	Naples, FL	CE 85507	AR-4208-14	ProStop Arthroeresis Subtalar Implant, 8 x 14 mm	IIb	46646	PLATE, SCREWS, WEDGE and STAPLES	8	II	6/2/2006
Arthrex, Inc.	Naples, FL	CE 85507	AR-4209-14	ProStop Arthroeresis Subtalar Implant, 9 x 14 mm	IIb	46646	PLATE, SCREWS, WEDGE and STAPLES	8	II	6/2/2006
Arthrex, Inc.	Naples, FL	CE 85507	AR-4210-14	ProStop Arthroeresis Subtalar Implant, 10 x 14 mm	IIb	46646	PLATE, SCREWS, WEDGE and STAPLES	8	II	6/2/2006
Arthrex, Inc.	Naples, FL	CE 85507	AR-4211-16	ProStop Arthroeresis Subtalar Implant, 11 x 16 mm	IIb	46646	PLATE, SCREWS, WEDGE and STAPLES	8	II	6/2/2006
Arthrex, Inc.	Naples, FL	CE 85507	AR-4212-16	ProStop Arthroeresis Subtalar Implant, 12 x 16 mm	IIb	46646	PLATE, SCREWS, WEDGE and STAPLES	8	II	6/2/2006
				RADIUS PLATE Family						
Arthrex, Inc.	Naples, FL	CE 85507	AR-7653H	Radial Head Fracture Plate, Head	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	5/25/2021
Arthrex, Inc.	Naples, FL	CE 85507	AR-7653HS	Radial Head Fracture Plate, Head, Sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	5/25/2021
Arthrex, Inc.	Naples, FL	CE 85507	AR-7653N	Radial Head Fracture Plate, Neck	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	5/25/2021
Arthrex, Inc.	Naples, FL	CE 85507	AR-7653NS	Radial Head Fracture Plate, Neck, Sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	5/25/2021
Arthrex, Inc.	Naples, FL	CE 85507	AR-8916DNL-04	Dorsal Distal Radius Plate, Ti, Narrow, Left, 4H	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	2/3/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8916DNL-04ST	Dorsal Distal Radius Plate, Ti, Narrow, Left, 4 H, Sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	11/10/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8916DNR-04	Dorsal Distal Radius Plate, Narrow, Right, 4H	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	2/3/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8916DNR-04ST	Dorsal Distal Radius Plate, Ti, Narrow, Right, 4 H, Sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	11/10/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8916DSL-04	Dorsal Distal Radius Plate, Ti, Standard, Left 4H	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	2/3/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8916DSL-04ST	Dorsal Distal Radius Plate, Ti, Standard, Left, 4 H, Sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	11/10/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8916DSR-04	Dorsal Distal Radius Plate, Standard, Right, 4H	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	2/3/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8916DSR-04ST	Dorsal Distal Radius Plate, Ti, Standard, Right, 4 H, Sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	11/10/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8916RSTY-05	Radial Styloid Plate, 5 Hole	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	2/3/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8916RSTY-05ST	Radial Styloid Plate, 5 Hole, Ti, Sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	12/8/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8916SPN	Wrist Spanning Plate, 9 Hole	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	2/3/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8916SPN-ST	Plate, Wrist Spanning, 9 Hole, Ti, Sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	12/8/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8916VH-04	Volar Distal Radius Hook Plate, 4 Hole	IIb	61689	PLATE, SCREWS, WEDGE and STAPLES	8	II	2/3/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8916VH-04ST	Volar Distal Radius Hook Plate, 4 Hole, Titanium, Sterile	IIb	61688	PLATE, SCREWS, WEDGE and STAPLES	8	II	11/10/2017

TF PLATE, SCREWS, WEDGE AND STAPLES, REVISION 47

Manufacturer Name	Manufacturing Location	EC QA Cert. Number	Product Code	Product Name	Class	GMDN code	Technical File	Rule	Annex	First DoC
Arthrex, Inc.	Naples, FL	CE 85507	AR-8708	Small Staple, 8mm, SS	IIb	35615	PLATE, SCREWS, WEDGE and STAPLES	8	II	7/8/2019
Arthrex, Inc.	Naples, FL	CE 85507	AR-8708-ST	Small Staple, 8 mm, Stainless Steel, sterile	IIb	35615	PLATE, SCREWS, WEDGE and STAPLES	8	II	7/8/2019
Arthrex, Inc.	Naples, FL	CE 85507	AR-8710	Small Staple, 10mm, SS	IIb	35615	PLATE, SCREWS, WEDGE and STAPLES	8	II	7/8/2019
Arthrex, Inc.	Naples, FL	CE 85507	AR-8710-S	Small Staple, 10 mm, Stainless Steel, sterile, IM	IIb	35615	PLATE, SCREWS, WEDGE and STAPLES	8	II	7/8/2019
Arthrex, Inc.	Naples, FL	CE 85507	AR-8717-0907	DynaNite Nitinol Staple	IIb	61669	PLATE, SCREWS, WEDGE and STAPLES	8	II	11/10/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8717-0910	DynaNite Nitinol Staple	IIb	61669	PLATE, SCREWS, WEDGE and STAPLES	8	II	11/10/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8717-1110	DynaNite Nitinol Staple	IIb	61669	PLATE, SCREWS, WEDGE and STAPLES	8	II	11/10/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8717-111512	DynaNite Nitinol Staple	IIb	61669	PLATE, SCREWS, WEDGE and STAPLES	8	II	11/10/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8717DS-0907	DynaNite Nitinol Staple with Instrumentation	IIb	61669	PLATE, SCREWS, WEDGE and STAPLES	8	II	11/10/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8717DS-0910	DynaNite Nitinol Staple with Instrumentation	IIb	61669	PLATE, SCREWS, WEDGE and STAPLES	8	II	11/10/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8717DS-1110	DynaNite Nitinol Staple with Instrumentation	IIb	61669	PLATE, SCREWS, WEDGE and STAPLES	8	II	11/10/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8717DS-111512	DynaNite Nitinol Staple with Instrumentation	IIb	61669	PLATE, SCREWS, WEDGE and STAPLES	8	II	11/10/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8718-1310	DynaNite Nitinol Staple	IIb	61669	PLATE, SCREWS, WEDGE and STAPLES	8	II	11/10/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8718-131512	DynaNite Nitinol Staple	IIb	61669	PLATE, SCREWS, WEDGE and STAPLES	8	II	11/10/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8718-1512	DynaNite Nitinol Staple	IIb	61669	PLATE, SCREWS, WEDGE and STAPLES	8	II	11/10/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8718DS-1310	DynaNite Nitinol Staple with Instrumentation	IIb	61669	PLATE, SCREWS, WEDGE and STAPLES	8	II	11/10/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8718DS-131512	DynaNite Nitinol Staple with Instrumentation	IIb	61669	PLATE, SCREWS, WEDGE and STAPLES	8	II	11/10/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8718DS-1512	DynaNite Nitinol Staple with Instrumentation	IIb	61669	PLATE, SCREWS, WEDGE and STAPLES	8	II	11/10/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8719-1515	DynaNite Nitinol Staple	IIb	61669	PLATE, SCREWS, WEDGE and STAPLES	8	II	11/10/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8719-1815	DynaNite Nitinol Staple	IIb	61669	PLATE, SCREWS, WEDGE and STAPLES	8	II	11/10/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8719-1818	DynaNite Nitinol Staple	IIb	61669	PLATE, SCREWS, WEDGE and STAPLES	8	II	11/10/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8719-181815	DynaNite Nitinol Staple	IIb	61669	PLATE, SCREWS, WEDGE and STAPLES	8	II	11/10/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8719-2015	DynaNite Nitinol Staple	IIb	61669	PLATE, SCREWS, WEDGE and STAPLES	8	II	11/10/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8719-2020	DynaNite Nitinol Staple	IIb	61669	PLATE, SCREWS, WEDGE and STAPLES	8	II	11/10/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8719-2520	DynaNite Nitinol Staple	IIb	61669	PLATE, SCREWS, WEDGE and STAPLES	8	II	11/10/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8719DS-1515	DynaNite Nitinol Staple with Instrumentation	IIb	61669	PLATE, SCREWS, WEDGE and STAPLES	8	II	11/10/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8719DS-1815	DynaNite Nitinol Staple with Instrumentation	IIb	61669	PLATE, SCREWS, WEDGE and STAPLES	8	II	11/10/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8719DS-1818	DynaNite Nitinol Staple with Instrumentation	IIb	61669	PLATE, SCREWS, WEDGE and STAPLES	8	II	11/10/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8719DS-181815	DynaNite Nitinol Staple with Instrumentation	IIb	61669	PLATE, SCREWS, WEDGE and STAPLES	8	II	11/10/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8719DS-2015	DynaNite Nitinol Staple with Instrumentation	IIb	61669	PLATE, SCREWS, WEDGE and STAPLES	8	II	11/10/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8719DS-2020	DynaNite Nitinol Staple with Instrumentation	IIb	61669	PLATE, SCREWS, WEDGE and STAPLES	8	II	11/10/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8719DS-2520	DynaNite Nitinol Staple with Instrumentation	IIb	61669	PLATE, SCREWS, WEDGE and STAPLES	8	II	11/10/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8719MX-1515	DynaNite SuperMX Staple, 15W x 15L With Implant on Delivery Device	IIb	61669	PLATE, SCREWS, WEDGE and STAPLES	8	II	4/5/2019
Arthrex, Inc.	Naples, FL	CE 85507	AR-8719MX-1815	DynaNite SuperMX Staple, 18W x 15L With Implant on Delivery Device	IIb	61669	PLATE, SCREWS, WEDGE and STAPLES	8	II	4/5/2019
Arthrex, Inc.	Naples, FL	CE 85507	AR-8719MX-1818	DynaNite SuperMX Staple, 18W x 18L With Implant on Delivery Device	IIb	61669	PLATE, SCREWS, WEDGE and STAPLES	8	II	4/5/2019
Arthrex, Inc.	Naples, FL	CE 85507	AR-8719MX-2015	DynaNite SuperMX Staple, 20W x 15L With Implant on Delivery Device	IIb	61669	PLATE, SCREWS, WEDGE and STAPLES	8	II	4/5/2019
Arthrex, Inc.	Naples, FL	CE 85507	AR-8719MX-2020	DynaNite SuperMX Staple, 20W x 20L With Implant on Delivery Device	IIb	61669	PLATE, SCREWS, WEDGE and STAPLES	8	II	4/5/2019
Arthrex, Inc.	Naples, FL	CE 85507	AR-8719MX-2520	DynaNite SuperMX Staple, 25W x 20L With Implant on Delivery Device	IIb	61669	PLATE, SCREWS, WEDGE and STAPLES	8	II	4/5/2019
Arthrex, Inc.	Naples, FL	CE 85507	AR-8719MXDS-1515	DynaNite SuperMX Staple with Instrumentation, 15W x 15L	IIb	61669	PLATE, SCREWS, WEDGE and STAPLES	8	II	4/5/2019
Arthrex, Inc.	Naples, FL	CE 85507	AR-8719MXDS-1815	DynaNite SuperMX Staple with Instrumentation, 18W x 15L	IIb	61669	PLATE, SCREWS, WEDGE and STAPLES	8	II	4/5/2019
Arthrex, Inc.	Naples, FL	CE 85507	AR-8719MXDS-1818	DynaNite SuperMX Staple with Instrumentation, 18W x 18L	IIb	61669	PLATE, SCREWS, WEDGE and STAPLES	8	II	4/5/2019
Arthrex, Inc.	Naples, FL	CE 85507	AR-8719MXDS-2015	DynaNite SuperMX Staple with Instrumentation, 20W x 15L	IIb	61669	PLATE, SCREWS, WEDGE and STAPLES	8	II	4/5/2019
Arthrex, Inc.	Naples, FL	CE 85507	AR-8719MXDS-2020	DynaNite SuperMX Staple with Instrumentation, 20W x 20L	IIb	61669	PLATE, SCREWS, WEDGE and STAPLES	8	II	4/5/2019
Arthrex, Inc.	Naples, FL	CE 85507	AR-8719MXDS-2520	DynaNite SuperMX Staple with Instrumentation, 25W x 20L	IIb	61669	PLATE, SCREWS, WEDGE and STAPLES	8	II	4/5/2019
TRANSFIX Family										
Arthrex, Inc.	Naples, FL	CE 85507	AR-1351	Transfix Implant, 3 x 40mm	IIb	46646	PLATE, SCREWS, WEDGE and STAPLES	8	II	1/2/2002
Arthrex, Inc.	Naples, FL	CE 85507	AR-1351L	Transfix Implant, 3 x 50mm	IIb	46646	PLATE, SCREWS, WEDGE and STAPLES	8	II	1/2/2002
WASHER Family										
Arthrex, Inc.	Naples, FL	CE 85507	AR-1349	WASHER, SPIKED	IIb	61671	PLATE, SCREWS, WEDGE and STAPLES	8	II	1/2/2002
Arthrex, Inc.	Naples, FL	CE 85507	AR-1349L	WASHER, SPIKED	IIb	61671	PLATE, SCREWS, WEDGE and STAPLES	8	II	1/2/2002
Arthrex, Inc.	Naples, FL	CE 85507	AR-7000-18S	Suture Washer with FiberWire and Curved Needle - SS	IIb	61671	PLATE, SCREWS, WEDGE and STAPLES	8	II	4/5/2014
Arthrex, Inc.	Naples, FL	CE 85507	AR-7000-18T	Suture Washer with FiberWire and Curved Needle - Ti	IIb	61671	PLATE, SCREWS, WEDGE and STAPLES	8	II	4/5/2014

Section

1

1. Declaration of Conformity

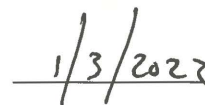
Technical File	Buttons and Suture
GMDN Codes	Refer to Parts List, Rev. 43 for a complete list of all GMDN Codes subject of this Technical File
Revision	43
MDD Class, Rule	Class IIb, Rule 8
Route of Compliance	Annex II (excluding Section 4)
Notified Body / Number	BSI / CE 2797 (Formerly - BSI / CE 0086)
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.



David Rogers
Director, Regulatory Affairs



Date

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:	GMDN Code	Technical File	Rule:	Ann ex:	First DoC:
BUTTON Family										
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1588-15	RetroButton®, 12 mm x 15 mm Loop	lib	45062	Buttons and Suture	8	II	10/13/2006
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1588-20	RetroButton®, 12 mm x 20 mm Loop	lib	45062	Buttons and Suture	8	II	10/13/2006
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1588-25	RetroButton®, 12 mm x 25 mm Loop	lib	45062	Buttons and Suture	8	II	10/13/2006
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1588-30	RetroButton®, 12 mm x 30 mm Loop	lib	45062	Buttons and Suture	8	II	10/13/2006
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1588-35	RetroButton®, 12 mm x 35 mm Loop	lib	45062	Buttons and Suture	8	II	10/13/2006
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1588-40	RetroButton®, 12 mm x 40 mm Loop	lib	45062	Buttons and Suture	8	II	10/13/2006
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1589-15	RetroButton®, Long, 15 mm x 15 mm Loop	lib	45062	Buttons and Suture	8	II	10/13/2006
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1589-20	RetroButton®, Long, 15 mm x 20 mm Loop	lib	45062	Buttons and Suture	8	II	10/13/2006
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1589-25	RetroButton®, Long, 15 mm x 25 mm Loop	lib	45062	Buttons and Suture	8	II	10/13/2006
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1589-30	RetroButton®, Long, 15 mm x 30 mm Loop	lib	45062	Buttons and Suture	8	II	10/13/2006
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1592	RetroButton®, XL, 20 mm x 11 mm Loop	lib	45062	Buttons and Suture	8	II	3/22/2010
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-2260	Implant Delivery System, Distal Biceps	lib	44093	Buttons and Suture	8	II	1/18/2008
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-2261	Biceps Button, 2.6 x 12 mm	lib	61671	Buttons and Suture	8	II	1/18/2008
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-2266	Button, Pec Repair, 2.6 x 10.9 mm	lib	61671	Buttons and Suture	8	II	3/28/2011
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-2267	Button, Pec Repair, Large Eyelets	lib	61671	Buttons and Suture	8	II	4/9/2013
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-2268	Implant Delivery System, Pec Repair	lib	45062	Buttons and Suture	8	II	3/25/2011
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-2269	Implant Delivery System, Pec Repair, Large Eyelets	lib	45062	Buttons and Suture	8	II	4/9/2013
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-2280	Implant System, Knotless Distal Biceps, 2.6 x 12 mm	lib	45062	Buttons and Suture	8	II	9/4/2013
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-2281	Implant, Knotless Distal Biceps, 2.6 x 12mm	lib	45062	Buttons and Suture	8	II	9/4/2013
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-2290	Implant System, Proximal Tenodesis	lib	45062	Buttons and Suture	8	II	5/17/2013
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-2291	Proximal Tenodesis Button	lib	45062	Buttons and Suture	8	II	5/17/2013
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-2296	Tenodesis Button, 2.6 x 7mm	lib	61671	Buttons and Suture	8	II	5/27/2020
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-4550	Implant System, Meniscal Root Repair	lib	13907	Buttons and Suture	8	II	6/14/2016
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-8920	Suture Button, 3.5 mm	lib	61671	Buttons and Suture	8	II	12/24/2003
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-8922	Suture Button, 12 mm	lib	61671	Buttons and Suture	8	II	12/24/2003
CINCH Family										
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-4500	Meniscal Cinch™	lib	45062	Buttons and Suture	8	II	1/18/2008
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-4501	Meniscal Cinch™ II	lib	45062	Buttons and Suture	8	II	10/19/2018
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-5800	SoftStitch™ Implant With #1 Nylon Monofilament	lib	45062	Buttons and Suture	8	II	10/23/2020
SUTURE Family										
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-13920DS	Meniscal Viper Repair- Small Disposables Kit	lib	44093	Buttons and Suture	8	II	4/30/2003
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-13930DS	Meniscal Viper Repair- Large Disposables Kit	lib	44093	Buttons and Suture	8	II	4/30/2003
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1530DS	Bio-Tenodesis Disposables Kit for 3 mm Screw	lib	44093	Buttons and Suture	8	II	12/7/2005
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1530DS-1	Bio-Tenodesis Disposables Kit for 3 mm Screw	lib	44093	Buttons and Suture	8	II	4/20/2018
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1676DS	Bio-Tenodesis Disposable Kit	lib	44093	Buttons and Suture	8	II	2/16/2007
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1676DS-1	Bio-Tenodesis Disposable Kit	lib	44093	Buttons and Suture	8	II	2/16/2007
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1676TS	Tenodesis Graft Sizing Kit with Tendon Sizer, #0 FiberLoop Suture and #2 FiberLoop Suture (5 Pack)	lib	13907	Buttons and Suture	8	II	7/12/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1676TS-1	Tenodesis Graft Sizing Kit with Tendon Sizer, #0 FiberLoop Suture and #2 FiberLoop Suture (Single Pack)	lib	13907	Buttons and Suture	8	II	7/12/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1676ST	Tenodesis Graft Sizing Kit with SutureTape with Tendon Sizer, #0 FiberLoop Suture, and 1.3 mm SutureTape FiberLoop Suture (5 Pack)	lib	13907	Buttons and Suture	8	II	7/12/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1676ST-1	Tenodesis Graft Sizing Kit with SutureTape with Tendon Sizer, #0 FiberLoop Suture, and 1.3 mm SutureTape FiberLoop Suture (Single Pack)	lib	13907	Buttons and Suture	8	II	7/12/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-2750	LoopLoc™ Knotless Suture	lib	13907	Buttons and Suture	8	II	5/25/2021
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-2750-1	LoopLoc™ Knotless Suture	lib	13907	Buttons and Suture	8	II	5/25/2021
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-4068-25TLF	SutureLasso, 25° Tight Curve Left, Small Diameter (SD), w/FiberStick	lib	57874	Buttons and Suture	8	II	3/15/2006
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-4068-25TRF	SutureLasso, 25° Tight Curve Right, Small Diameter (SD), w/FiberStick	lib	57874	Buttons and Suture	8	II	3/15/2006
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-6068-25L	25°, Curve, Left, QuickPass™ Lasso, Low Profile Tip With #2-0 FiberStick	lib	13907	Buttons and Suture	8	II	11/17/2016
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-6068-25R	25° Curve, Right, QuickPass™ Lasso, Low Profile Tip With #2-0 FiberStick	lib	13907	Buttons and Suture	8	II	11/17/2016
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7200	FiberWire, Braided PolyBlend #2 Suture, blue with needle	lib	13907	Buttons and Suture	8	II	6/28/2001
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7200-1	FW,BPB #2 SUTR,BLU W/NDL	lib	13907	Buttons and Suture	8	II	11/17/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7201	FiberWire, Braided PolyBlend #2 Suture, one blue, one white/black	lib	13907	Buttons and Suture	8	II	6/28/2001
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7201-1	FW BPB #2 SUTR, 1 BLU, 1 WH/BLK	lib	13907	Buttons and Suture	8	II	11/30/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7202	FiberWire, Braided PolyBlend #2 Suture, blue with needle	lib	13907	Buttons and Suture	8	II	6/28/2001
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7202-1	FiberWire with needles	lib	13907	Buttons and Suture	8	II	11/17/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7203	#2 TigerWire, Braided PolyBlend Suture, 38", white/black	lib	13907	Buttons and Suture	8	II	1/24/2003
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7203-1	TigerWire 2/5 metric, White/Black, 38" (96.5 cm)	lib	13907	Buttons and Suture	8	II	12/20/2018

Manufacturer name:	Manufacturing location:	EC QA Cert. number:	Product Code:	Product Name:	Class:	GMDN Code	Technical File	Rule:	Ann ex:	First DoC:
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7205	#2 FiberWire, 38" with Two Tapered Needles	IIb	13907	Buttons and Suture	8	II	8/11/2003
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7205-1	FiberLoop with needles	IIb	13907	Buttons and Suture	8	II	11/17/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7205T	#2 TigerWire, 38" with Two Tapered Needles	IIb	13907	Buttons and Suture	8	II	8/11/2003
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7205T-1	FiberLoop with needles	IIb	13907	Buttons and Suture	8	II	11/17/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7206	#2 FiberWire with Tapered Needle, 36.6mm 1/2 Circle	IIb	13907	Buttons and Suture	8	II	4/11/2005
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7206-1	FiberLoop with needles	IIb	13907	Buttons and Suture	8	II	11/17/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7208	FiberWire 38" 26.5 mm Two Strands Tapered Needle	IIb	13907	Buttons and Suture	8	II	4/11/2005
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7208-1	FiberLoop with needles	IIb	13907	Buttons and Suture	8	II	11/17/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7209	#2 FiberStick, #2 FiberWire	IIb	13907	Buttons and Suture	8	II	6/28/2001
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7209-1	FIBERSTICK	IIb	13907	Buttons and Suture	8	II	12/22/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7209SN	#2 FiberSnare, #2 FiberWire, 26"	IIb	13907	Buttons and Suture	8	II	12/4/2003
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7209SNL	#2 FiberSnare 26", white/blue (5 pack)	IIb	13907	Buttons and Suture	8	II	5/25/2021
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7209SNL-1	#2 FiberSnare 26", white/blue (1 pack)	IIb	13907	Buttons and Suture	8	II	5/25/2021
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7209SNT	#2 FiberSnare 26", black/white (5 pack)	IIb	13907	Buttons and Suture	8	II	5/25/2021
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7209SNT-1	#2 FiberSnare 26", black/white (1 pack)	IIb	13907	Buttons and Suture	8	II	5/25/2021
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7209T	TigerStick, #2 TigerWire	IIb	13907	Buttons and Suture	8	II	4/30/2003
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7209T-1	TIGERSTICK	IIb	13907	Buttons and Suture	8	II	12/22/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7210	#5 FiberWire, 38" Long, Blue	IIb	13907	Buttons and Suture	8	II	8/2/2001
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7211	FiberWire, Braided PolyBlend #5 Suture, blue with needle	IIb	13907	Buttons and Suture	8	II	8/2/2001
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7211-1	FiberLoop with needles	IIb	13907	Buttons and Suture	8	II	11/17/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7212	FiberWire®, 5/7 metric, 1 FW (blue), 1 FW (white), and 1 TigerWire® (White/Black) each with 1/2 circle CC needle	IIb	13907	Buttons and Suture	8	II	5/29/2013
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7213	#5 FiberWire w/needles for Sutureplate	IIb	13907	Buttons and Suture	8	II	12/7/2005
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7213-1	FiberLoop with needles	IIb	13907	Buttons and Suture	8	II	11/17/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7215	FiberWire, #5, White, 38"	IIb	13907	Buttons and Suture	8	II	5/23/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7216	FiberWire® Blue Suture 1 (4 metric), Braided Polyblend Suture 38" (96.5 cm)	IIb	13907	Buttons and Suture	8	II	2/10/2012
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7217	FiberWire® #2/5 metric (38" long), 1 FiberWire (Blue) & 1 TigerWire (White/Black) each w/Reverse Cutting Needle	IIb	13907	Buttons and Suture	8	II	9/19/2012
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7219	FiberWire® Suture Kit	IIb	13907	Buttons and Suture	8	II	10/1/2002
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7220	FiberWire, Braided PolyBlend 2-0 Suture, blue with needle	IIb	13907	Buttons and Suture	8	II	6/28/2001
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7220-1	FiberLoop with needles	IIb	13907	Buttons and Suture	8	II	11/17/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7221	FiberWire, Braided PolyBlend 2-0 Suture, blue	IIb	13907	Buttons and Suture	8	II	6/28/2001
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7221-1	FIBERWIRE, BRAIDED PB 2-0 SUTURE, BLUE	IIb	13907	Buttons and Suture	8	II	11/17/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7222	2-0 FiberStick, 2-0 FiberWire	IIb	13907	Buttons and Suture	8	II	1/24/2003
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7222-1	FIBERSTICK	IIb	13907	Buttons and Suture	8	II	12/22/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7223	2-0 FiberWire Meniscus Repair Needles	IIb	13907	Buttons and Suture	8	II	7/29/2004
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7223-1	2-0 FIBERWIRE MENISCUS REPAIR NEEDLES	IIb	13907	Buttons and Suture	8	II	10/2/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7223SM	2-0 FiberWire Meniscal Needles, Small	IIb	13907	Buttons and Suture	8	II	3/15/2006
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7225	#3-0 FiberWire, Braided PolyBlend Suture, 18"	IIb	13907	Buttons and Suture	8	II	8/2/2001
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7227-01	3-0 FiberWire, 18" Blue with Tapered Needle 15 mm	IIb	13907	Buttons and Suture	8	II	6/7/2004
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7227-01-1	FiberWire 3-0/2 metric, Blue, Taper Point Needle	IIb	13907	Buttons and Suture	8	II	12/20/2018
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7227-02	3-0 FiberWire, 18" with Reverse Cutting Needle, 16.3 mm	IIb	13907	Buttons and Suture	8	II	6/7/2004
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7228	4-0 FiberWire, Braided PolyBlend Suture 18" blue	IIb	13907	Buttons and Suture	8	II	10/1/2002
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7228-1	#4-0 FW, BRAID POLYBLEND SUTR 18" BLU	IIb	13907	Buttons and Suture	8	II	6/22/2018
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7229-12	4-0 FiberLoop, 12 inches with needle	IIb	13907	Buttons and Suture	8	II	12/4/2003
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7229-12-1	FiberLoop 4-0/1.5 metric, Blue, Looped, Taper Point Needle	IIb	13907	Buttons and Suture	8	II	12/20/2018
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7229-20	4-0 FiberLoop, 20 inches with needle	IIb	13907	Buttons and Suture	8	II	12/4/2003
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7229-20-1	4-0 FIBERLOOP, 20 INCHES WITH NEEDLE	IIb	13907	Buttons and Suture	8	II	6/22/2018
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7230-01	4-0 FiberWire, 18"	IIb	13907	Buttons and Suture	8	II	6/7/2004
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7230-02	4-0 FiberWire w/Reverse Cutting Needle, 18" 11.9 mm	IIb	13907	Buttons and Suture	8	II	6/7/2004
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7232-01	2-0 FiberLoop, 60" with diamond needle, 48 mm	IIb	13907	Buttons and Suture	8	II	4/11/2005
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7232-02	2-0 FIBERWIRE LOOP 48" W/DIAMOND NEEDLE 26MM	IIb	13907	Buttons and Suture	8	II	4/11/2005
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7232-02-1	FiberLoop with needles	IIb	13907	Buttons and Suture	8	II	11/17/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7232-03	2-0 FiberLoop, 60" with diamond point strait needle	IIb	13907	Buttons and Suture	8	II	4/11/2005
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7232-03-1	2-0 FL, 26" W/DIAMOND PNT ST. NDL	IIb	13907	Buttons and Suture	8	II	11/17/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7232-05	FiberLoop® Blue Suture Looped with Needle 2-0 (3 metric)	IIb	13907	Buttons and Suture	8	II	6/30/2016
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7232-05-1	FiberLoop 2-0/3 metric, Blue, Looped with Curved Needle	IIb	13907	Buttons and Suture	8	II	12/20/2018
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7233	# 2 Fiber Wire, 38 inches (Blue), Quantity 12	IIb	13907	Buttons and Suture	8	II	12/7/2005
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7233-1	FiberWire®, 2/5 metric, Braided Polyblend Suture, Blue	IIb	13907	Buttons and Suture	8	II	11/17/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7234	#2 FiberLoop with Straight Straight 20"	IIb	13907	Buttons and Suture	8	II	7/6/2006

Manufacturer name:	Manufacturing location:	EC QA Cert. number:	Product Code:	Product Name:	Class:	GMDN Code	Technical File	Rule:	Ann ex:	First DoC:
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7234-01	FiberLoop®, 2 / 5 metric, 40", Braided PB White Suture Looped with Straight Needle	IIb	13907	Buttons and Suture	8	II	5/29/2013
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7234-01-1	FiberLoop® 2/5 metric, White, Straight Needle, 40" (101.6 cm)	IIb	13907	Buttons and Suture	8	II	8/16/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7234-1	FiberLoop, #2, Blue	IIb	13907	Buttons and Suture	8	II	8/16/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7234C	FiberLoop® Blue Suture Looped with Curved Needle 2 (5 metric), Braided Polyblend Suture, 40" (101.6 cm), 20" Working Length	IIb	13907	Buttons and Suture	8	II	9/22/2008
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7234C-1	FiberLoop® 2 / 5 metric - 40" (101.6 cm), 20" Working Length, Braided Polyblend, Blue Suture, Looped with Curved 26.5 mm Needle	IIb	13907	Buttons and Suture	8	II	8/16/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7234T	#2 TigerLoop with Straight Needle, 20"	IIb	13907	Buttons and Suture	8	II	10/13/2006
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7234T-1	TigerLoop™ 2/5 metric, White/Green, Looped with Straight Needle, 40" (101.6 cm)	IIb	13907	Buttons and Suture	8	II	8/16/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7235	#2 FiberLink Braided PolyBlend Suture Blue with Closed Loop	IIb	13907	Buttons and Suture	8	II	2/16/2007
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7235-1	FiberLink™ 2/5 metric, Blue with Closed Loop on One End, 26" (66 cm)	IIb	13907	Buttons and Suture	8	II	8/16/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7235T	TigerLink™ 2/5 metric	IIb	13907	Buttons and Suture	8	II	3/28/2011
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7235T-1	TigerLink™ 2/5 metric, White/Black with Closed Loop on One End, 26" (66 cm)	IIb	13907	Buttons and Suture	8	II	8/16/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7237	FiberTape® Blue Suture, 2 mm, FiberWire Braided Polyblend Suture, 36" Working Length	IIb	13907	Buttons and Suture	8	II	8/11/2003
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7237-1	FiberTape® Blue Suture, 2 mm, FiberWire Braided Polyblend Suture, 36" Working Length (1 pack)	IIb	13907	Buttons and Suture	8	II	7/29/2014
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7237-17LN	FiberTape™ 2 mm With Braided Polyblend Suture Blue with Straight Needle	IIb	13907	Buttons and Suture	8	II	3/1/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7237-17LN-1	FiberTape, 2mm with Braided Polyblend Blue Suture with Straight Needle	IIb	13907	Buttons and Suture	8	II	12/20/2018
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7237-17N	FiberTape, 2 mm, 17" long, Braided PB Suture Blue with 2 Tapered Needles	IIb	13907	Buttons and Suture	8	II	2/10/2012
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7237-17N-1	FiberTape® 2mm, Blue with 2 Tapered Needles, 34" (86.36 cm)	IIb	13907	Buttons and Suture	8	II	12/22/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7237-7	FiberTape® Blue Suture, 2 mm, FiberWire Braided Polyblend Suture, 7" working Length	IIb	13907	Buttons and Suture	8	II	6/16/2008
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7237-7-1	FiberTape® Blue Suture, 2 mm, FiberWire Braided Polyblend Suture, 7" working Length (1 pack)	IIb	13907	Buttons and Suture	8	II	4/9/2014
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7237-7T	TigerTape™, White/Black Suture 2 mm, FiberWire Braided Polyblend Suture, 7" working Length	IIb	13907	Buttons and Suture	8	II	6/16/2008
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7237-7T-1	TigerTape™, White/Black Suture 2 mm, FiberWire Braided Polyblend Suture, 7" working Length (1 pack)	IIb	13907	Buttons and Suture	8	II	4/9/2014
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7538	FiberLink Plus™ 1.7mm SutureTape Suture, White/Blue with Closed Loop	IIb	13907	Buttons and Suture	8	II	12/23/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7538-1	FiberLink Plus™ 1.7mm SutureTape Suture, White/Blue with Closed Loop, single pack	IIb	13907	Buttons and Suture	8	II	12/23/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7538T	TigerLink Plus™ 1.7mm SutureTape Suture, White/Black with Closed Loop	IIb	13907	Buttons and Suture	8	II	12/23/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7538T-1	TigerLink Plus™ 1.7mm SutureTape Suture, White/Black with Closed Loop, single pack	IIb	13907	Buttons and Suture	8	II	12/23/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7240	FIBERWIRE BRAIDED PB # 2 SUTURE, 1 WH, 1 BL/BLK	IIb	13907	Buttons and Suture	8	II	12/14/2009
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7242	2-0 FiberWire Braided PolyBlend Suture Blue w/Tapered Needle	IIb	13907	Buttons and Suture	8	II	10/13/2006
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7246	FiberWire, #2, Blue, 1 needle with straight diamond point	IIb	13907	Buttons and Suture	8	II	7/10/2013
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7246-02	FiberWire, #2, Blue, 2 needles with straight diamond point	IIb	13907	Buttons and Suture	8	II	7/10/2013
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7248	4-0 FiberWire, white 18", with Point Needle	IIb	13907	Buttons and Suture	8	II	10/13/2006
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7249-12	4-0 FiberLoop, with needle, white, 12 inches	IIb	13907	Buttons and Suture	8	II	2/16/2007
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7249-12-1	4-0 FW LOOP W/NDL, WHITE 12"	IIb	13907	Buttons and Suture	8	II	11/30/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7249-20	4-0 FiberLoop with needle, white 20"	IIb	13907	Buttons and Suture	8	II	2/16/2007
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7249-20-1	FiberLoop with needles	IIb	13907	Buttons and Suture	8	II	11/17/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7250	0 FiberWire 38" Blue 22.2 mm taper point needle	IIb	13907	Buttons and Suture	8	II	11/15/2004
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7250-1	FiberLoop with needles	IIb	13907	Buttons and Suture	8	II	11/17/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7251	0 FiberWire 38" Blue 22.2 mm with diamond point	IIb	13907	Buttons and Suture	8	II	11/15/2004
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7251-1	FiberLoop with needles	IIb	13907	Buttons and Suture	8	II	11/17/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7253	FiberLoop®, Blue Suture Looped with Straight Needle 0 (3.5 metric)	IIb	13907	Buttons and Suture	8	II	1/18/2008
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7253-1	FiberLoop® 0/3.5 metric, Blue Looped, Straight Needle (1 pack)	IIb	13907	Buttons and Suture	8	II	8/16/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7253T	TigerLoop™ White/Green Suture Looped with Straight Needle 0 (3.5 metric)	IIb	13907	Buttons and Suture	8	II	3/28/2011
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7254	FiberWire® Blue Suture 0 (3.5 metric), Braided Polyblend Suture (12 pack)	IIb	13907	Buttons and Suture	8	II	9/7/2012
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7255	FiberWire® #0/3.5 metric (38" long), Braided PB Suture White	IIb	13907	Buttons and Suture	8	II	9/7/2012
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7258	FiberLink #0, Blue	IIb	13907	Buttons and Suture	8	II	8/8/2016
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7258-1	FiberLink™ 0/3.5 metric, Blue w/ Closed Loop on One End (1 pack)	IIb	13907	Buttons and Suture	8	II	12/20/2018

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Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7258T	TigerLink #0, White/Black	IIb	13907	Buttons and Suture	8	II	8/8/2016
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7258T-1	TigerLink™ 0/3.5 metric, White/Black w/ Closed Loop on One End (1 pack)	IIb	13907	Buttons and Suture	8	II	12/20/2018
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7264	FiberLoop with FiberTag	IIb	13907	Buttons and Suture	8	II	1/26/2015
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7264-1	FiberLoop with FiberTag	IIb	13907	Buttons and Suture	8	II	10/2/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7266	FiberLoop with FiberTag with Swaged Straight Needle	IIb	13907	Buttons and Suture	8	II	6/30/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7267	FiberTape® Cerclage Suture With FiberTape Loop Suture (blue) with Sheath and 2-0 Double Loop Suture (blue)	IIb	61690	Buttons and Suture	8	II	10/27/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7267-1	FiberTape® Cerclage Suture With FiberTape Loop Suture (blue) with Sheath and 2-0 Double Loop Suture (blue) - (1 pack)	IIb	61690	Buttons and Suture	8	II	3/22/2018
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7267T	TigerTape™ Cerclage Suture With TigerTape Loop Suture (white/black) with Sheath and 2-0 Double Loop Suture (blue)	IIb	61690	Buttons and Suture	8	II	10/27/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7267T-1	TigerTape™ Cerclage Suture With TigerTape Loop Suture (white/black) with Sheath and 2-0 Double Loop Suture (blue) - (1 pack)	IIb	61690	Buttons and Suture	8	II	3/22/2018
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7268	FiberTape® Cerclage With TigerLink™ Shuttle Suture	IIb	61690	Buttons and Suture	8	II	4/30/2021
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7268T	TigerTape™ Cerclage With FiberLink™ Shuttle Suture	IIb	61690	Buttons and Suture	8	II	4/30/2021
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7270	Fiberchain, #2 FiberWire with 10 loops7 mm long	IIb	13907	Buttons and Suture	8	II	12/7/2005
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7272	FiberWire CL White/Black 38"	IIb	13907	Buttons and Suture	8	II	10/16/2015
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7272T	TigerWire CL White/Black 38" w/NDL	IIb	13907	Buttons and Suture	8	II	10/16/2015
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7273-8	0 FiberTape, 8", blue (6 pack)	IIb	13907	Buttons and Suture	8	II	5/25/2021
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7273-8-1	0 FiberTape, 8", blue (1 pack)	IIb	13907	Buttons and Suture	8	II	5/25/2021
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7273T	0 FiberTape, 36", white/black (6 pack)	IIb	13907	Buttons and Suture	8	II	5/25/2021
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7273T-1	0 FiberTape, 36", white/black (1 pack)	IIb	13907	Buttons and Suture	8	II	5/25/2021
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7273-8T	0 TigerTape, 8", white/black (6 pack)	IIb	13907	Buttons and Suture	8	II	5/25/2021
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7273-8T-1	0 TigerTape, 8", white/black (1 pack)	IIb	13907	Buttons and Suture	8	II	5/25/2021
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7273-17N	0 FiberTape, 17", blue w/ tapered needle (6 pack)	IIb	13907	Buttons and Suture	8	II	5/25/2021
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7273-17N-1	0 FiberTape, 17", blue w/ tapered needle (1 pack)	IIb	13907	Buttons and Suture	8	II	5/25/2021
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7273-17TN	0 TigerTape, 17", white/black w/ tapered needle (6 pack)	IIb	13907	Buttons and Suture	8	II	5/25/2021
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7273-17TN-1	0 TigerTape, 17", white/black w/ tapered needle (1 pack)	IIb	13907	Buttons and Suture	8	II	5/25/2021
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7275	FiberTape® Loop 2mm, 24", Braided PB Suture, Blue, Looped	IIb	13907	Buttons and Suture	8	II	2/10/2012
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7275-1	FIBERTAPE LOOP	IIb	13907	Buttons and Suture	8	II	8/16/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7275T	TigerTape™ Loop 2mm, 24", Braided PB Suture, White/Black, Looped	IIb	13907	Buttons and Suture	8	II	2/10/2012
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7275T-1	TIGERTAPE LOOP	IIb	13907	Buttons and Suture	8	II	8/16/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7276	LabralTape, 1.5mm, 36", Braided Polyethylene Suture, White, UHMWPE	IIb	13907	Buttons and Suture	8	II	11/13/2012
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7276-1	LABRALTAPE, WHITE 1.5MM 36"	IIb	13907	Buttons and Suture	8	II	8/16/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7276T	LabralTape (White/Black), 1.5mm, 36", Braided Polyethylene Suture, UHMWPE	IIb	13907	Buttons and Suture	8	II	5/12/2014
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7276T-1	LABRALTAPE, WHITE/BLACK 1.5MM	IIb	13907	Buttons and Suture	8	II	8/16/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7282-25	#2 FiberRing™ 25 mm	IIb	13907	Buttons and Suture	8	II	5/25/2021
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7282-25-1	#2 FiberRing™ 25 mm	IIb	13907	Buttons and Suture	8	II	5/25/2021
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7282-35	#2 FiberRing™ 35 mm	IIb	13907	Buttons and Suture	8	II	5/25/2021
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7282-35-1	#2 FiberRing™ 35 mm	IIb	13907	Buttons and Suture	8	II	5/25/2021
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7282-45	#2 FiberRing™ 45 mm	IIb	13907	Buttons and Suture	8	II	5/25/2021
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7282-45-1	#2 FiberRing™ 45 mm	IIb	13907	Buttons and Suture	8	II	5/25/2021
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7282-55	#2 FiberRing™ 55 mm	IIb	13907	Buttons and Suture	8	II	5/25/2021
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7282-55-1	#2 FiberRing™ 55 mm	IIb	13907	Buttons and Suture	8	II	5/25/2021
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7284	#2 FiberLoop with Swaged Straight Needle, Blue	IIb	13907	Buttons and Suture	8	II	8/17/2016
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7288	FiberTape® Sternal Closure With Attached Reverse Cutting Needle	IIb	61690	Buttons and Suture	8	II	5/25/2021
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7288T	TigerTape™ Sternal Closure WithAttached Reversed Cutting Needle	IIb	61690	Buttons and Suture	8	II	5/25/2021
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7289	FiberTape® Sternal Closure With Attached Blunt Tapered Needle	IIb	61690	Buttons and Suture	8	II	5/25/2021
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7289T	TigerTape™ Sternal Closure With Attached Blunt Tapered Needle	IIb	61690	Buttons and Suture	8	II	5/25/2021
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7298	Univers Apex Suture Kit (SutureLasso)	IIb	37839	Buttons and Suture	8	II	6/15/2015
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7500	SutureTape, White/Blue, 1.3mm with Needle	IIb	13907	Buttons and Suture	8	II	1/22/2016
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7500-1	SutureTape, White/Blue, 1.3mm with Needle (1 pack)	IIb	13907	Buttons and Suture	8	II	6/22/2018
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7501	SutureTape, 1.3 mm Sutures, 1 White/Blue and 1 White/Black (12 pack)	IIb	13907	Buttons and Suture	8	II	12/20/2018

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Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7501-1	SutureTape, 1.3 mm Sutures, 1 White/Blue and 1 White/Black (1 pack)	IIb	13907	Buttons and Suture	8	II	7/6/2020
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7502	SutureTape 1.3 mm Suture White/Blue with Needle	IIb	13907	Buttons and Suture	8	II	8/16/2018
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7502-1	SutureTape 1.3 mm Suture, White/Blue with Needle (1 pack)	IIb	13907	Buttons and Suture	8	II	11/5/2020
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7505	1.3 mm SutureTape 38", white/blue, w/two 1/2, 26.5mm curved, tapered needles (12 pack)	IIb	13907	Buttons and Suture	8	II	5/25/2021
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7505-1	1.3 mm SutureTape 38", white/blue, w/two 1/2, 26.5mm curved, tapered needles (1 pack)	IIb	13907	Buttons and Suture	8	II	5/25/2021
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7505TT-02	1.3 mm SutureTape 38", black/white, w/two 1/2, 26.5mm curved tapered needles (12 pack)	IIb	13907	Buttons and Suture	8	II	5/25/2021
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7505TT-02-1	1.3 mm SutureTape 38", black/white, w/two 1/2, 26.5mm curved tapered needles (1 pack)	IIb	13907	Buttons and Suture	8	II	5/25/2021
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7506	SutureTape 1.3 mm, Blue with Needle	IIb	13907	Buttons and Suture	8	II	11/5/2020
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7506-1	SutureTape 1.3 mm, Blue with Needle (1 pack)	IIb	13907	Buttons and Suture	8	II	11/5/2020
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7506T	SutureTape 1.3 mm, Black/White with Needle	IIb	13907	Buttons and Suture	8	II	11/5/2020
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7506T-1	SutureTape 1.3 mm, Black/White with Needle (1 pack)	IIb	13907	Buttons and Suture	8	II	11/5/2020
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7511	1.7mm SutureTape Suture, White/Blue with Needle	IIb	13907	Buttons and Suture	8	II	3/3/2020
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7511-1	1.7mm SutureTape Suture, White/Blue with Needle, single pack	IIb	13907	Buttons and Suture	8	II	3/3/2020
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7521	SutureTape 0.9 mm, 38" (96.5 cm)	IIb	13907	Buttons and Suture	8	II	7/20/2018
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7521-1	SutureTape 0.9 mm, 38" (96.5 cm), Single Pack	IIb	13907	Buttons and Suture	8	II	7/20/2018
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7523	SutureTape 0.9 mm, 38" (96.5 cm) Meniscus Repair Needles with 0.9 mm SutureTape and two Needles	IIb	13907	Buttons and Suture	8	II	7/20/2018
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7523-1	SutureTape 0.9 mm, 38" (96.5 cm) Meniscus Repair Needles with 0.9 mm SutureTape and two Needles, Single Pack	IIb	13907	Buttons and Suture	8	II	7/20/2018
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7524	0.9 mm SutureTape Loop 20", white/blue, w/straight needle (12 pack)	IIb	13907	Buttons and Suture	8	II	5/25/2021
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7524-1	0.9 mm SutureTape Loop 20", white/blue, w/straight needle (1 pack)	IIb	13907	Buttons and Suture	8	II	5/25/2021
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7524C	0.9 mm SutureTape Loop 20", white/blue, w/ 1/2 curved tapered needle (12 pack)	IIb	13907	Buttons and Suture	8	II	5/25/2021
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7524C-1	0.9 mm SutureTape Loop 20", white/blue, w/ 1/2 curved tapered needle (1 pack)	IIb	13907	Buttons and Suture	8	II	5/25/2021
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7531-02	1.3 mm SutureTape 38", white/blue, w/two 1/2 curved tapered 36.6mm needles (12 pack)	IIb	13907	Buttons and Suture	8	II	5/25/2021
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7531-02-1	1.3 mm SutureTape 38", white/blue, w/two 1/2 curved tapered 36.6mm needles (12 pack)	IIb	13907	Buttons and Suture	8	II	5/25/2021
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7532-05	0.9 mm SutureTape Loop 20", white/blue, w/curved 3/8 tapered needle (12 pack)	IIb	13907	Buttons and Suture	8	II	5/25/2021
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7532-05-1	0.9 mm SutureTape Loop 20", white/blue, w/curved 3/8 tapered needle (1 pack)	IIb	13907	Buttons and Suture	8	II	5/25/2021
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7534	FiberLoop, 1.3mm SutureTape Suture, white/blue Looped with Needle	IIb	13907	Buttons and Suture	8	II	5/4/2018
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7534-1	FiberLoop, 1.3mm SutureTape Suture, white/blue Looped with Needle	IIb	13907	Buttons and Suture	8	II	7/12/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7534T	TigerLoop, 1.3mm SutureTape Suture, white/black Looped with Needle	IIb	13907	Buttons and Suture	8	II	5/4/2018
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7534T-1	TigerLoop, 1.3mm SutureTape Suture, white/black Looped with Needle	IIb	13907	Buttons and Suture	8	II	7/12/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7535	FiberLink, 1.3mm SutureTape Suture, white/blue with Closed Loop	IIb	13907	Buttons and Suture	8	II	5/4/2018
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7535-1	FiberLink, 1.3mm SutureTape Suture, white/blue with Closed Loop	IIb	13907	Buttons and Suture	8	II	7/12/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7535T	TigerLink, 1.3mm SutureTape Suture, white/black with Closed Loop	IIb	13907	Buttons and Suture	8	II	5/4/2018
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7535T-1	TigerLink, 1.3mm SutureTape Suture, white/black with Closed Loop	IIb	13907	Buttons and Suture	8	II	7/12/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7546-02	1.3 mm SutureTape 38", white/blue, w/two straight diamond point needles 64.8mm (12 pack)	IIb	13907	Buttons and Suture	8	II	5/25/2021
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7546-02-1	1.3 mm SutureTape 38", white/blue, w/two straight diamond point needles 64.8mm (1 pack)	IIb	13907	Buttons and Suture	8	II	5/25/2021
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7546TT-02	1.3 mm SutureTape 38", black/white, w/two straight diamond point needles 64.8mm(12 pack)	IIb	13907	Buttons and Suture	8	II	5/25/2021
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7546TT-02-1	1.3 mm SutureTape 38", black/white, w/two straight diamond point needles 64.8mm (1 pack)	IIb	13907	Buttons and Suture	8	II	5/25/2021
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7547T	0.9 mm SutureTape 38", white/black, w/one straight needle (12 pack)	IIb	13907	Buttons and Suture	8	II	5/25/2021
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7547T-1	0.9 mm SutureTape 38", white/black, w/one straight needle (1 pack)	IIb	13907	Buttons and Suture	8	II	5/25/2021
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7559	FiberLink 0.9mm SutureTape suture, white/blue with closed loop	IIb	13907	Buttons and Suture	8	II	3/22/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7559-1	FiberLink 0.9mm SutureTape suture, white/blue with closed loop, single pack	IIb	13907	Buttons and Suture	8	II	3/22/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7559T	TigerLink 0.9mm SutureTape suture, white/black with closed loop	IIb	13907	Buttons and Suture	8	II	3/22/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7559T-1	TigerLink 0.9mm SutureTape suture, white/black with closed loop, single pack	IIb	13907	Buttons and Suture	8	II	3/22/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7570-02	0.9 mm SutureTape 38", white/blue, w/two 1/2, 22.2mm curved tapered needles (12 pack)	IIb	13907	Buttons and Suture	8	II	5/25/2021
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7570-02-1	0.9 mm SutureTape 38", white/blue, w/two 1/2, 22.2mm curved tapered needles (1 pack)	IIb	13907	Buttons and Suture	8	II	5/25/2021

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Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7571-02	0.9 mm SutureTape 38", white/blue, w/two 1/2, 36.6mm curved tapered needles (12 pack)	IIb	13907	Buttons and Suture	8	II	5/25/2021

Manufacturer name:	Manufacturing location:	EC QA Cert. number:	Product Code:	Product Name:	Class:	GMDN Code	Technical File	Rule:	Ann ex:	First DoC:
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7571-02-1	0.9 mm SutureTape 38", white/blue, w/two 1/2, 36.6mm curved tapered needles (1 pack)	IIb	13907	Buttons and Suture	8	II	5/25/2021
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7572-02	0.9 mm SutureTape 38", white/blue, w/two 1/2, 26.5mm curved tapered needles (12 pack)	IIb	13907	Buttons and Suture	8	II	5/25/2021
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7572-02-1	0.9 mm SutureTape 38", white/blue, w/two 1/2, 26.5mm curved tapered needles (1 pack)	IIb	13907	Buttons and Suture	8	II	5/25/2021
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7572T-02	0.9 mm SutureTape 38", white/black, w/two 1/2, 26.5mm curved tapered needles (12 pack)	IIb	13907	Buttons and Suture	8	II	5/25/2021
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7572T-02-1	0.9 mm SutureTape 38", white/black, w/two 1/2, 26.5mm curved tapered needles (1 pack)	IIb	13907	Buttons and Suture	8	II	5/25/2021
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7715-4.5	UCL SUTURE PASSING DISPOSABLES KIT	IIb	44093	Buttons and Suture	8	II	3/22/2009
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7580	0.9 mm SutureTape 18" with small loop, white/blue, w/curved 3/8 tapered needle (12 pack)	IIb	13907	Buttons and Suture	8	II	5/25/2021
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7580-1	0.9 mm SutureTape 18" with small loop, white/blue, w/curved 3/8 tapered needle (1 pack)	IIb	13907	Buttons and Suture	8	II	5/25/2021
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7580T	0.9 mm SutureTape 18" with small loop, white/black, w/curved 3/8 tapered needle (12 pack)	IIb	13907	Buttons and Suture	8	II	5/25/2021
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7580T-1	0.9 mm SutureTape 18" with small loop, white/black, w/curved 3/8 tapered needle (1 pack)	IIb	13907	Buttons and Suture	8	II	5/25/2021
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-8692DS	Implant System, CPR Viper	IIb	45062	Buttons and Suture	8	II	10/9/2014
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-8816DS	TFCC Suture Kit	IIb	13907	Buttons and Suture	8	II	10/8/2018
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-8860DS	PARS Suture Kit	IIb	13907	Buttons and Suture	8	II	9/22/2008
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-8862DS	Implant System, PARS SutureTape	IIb	13907	Buttons and Suture	8	II	10/2/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-9517	FxBridge™ Tuberosity Suture Repair System	IIb	13907	Buttons and Suture	8	II	5/25/2021
TIGHTROPE FAMILY										
ANKLE										
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-8920CDS	TightRope® Syndesmosis Repair Implant, Titanium	IIb	44093	Buttons and Suture	8	II	7/26/2007
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-8921CDS	TightRope® Syndesmosis Repair Implant, Stainless Steel	IIb	44093	Buttons and Suture	8	II	7/20/2006
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-8924SS	Knotless TightRope Syndesmosis Repair, Implant Only, Stainless Steel	IIb	45062	Buttons and Suture	8	II	5/23/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-8924T	Knotless TightRope Syndesmosis Repair, Implant Only, Titanium	IIb	45062	Buttons and Suture	8	II	5/23/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-8925SS	Syndesmosis TightRope® XP, Stainless Steel (Kit)	IIb	45062	Buttons and Suture	8	II	2/16/2018
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-8925SS-01	Syndesmosis TightRope® XP, Implant Only, Stainless Steel	IIb	45062	Buttons and Suture	8	II	5/25/2021
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-8925T	Syndesmosis TightRope XP, Titanium Kit	IIb	45062	Buttons and Suture	8	II	2/16/2018
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-8925T-01	Syndesmosis TightRope® XP, Implant Only, Titanium	IIb	45062	Buttons and Suture	8	II	5/25/2021
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-8926SS	Knotless TightRope® Syndesmosis Repair Implant, Stainless Steel	IIb	45062	Buttons and Suture	8	II	3/25/2011
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-8926T	Knotless TightRope® Syndesmosis Repair Implant, Titanium	IIb	45062	Buttons and Suture	8	II	3/28/2011
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-8947DS	Implant Delivery, TightRope Syndesmosis Buttress Plate	IIb	45062	Buttons and Suture	8	II	9/19/2008
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-8958TDS	Implant System, Dual TightRope Syndesmosis 2 Hole Buttress Plate	IIb	61688	Buttons and Suture	8	II	3/1/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-8959-01S	Two-Hole Syndesmosis Plate, 1.5 mm, Stainless Steel	IIb	61688	Buttons and Suture	8	II	10/23/2020
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-8959-02S	Two-Hole Syndesmosis Plate, 1.5 mm, Titanium	IIb	61688	Buttons and Suture	8	II	10/23/2020
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-8959TDS	Syndesmosis TightRope XP Buttress Plate Implant System, Syndesmosis 2 Hole Buttress Plate, 1.5 mm, Titanium With 1.5 mm Syndesmosis Plate, Syndesmosis TightRope XP Assemblies with Inserters, Suture Tension Handles, Solid Drill Bit, Cannulated Drill Bit, Trocar Tip Guidewire, Drill Guide, Guidewire Sleeve and BB-Taks	IIb	61688	Buttons and Suture	8	II	10/23/2020
HAND/FOOT										
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-8906DS	Knotless Mini TightRope® Implant System, 1.1 mm, Titanium	IIb	44093	Buttons and Suture	8	II	5/25/2021
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-8907DS	Knotless Mini TightRope® Implant System, 1.1 mm, Dual-Fixation, Titanium	IIb	44093	Buttons and Suture	8	II	5/25/2021
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-8908DS	Knotless Mini TightRope® Implant System, 2.7 mm, Titanium	IIb	44093	Buttons and Suture	8	II	5/25/2021
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-8911DS	Mini TightRope® Repair Implant, Cannulated, Stainless Steel (only to be used in the Foot)	IIb	44093	Buttons and Suture	8	II	7/20/2006
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-8913DS	Mini TightRope® Implant with Inserter	IIb	44093	Buttons and Suture	8	II	9/22/2008
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-8914DS	Implant System, Mini TightRope® 1.1 mm	IIb	45062	Buttons and Suture	8	II	7/7/2008
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-8917DS	Mini TightRope® FT with 3.5 mm Corkscrew® FT Suture Anchor	IIb	44093	Buttons and Suture	8	II	3/4/2009
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-8919DS	Implant System, CMC Mini TightRope®, 1.1 mm	IIb	45062	Buttons and Suture	8	II	7/12/2013
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-8919-SS	DX Button, 2.6 mm x 8 mm	IIb	61671	Buttons and Suture	8	II	4/30/2021
Knee										

Manufacturer name:	Manufacturing location:	EC QA Cert. number:	Product Code:	Product Name:	Class:	GMDN Code	Technical File	Rule:	Annex:	First DoC:
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1588BTB	BTB TightRope®	IIb	45062	Buttons and Suture	8	II	8/30/2011
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1588BTB-J	BTB TightRope®, Double Loaded Passing Sutures	IIb	45062	Buttons and Suture	8	II	12/17/2014
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1588BTB-2	BTB TightRope® II	IIb	45062	Buttons and Suture	8	II	2/19/2021

Manufacturer name:	Manufacturing location:	EC QA Cert. number:	Product Code:	Product Name:	Class:	GMDN Code	Technical File	Rule:	Ann ex:	First DoC:
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1588BTB-2J	BTB TightRope® II, Double loaded Passing Sutures	IIb	45062	Buttons and Suture	8	II	2/19/2021
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1588BTB-IB	BTB TightRope® II, with InternalBrace™ Ligament Augmentation	IIb	45062	Buttons and Suture	8	II	4/9/2021
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1588R-IB	ACL Repair TightRope®, with InternalBrace™ Ligament Augmentation	IIb	45062	Buttons and Suture	8	II	5/25/2021
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1588RT	ACL TightRope® RT	IIb	45062	Buttons and Suture	8	II	9/10/2010
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1588RT-2	ACL TightRope® II RT	IIb	45062	Buttons and Suture	8	II	2/19/2021
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1588RT-2J	ACL TightRope® II RT, Double Loaded Passing Sutures	IIb	45062	Buttons and Suture	8	II	2/19/2021
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1588RT-IB	ACL TightRope® II RT, with InternalBrace™ Ligament Augmentation	IIb	45062	Buttons and Suture	8	II	4/9/2021
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1588RT-J	ACL TightRope® RT, Double Loaded Passing Sutures	IIb	45062	Buttons and Suture	8	II	12/17/2014
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1588RTS	Implant Delivery System, ACL TightRope® RT	IIb	45062	Buttons and Suture	8	II	8/30/2011
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1588RTT	ACL FiberTag® TightRope® Implant	IIb	45062	Buttons and Suture	8	II	8/23/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1588T	ACL TightRope®	IIb	45062	Buttons and Suture	8	II	3/22/2010
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1588TB	TightRope® ABS, Button, 8 x 12mm	IIb	45062	Buttons and Suture	8	II	12/20/2010
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1588TB-1	TightRope ABS, Button, Round, Ø 14mm	IIb	45062	Buttons and Suture	8	II	11/5/2014
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1588TB-2	TightRope® ABS, Button Oblong, 3.4 x 13 mm	IIb	45062	Buttons and Suture	8	II	12/6/2012
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1588TB-3	TightRope ABS, Button, Round, Ø 11mm Concave	IIb	45062	Buttons and Suture	8	II	2/8/2016
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1588TB-4	TightRope ABS, Button, Round, Ø 14mm Concave	IIb	45062	Buttons and Suture	8	II	2/8/2016
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1588TB-5	TightRope ABS, Button, Round, Ø 20mm Concave	IIb	45062	Buttons and Suture	8	II	2/8/2016
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1588TB-IB	ACL InternalBrace™ Ligament Augmentation Button	IIb	45062	Buttons and Suture	8	II	5/25/2021
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1588TN	TightRope® ABS, Implant (no button)	IIb	13907	Buttons and Suture	8	II	12/17/2010
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1588TN-1	TightRope Implant, Open	IIb	45062	Buttons and Suture	8	II	3/18/2013
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1588TN-2	Tibial Fixation Kit, 11mm Button	IIb	45062	Buttons and Suture	8	II	8/16/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1588TN-3	Tibial Fixation Kit, 14mm Button	IIb	45062	Buttons and Suture	8	II	8/16/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1588TN-4	Tibial Fixation Kit, 20mm Button	IIb	45062	Buttons and Suture	8	II	8/16/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1588TN-20	TightRope® II ABS, Implant	IIb	45062	Buttons and Suture	8	II	2/19/2021
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1588TN-21	TightRope® II ABS, Implant, Open	IIb	45062	Buttons and Suture	8	II	2/19/2021
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1588TNT	ACL FiberTag® TightRope® ABS Implant	IIb	13907	Buttons and Suture	8	II	8/23/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1589RT	TightRope® Button Extender, 5 x 20mm	IIb	45062	Buttons and Suture	8	II	12/6/2012
				SHOULDER						
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-2257	AC TightRope® Repair Kit, Titanium	IIb	45062	Buttons and Suture	8	II	12/7/2005
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-2264	AC TightRope®, Twin Tail	IIb	45062	Buttons and Suture	8	II	9/19/2008
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-2270	Button, Dog Bone™	IIb	61671	Buttons and Suture	8	II	3/14/2011
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-2271	Implant System, Acute AC Repair	IIb	45062	Buttons and Suture	8	II	9/24/2012
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-2370	Low-Profile AC Implant Device (Knotless)	IIb	45062	Buttons and Suture	8	II	1/29/2016
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-2370BL	Knotless AC Repair Implant with Dog Bone™ Button Clavicle Cup Button Implant, Dog Bone™ Button	IIb	45062	Buttons and Suture	8	II	5/25/2021
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-2371	Low-Profile AC Implant Device (Knotless)	IIb	45062	Buttons and Suture	8	II	3/1/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-2371BL	Knotless AC Repair System Clavicle Cup Button Implant, Dog Bone™ Button, 3.0 mm Cannulated Drill, Nitinol Wire Loop	IIb	45062	Buttons and Suture	8	II	5/25/2021
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-2372BLO	Knotless AC Open Repair Implant Clavicle Cup Button Implant, Pec Button	IIb	45062	Buttons and Suture	8	II	5/25/2021
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-2658BL	Knotless Distal Clavicle Repair Assembly with Dog Bone™ Button Clavicle Plate Button Implant, Dog Bone™ Button	IIb	45062	Buttons and Suture	8	II	5/25/2021
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-2658BLO	Knotless Distal Clavicle Plate Button Implant Clavicle Plate Button Implant, Pec Button	IIb	45062	Buttons and Suture	8	II	5/25/2021
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-2658TR	Knotless Distal Clavicle Plate Button TightRope®	IIb	61688	Buttons and Suture	8	II	6/30/2017

Section

1

1. Declaration of Conformity

Technical File Anchors

GMDN Codes Refer to Parts List Rev. 35 for a complete list of all GMDN Codes subject of this Technical File

Revision 35

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.

Courtney Smith 2/19/21
Courtney Smith 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	GMDN Code	TF	Rule	Annex	First DoC
Corkscrew and Corkscrew II										
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-19025F	Suture Anchor, Corkscrew® II with #2 FiberWire® and #2 TigerWire®	IIb	45062	ANCHORS	8	II	9/14/2002
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-19025F-1	Suture Anchor, Corkscrew® II with #2 FiberWire® and #2 TigerWire® (1 pack)	IIb	45062	ANCHORS	8	II	8/20/2012
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1915S	Suture Anchor, Corkscrew® With #2 Braided Polyester Suture	IIb	45062	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	45062	ANCHORS	8	II	8/20/2012
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1915SF	Suture Anchor, Corkscrew® With #2 FiberWire®	IIb	45062	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	45062	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	45062	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	45062	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	45062	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	45062	ANCHORS	8	II	8/20/2012
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1920S	Suture Anchor, Corkscrew® With #2 Braided Polyester Suture	IIb	45062	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	45062	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	45062	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	45062	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	45062	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	45062	ANCHORS	8	II	8/23/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1925SF	Suture Anchor, Corkscrew® with #2 FiberWire® and #2 TigerWire®	IIb	45062	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	45062	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	45062	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	45062	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	45062	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	45062	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	45062	ANCHORS	8	II	12/23/2019
Corkscrew FT and Corkscrew FTII										
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1317FT	Suture Anchor, Nano Corkscrew® Fully Threaded, With 3-0 FiberWire® Suture with two 1/2 Circle Taper Point Needles and K-Wires, 1.7 x 5 mm, Bone Anchor	IIb	45062	ANCHORS	8	II	2/16/2018
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1317FT-1	Suture Anchor, Nano Corkscrew® Fully Threaded, With 3-0 FiberWire® Suture with two 1/2 Circle Taper Point Needles and K-Wires, 1.7 x 5 mm, Bone Anchor (1 Pack)	IIb	45062	ANCHORS	8	II	2/16/2018
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1318FT	Suture Anchor, Micro Corkscrew® Fully Threaded, With 2-0 FiberWire® Suture and two Needles, Soft Bone K-Wire and Hard Bone K-wire, 2.2 x 4 mm, Bone Anchor	IIb	45062	ANCHORS	8	II	9/19/2008
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1318FT-1	Suture Anchor, Micro Corkscrew® Fully Threaded, With 2-0 FiberWire® Suture and two Needles, Soft Bone K-Wire and Hard Bone K-wire, 2.2 x 4 mm, Bone Anchor (1 pack)	IIb	45062	ANCHORS	8	II	10/2/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1318FT-40	Suture Anchor, Micro Corkscrew® Fully Threaded, With 4-0 FiberWire® Suture and two Needles, Soft Bone K-Wire and Hard Bone K-Wire, 2.2 x 4 mm, Bone Anchor	IIb	45062	ANCHORS	8	II	9/15/2011
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1318FT-40-1	Suture Anchor, Micro Corkscrew® Fully Threaded, With 4-0 FiberWire® Suture and two Needles, Soft Bone K-Wire and Hard Bone K-Wire, 2.2 x 4 mm, Bone Anchor (1 pack)	IIb	45062	ANCHORS	8	II	10/2/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1319FT	Suture Anchor, Mini Corkscrew® Fully Threaded, With 2-0 FiberWire® Suture and two Needles, Soft Bone K-wire and Hard Bone K-Wire, 2.7 x 7 mm, Bone Anchor	IIb	45062	ANCHORS	8	II	9/19/2008
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1319FT-1	Suture Anchor, Mini Corkscrew® Fully Threaded, With 2-0 FiberWire® Suture and two Needles, Soft Bone K-wire and Hard Bone K-Wire, 2.7 x 7 mm, Bone Anchor (1 pack)	IIb	45062	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	45062	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	45062	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	45062	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	45062	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	45062	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	45062	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	45062	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	45062	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	45062	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	45062	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	45062	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	45062	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	45062	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	45062	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	45062	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	45062	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	45062	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	45062	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	45062	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	45062	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	45062	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	45062	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	45062	ANCHORS	8	II	7/24/2007

Manufacturer Name	Manufacturing Location	EC QA Cert. Number	Product Code	Product Name	Class	GMDN Code	TF	Rule	Annex	First DoC
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	45062	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	45062	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	45062	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	45062	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	45062	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	IIb	45062	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	45062	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	45062	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 Needles, 2.4 x 7.5 mm	IIb	45062	ANCHORS	8	II	9/14/2002
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	45062	ANCHORS	8	II	6/30/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1322SXF	Suture Anchor FASTak™	IIb	45062	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, Bone Anchor	IIb	45062	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, Bone Anchor (1 pack)	IIb	45062	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, Bone Anchor	IIb	45062	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	45062	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	45062	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	45062	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	45062	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	45062	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	45062	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	45062	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	45062	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	45062	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	45062	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	45062	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	45062	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	45062	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	45062	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	45062	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	45062	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	45062	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	45062	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	45062	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	45062	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	45062	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	45062	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	45062	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	45062	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	45062	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	45062	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	45062	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	45062	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	45062	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	45062	ANCHORS	8	II	10/15/2020
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3638	Knotless FiberTak Pro, with #2 Suture	IIb	45062	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	45062	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	45062	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	45062	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	45062	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	45062	ANCHORS	8	II	12/2/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3641	Knotless FiberTak Pro, with #5 Suture	IIb	45062	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	45062	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	45062	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	45062	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	45062	ANCHORS	8	II	5/3/2016
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3651-1	Self-Punching FiberTak® DR With LabralTape™ (White/Black) and #2 TigerTail® (White/Green/Black)	IIb	45062	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	45062	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	45062	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	45062	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	45062	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	45062	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	45062	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	45062	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	45062	ANCHORS	8	II	6/30/2017

Manufacturer Name	Manufacturing Location	EC QA Cert. Number	Product Code	Product Name	Class	GMDN Code	TF	Rule	Annex	First DoC
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3651TTSP	Self-Punching FiberTak® DR With LabralTape™ (White/Blue) and #2 TigerTail® (White/Black)	IIb	45062	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	45062	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	45062	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	45062	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	45062	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	45062	ANCHORS	8	II	10/23/2020
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-8990	FiberTak DX with #1 FiberWire Suture and Needles	IIb	45062	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	45062	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	45062	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	45062	ANCHORS	8	II	6/22/2018
Implant Systems										
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1778P-CP	InternalBrace™ Implant System, Ligament Augmentation Repair, PEEK	IIb	45062	ANCHORS	8	II	12/2/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-2600SBS-6	SpeedBridge™ Implant System with PEEK SwiveLock® Anchors With two Anchors with #2 FiberWire® Suture, one Anchor with FiberTape® Loop Suture, one Anchor with TigerTape™ Loop Suture, and Punch	IIb	45062	ANCHORS	8	II	11/28/2016
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-2600SBS-7	SpeedBridge™ Implant System with PEEK SwiveLock® 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	45062	ANCHORS	8	II	11/28/2016
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-4550P	Implant System, Meniscal Root Repair with PEEK SwiveLock® With 4.75 x 19.1 mm PEEK SwiveLock Suture Anchor, Punch/Tap fro 4.75 mm SwiveLock, Spade Tip Drill, 6 mm FlipCutter® II, Knee Scorpion™ Needle, 8x 3 PassPort Button™ Cannula, SutureLasso™ Needle, QuickPass™ Lasso Wire, two 2-0 FiberStick™ Suture, 0 FiberLink™ Suture and 0 TigerLink Suture	IIb	45062	ANCHORS	8	II	8/23/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-8826DS	Implant Delivery System, Graft Anchor	IIb	45062	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 SwiveLock® 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	45062	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 SwiveLock® 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	45062	ANCHORS	8	II	10/27/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-9400-SBK	Eclipse™ SpeedScap™ Implant System, With three 2.6 mm FiberTak® DR Suture Anchors, two 3.9 mm PEEK SwiveLock® Suture Anchors, Drill Bits, Free Needle with Nitinol Loop, SutureTape TigerLink™ and two SutureTapes with Needle	IIb	45062	ANCHORS	8	II	2/19/2021
PushLock										
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1663PC-8	PEEK PushLock Tenodesis Anchor, Closed Eyelet, 8 x 13.4 mm	IIb	45062	ANCHORS	8	II	9/21/2018
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1922PS	Suture Anchor, PushLock®, 4.5 x 24 mm	IIb	45062	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	45062	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	45062	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	45062	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	45062	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	45062	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	45062	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	45062	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	45062	ANCHORS	8	II	3/9/2007
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1926PS	Suture Anchor, PushLock®, 3.5 X19.5 mm	IIb	45062	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	45062	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	45062	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	45062	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	45062	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	45062	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	45062	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	45062	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	45062	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	45062	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	45062	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	45062	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	45062	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	45062	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	45062	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	45062	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	45062	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	45062	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	45062	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	45062	ANCHORS	8	II	8/20/2012
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1934PST-2	PEEK SutureTak® Double Loaded with SutureTape Suture With one 1.3 mm blue Suture and one 1.3 mm black/white Suture, 3 x 14.5 mm	IIb	45062	ANCHORS	8	II	11/20/2020
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1934PST-2-1	PEEK SutureTak® Double Loaded with SutureTape Suture With one 1.3 mm blue Suture and one 1.3 mm black/white Suture, 3 x 14.5 mm (1 pack)	IIb	45062	ANCHORS	8	II	11/20/2020
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1938PHS	Suture Anchor, PEEK, Knotless Hip SutureTak® With # 2 Suture, 3 x 12.7 mm	IIb	45062	ANCHORS	8	II	8/30/2018

Manufacturer Name	Manufacturing Location	EC QA Cert. Number	Product Code	Product Name	Class	GMDN Code	TF	Rule	Annex	First DoC
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	45062	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	45062	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	45062	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	45062	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	45062	ANCHORS	8	II	2/16/2018
SwiveLock										
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1662PSL-7	Suture Anchor, SwiveLock® Tenodesis, PEEK with Fork Tip PEEK Eyelet and #2 FiberWire®, 7 x 19.5 mm	IIb	45062	ANCHORS	8	II	9/15/2011
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1662PSL-7-1	Suture Anchor, SwiveLock® Tenodesis, PEEK with Fork Tip PEEK Eyelet and #2 FiberWire®, 7 x 19.5 mm (1 pack)	IIb	45062	ANCHORS	8	II	11/30/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1662PSL-8	Suture Anchor, SwiveLock® Tenodesis, PEEK with Fork Tip PEEK Eyelet and #2 FiberWire®, 8 x 19.5 mm	IIb	45062	ANCHORS	8	II	9/15/2011
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1662PSL-8-1	Suture Anchor, SwiveLock® Tenodesis, PEEK with Fork Tip PEEK Eyelet and #2 FiberWire®, 8 x 19.5 mm (1 pack)	IIb	45062	ANCHORS	8	II	8/23/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1662PSL-9	Suture Anchor, SwiveLock® Tenodesis, PEEK with Fork Tip PEEK Eyelet and #2 FiberWire®, 9 x 19.5 mm	IIb	45062	ANCHORS	8	II	9/15/2011
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1662PSL-9-1	Suture Anchor, SwiveLock® Tenodesis, PEEK with Fork Tip PEEK Eyelet and #2 FiberWire®, 9 x 19.5 mm (1 pack)	IIb	45062	ANCHORS	8	II	11/17/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-2323KPSLC	PEEK Knotless SwiveLock® Suture Anchor, 5.5 x 19.1 mm With Blue #2 Suture	IIb	45062	ANCHORS	8	II	3/23/2020
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-2323KPSLC-1	PEEK Knotless SwiveLock® Suture Anchor, 5.5 x 19.1 mm With Blue #2 Suture (1 pack)	IIb	45062	ANCHORS	8	II	3/23/2020
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-2323PSL	Suture Anchor, PEEK SwiveLock® With PEEK Eyelet and #2 FiberWire®, 5.5 x 20 mm	IIb	45062	ANCHORS	8	II	12/8/2006
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-2323PSLC	Suture Anchor, PEEK SwiveLock® C With Closed PEEK Eyelet and #2 FiberWire®, 5.5 x 19.1 mm	IIb	45062	ANCHORS	8	II	9/19/2008
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-2323PSLC-1	Suture Anchor, PEEK SwiveLock® C With Closed PEEK Eyelet and #2 FiberWire®, 5.5 x 19.1 mm (1 pack)	IIb	45062	ANCHORS	8	II	8/23/2017
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	45062	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	45062	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	45062	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	45062	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	45062	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	45062	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	IIb	45062	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	45062	ANCHORS	8	II	3/23/2020
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-2324PSLC	PEEK Knotless SwiveLock® Suture Anchor With Blue #2 Suture, 4.75 x 19.1 mm	IIb	45062	ANCHORS	8	II	3/23/2020
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-2324PSLC-1	PEEK Knotless SwiveLock® Suture Anchor With Blue #2 Suture, 4.75 x 19.1 mm (1 pack)	IIb	45062	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	45062	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	45062	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	45062	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	45062	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	45062	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	45062	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	45062	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	45062	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	45062	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	45062	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	45062	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	45062	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	45062	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	45062	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	45062	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	45062	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	45062	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	45062	ANCHORS	8	II	10/27/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-8979P	DX SwiveLock® 3.5 x 13.5mm	IIb	45062	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	45062	ANCHORS	8	II	10/27/2017
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	45062	ANCHORS	8	II	10/15/2020

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No.**CE 85507**

Issued To:

**Arthrex, Inc.
1370 Creekside Boulevard
Naples
Florida
34108-1945
USA**

In respect of:

See certificate scope page.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2004-06-18**Date: **2021-04-21**Expiry Date: **2024-05-26****...making excellence a habit.™**

Page 1 of 2

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

Certificate No: CE 85507

Certificate Scope:

The design, development and manufacture of metallic, non-metallic and bioabsorbable implants, suture, total joint replacement devices and associated trials and instrumentation, partial joint resurfacing devices, arthroscopic and minimally invasive surgical instruments, cannula, electromechanical/electrosurgical ablation, cutting and fluid management devices, blood cell separators, centrifuges, and sterile disposable processing sets. Those aspects of Annex II related to securing and maintaining sterility in the manufacture of noninvasive traction devices, drape sets, cushions and limb positioners, backflow caps, marking pens, syringes, and retractors, and related to the accuracy of metrology in the manufacture of general surgical devices with measuring functions.

First Issued: **2004-06-18**Date: **2021-04-21**Expiry Date: **2024-05-26**

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Page 2 of 2

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 85507**
 Date: **2021-04-21**
 Issued To: **Arthrex, Inc.**
1370 Creekside Boulevard
Naples
Florida
34108-1945
USA

Subcontractor:	Service(s) supplied
Arthrex California Technology, Inc 460 Ward Drive Santa Barbara California 93111 USA	Manufacture
Arthrex GmbH Ervin-Hielscher Strasse 9 Munich 81249 Germany	EU Representative
Arthrex GmbH Oskar-von-Miller Strasse 6 Odelzhausen 85235 Germany	Manufacture

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 85507**
 Date: **2021-04-21**
 Issued To: **Arthrex, Inc.**
1370 Creekside Boulevard
Naples
Florida
34108-1945
USA

Subcontractor:	Service(s) supplied
Arthrex Inc. 1265 Creekside Parkway Naples Florida 34108 USA	Other Critical Processes
Arthrex Logistics Center 14550 Plantation Rd Ft Myers Florida 33912 USA	Final Inspection
Arthrex Manufacturing, Inc. 130 Arthrex Drive Pendleton South Carolina 29670 USA	Manufacture

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 85507**
Date: **2021-04-21**
Issued To: **Arthrex, Inc.**
1370 Creekside Boulevard
Naples
Florida
34108-1945
USA

Subcontractor:	Service(s) supplied
Arthrex, Inc. 6875 Arthrex Commerce Drive Ave Maria Florida 34142 USA	Manufacture
Arthrex, Inc. 1360/1370 Creekside Boulevard Naples Florida 34108-1945 USA	Manufacture
Arthrex, Inc. 6861 Arthrex Commerce Drive Ave Maria Florida 34142 USA	ETO Sterilization

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USA

Subcontractor:	Service(s) supplied
Arthrex, Inc. 168 Brea Canyon Road Walnut California 91789 USA	Manufacture
Autocam Medical 24 Aldrin Road Plymouth Massachusetts 02360 USA	Manufacture
Autocam Medical, LLC 4162 East Paris Ave SE Kentwood Michigan 49512 USA	Manufacture

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Subcontractor:	Service(s) supplied
BBF Sterilisationsservice GmbH Willy-Rüsch-Strasse 10/1 Kernen 71394 Germany	Radiation (Gamma Sterilization)
Bioiks d.o.o. also trading as Bioprod d.o.o. Stenge 11 Ljubjana 1000 Slovenia	Manufacture
Centurion Medical Products Corporation 3310 S. Main Street Salisbury North Carolina 28147 USA	Radiation (Gamma Sterilization)

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Subcontractor:	Service(s) supplied
Cintron Medical Corporation 1275 W. 124th Ave Westminster Colorado 80234 USA	Assembly
Cirtec Medical Corporation 9200 Xylon Avenue North Brooklyn Park Minnesota 55445 USA	Manufacture
CORONATI CONSULTING Sr.l. Via L. Gaviolo 3 Franziona San Giacomo Roncole IT Mirandola 41037 Italy	Microbiology Service

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Subcontractor:	Service(s) supplied
D&R Products Co. Inc. 455 River Road Hudson MA 01749 USA	Manufacture Other Critical Processes
DOT GmbH Charles-Darwin-Ring 1 a Rostock 18059 Germany	Manufacture Other Critical Processes
DSM Biomedical Inc., d.b.a. DSM Biomedical d.b.a. Actamax Surgical Materials, LLC 735 Pennsylvania Drive Exton PA 19341 USA	Control of Sterilization Manufacture Packaging

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Subcontractor:	Service(s) supplied
Eptam Plastics LTD 2 Riverside Road Business Park Northfield New Hampshire 03276 USA	Manufacture
Früh Verpackungstechnik AG Allmendstrasse 47 Fehraltorf 8320 Switzerland	Packaging
Gb Implantat-Technologie GmbH Harkortstrabe 65 Essen 45145 Deutschland	Manufacture

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Subcontractor:	Service(s) supplied
Gebr. Brasseler GmbH & Co. KG Trophagener Weg 25 Lemgo 32657 Germany	Manufacture
Hermann Medizintechnik GmbH Württemberger Strasse 26 Fridingen 78567 Germany	Manufacture
HG Medical GmbH Gewerbegebiet 16 Raisting 82399 Germany	Manufacture

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Subcontractor:	Service(s) supplied
Hofmann S.r.l. Via Carlo Carra 19 Monza 20900 Italy	Manufacture
Icotec AG Industriestrasse 12 Altstätten 9450 Switzerland	Manufacture
Integrated Medical Solutions, Inc. 7124 Industrial Park Blvd. Mentor OH, 44060 USA	Manufacture

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Subcontractor:	Service(s) supplied
International Sterilization Laboratories 217 Sampey Road Groveland Florida 34736 USA	ETO Sterilization
Invio Ltd Invio Technology Centre Hillhouse International Thornton-Cleveleys Lancashire FY5 4DQ UK	Manufacture
Isomedix Operations, Inc. 9 Apollo Drive Whippany New Jersey 07981 USA	Radiation (Gamma Sterilization)

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Subcontractor:	Service(s) supplied
Isomedix Operations, Inc. 2072 Southport Road Spartanburg South Carolina 29306 USA	Radiation (Gamma Sterilization)
Lake Region Medical Formerly Accellent Inc. 3902 California Road Orchard Park New York 14127 USA	Manufacture
Lenkbar, LLC 11430 Tamiami Trail Florida Naples 34113-7915 USA	Manufacture

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Subcontractor:	Service(s) supplied
Mangar Industries, Inc. 97 Britain Drive New Britain Pennsylvania 18901 USA	Manufacture
MediMet GmbH Ohle Ring 23-25 Stade-Wiepenkathen 21684 Germany	Manufacture
Memry Corporation 3 Berkshire Blvd Bethel Connecticut 06801-1037 USA	Manufacture

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Subcontractor:	Service(s) supplied
Metal Craft Machine & Engineering, Inc. 13760 Business Center Drive Elk River Minnesota 55330 USA	Manufacture
Micropulse, Inc. 5865 East State Road 14 Columbia City Indiana 46725 USA	Manufacture
Millstone Medical Outsourcing, LLC 580 Commerce Drive Fall River Massachusetts 02720 USA	Packaging

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Subcontractor:	Service(s) supplied
MTD Micro Molding Inc. 15 Trolley Crossing Road Charlton Massachusetts 01507 USA	Manufacture
New Deantronics, Taiwan Ltd. 12F, No 51, Sec. 4 Chong Yang Road Tu Cheng Dist. New Taipei City 23675 Taiwan (R.O.C)	Manufacture
Nextphase Medical Devices LLC 150 Hopper Avenue Waldwick New Jersey 07463 USA	Manufacture

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Subcontractor:	Service(s) supplied
NN, Inc. Precision Engineered Products Group Vandalia, LLC 4201 Little York Road Dayton Ohio 45414 USA	Manufacture
Norman Noble, Inc. Medtech Manufacturing Division 5507 Avion Park Drive Highland Heights Ohio 44143 USA	Manufacture
Oerlikon AM Medical Inc. 10 Constitution Blvd. South Shelton Connecticut 06484 USA	Manufacture

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Subcontractor:	Service(s) supplied
Orchid Bridgeport 6688 Dixie Highway Bridgeport Michigan 48722 USA	Manufacture
Orchid Orthopaedics Switzerland GmbH Tafernstrasse 39 Baden-Dattwil 5405 Switzerland	Manufacture
Orchid Orthopedic Solutions 13963 Fir Street Oregon City Oregon 97045 USA	Manufacture

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Subcontractor:	Service(s) supplied
Orchid Orthopedic Solutions Chelsea, LLC 13800 Luick Drive Chelsea Michigan 48118 USA	Manufacture
Orchid Orthopedic Solutions DBA Orchid Lansing 1489 Cedar Street Holt MI 48842 USA	Manufacture
Orthoplastics Ltd Grove Mill Todmorden Road Bacup Lancashire OL13 9EF UK	Manufacture

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Subcontractor:	Service(s) supplied
PCC Structurals, Inc. SSBO 13340 SE 84th Avenue Clackamas Oregon 97015 USA	Manufacture
Pearsalls Limited Tancred St. Taunton Somerset TA1 1RY United Kingdom	Manufacture
Perryman Company 149 South Johnson Road Houston Pennsylvania 15342 USA	Manufacture

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Subcontractor:	Service(s) supplied
Phoenix Medical Products, Inc 1535 Cold Springs Road Mountain City TN 37683 USA	Control of Sterilization Manufacture Packaging
Plastic Ingenuity Inc. 1017 Park Street Cross Plains Wisconsin 53528 USA	Manufacture
Praxis Powder Technology Inc. 604 Queensbury Avenue Queensbury New York 12804 USA	Manufacture

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Subcontractor:	Service(s) supplied
puracon GmbH Isarstrasse 1 83026 Rosenheim Germany	Packaging
R.K. Manufacturing Corporation 34 Executive Drive Danbury Connecticut 06810 USA	Control of Sterilization Manufacture Packaging
Raumedic AG Hermann-Straudinger-Strasse 2 Helmbrechts 95233 Germany	Control of Sterilization Manufacture

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Subcontractor:	Service(s) supplied
rms Company 8600 Evergreen Boulevard Minneapolis Minnesota 55433 USA	Manufacture
Sites Medical 5865 East State Road 14 Columbia City Indiana 46725 USA	Manufacture
Southeastern Technology Inc. 905 Industrial Drive Murfreesboro Tennessee 37129 USA	Manufacture

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Subcontractor:	Service(s) supplied
Sparton Medical Systems Colorado, LLC. 4300 Godding Hollow Parkway Frederick Colorado 80504 USA	Manufacture
Spectrum Plastics Group 7309 West 27th Street Minneapolis Minnesota 55426 USA	Manufacture
SQ Products AG Sumpfstrasse 5 Steinhausen 6312 Switzerland	Manufacture

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Subcontractor:	Service(s) supplied
Sterigenics, US, LLC 10821 Withers Cove Park Drive Charlotte North Carolina 28278 USA	ETO Sterilization
Sterigenics, US, LLC 502 Prairie Mine Road Mulberry Florida 33860 USA	Radiation (Gamma Sterilization)
Sterilization Services of Georgia 6005 Boat Rock Boulevard Atlanta Georgia 30336 USA	ETO Sterilization

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Subcontractor:	Service(s) supplied
Steritec, Inc. PO Box 1969 1705 Enterprise Street Athens Texas 75751 USA	Radiation (Gamma Sterilization)
Structure Medical, LLC 3511 Plover Avenue Naples FL 34117 United States	Manufacture
Surgical Specialties Mexico S. DE R.L DE C.V. Corredor Tijuana-Rosarito 2000 #24702-B, Ejido Francisco Villa Tijuana B.C., C.P. 22235 Mexico	Manufacture

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Subcontractor:	Service(s) supplied
Synergy Health Daniken AG Hogenweidstrasse 6 Däniken CH-4658 Switzerland	Radiation (Gamma Sterilization)
Synergy Health Radeberg GmbH Juri-Gagarin-Strasse 15 Radeberg 01454 Germany	Radiation (Gamma Sterilization)
Tecomet Riviera Beach 1006 West 15th Street Riviera Beach Florida 33404 USA	Manufacture

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Subcontractor:	Service(s) supplied
Tecomet, Inc. 7145 Colonial Lane Pennsauken New Jersey 08109 USA	Manufacture
TESco Associates, Inc. 500 Business Park Drive Tyngsborough Massachusetts 01879 USA	Manufacture
Texmo Precision Coatings 596 East 200 North Warsaw Indiana 46582 USA	Manufacture

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Subcontractor:	Service(s) supplied
Transcoject GmbH Rugenstr. 8 Neumunster 24539 Germany	Manufacture
USHIO America, Inc. 101 Panton Road Vergennes Vermont 05491-1039 USA	Manufacture
Viant San Antonio Inc. 7027 Fairgrounds Parkway San Antonio TX 78238 USA	Control of Sterilization Manufacture Packaging

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Date	Reference Number	Action
18 June 2004	-	First Issue (transfer from TUV certificate No. GI 03 05 43640 014)
14 January 2005	-	Addition of Kensey Nash Corporation (Pennsylvania), Tesco Associates (Massachusetts), STS/DuoTek (Farmington), Steris Isomedix (Whippany) and Sterilization Services of Georgia (Georgia), the removal of Avid Medical Inc. as subcontractors, change of scope and reissue of certificate to align the QMS certificates to the design certificates.
4 May 2005	-	Alignment with CE 90296, addition of subcontractor Midwest Plastic Components and approval of VHP Sterilisation performed by Arthrex Inc.
19 December 2005	-	Removal of STS/DuoTek, Inc. (Farmington) and Command Medical Products (Florida) as subcontractors
01 March 2007	-	Deletion of STS/DuoTek, Inc. Addition of following to the list of significant sub-contractors a) Ethox Corp. Buffalo, NY 14204, for Control of Sterilization, Manufacturing and Sterilization activities b) Arthrex Med. Inst. GmbH, 85757 Karlsfeld as EU rep.
24 April 2007	-	Addition of "Food Technology Service, Inc." to the list of significant sub contractors as Gamma Sterilization activity Deletion of "Clairson Plastics, FL 34470, USA" from the list of significant sub contractors.
16 June 2009	7215089	Amendment to scope to include 'suture' Addition of subcontractors; '3-D Machining', 'Autocam Medical', 'Marox Corporation', 'Marson Medical', 'Symmetry Medical Inc', 'Orchid Unique Orthopedic Solutions', 'Pearsalls Limited', 'New Deantronics Ltd', 'STERIS Isomedix Services' and 'Rapidwerks Inc'

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.
 This certificate was issued electronically and is bound by the conditions of the contract.

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Date	Reference Number	Action
		Change of address for subcontractors; 'Accellent Endoscopy', 'Kensey Nash Corporation' and 'Tesco Associates Inc' Change of name for subcontractors; from 'Aaron Medical' to 'Bovie Medical Corporation', from 'Midwest Plastic Components' to 'Spectrum Plastics Group' Change of subcontractor activity for; 'Kensey Nash Corporation', 'Tesco Associates Inc', 'Ethox International', 'Bovie Medical Corporation', 'Coastal Life Technologies Inc', 'Pheonix Medical Products Inc' and 'R.K. Manufacturing', Certificate renewal
1 March 2010	7432390	Addition of uni-compartmental knee devices to certificate scope. Removal of subcontractor 'Ethox International'. Addition of subcontractors 'AstroMedical Devices', 'Hansa Medical', 'Instrumedical Technologies, Inc' and 'Orchid Bio-Coat'
27 September 2012	7905383	Expansion of scope to include: "Those aspects of Annex II related to securing and maintaining sterility in the manufacture of non-invasive traction devices, drape sets, cushions and limb positioners, backflow caps, marking pens, syringes, and retractors, and related to the accuracy of metrology in the manufacture of graft preparation accessories." Addition of significant subcontractors RMS Company, Norman Noble Inc, Phillips Precision Inc, Tri-State Centurion Sterilization, Steritec Inc, STERIS Isomedix Services. Removal of significant subcontractors Bovie Medical Corp, Instrumedical Technologies Inc, Marson Medical, Rapidwerks Inc.

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Date	Reference Number	Action
16 May 2014	8153062	Certificate renewal. Change of Scope: From: "...the manufacture of graft preparation accessories." To: "... the manufacture of general arthroscopic devices with measuring functions." Addition of Subcontractors: "Arthrex, Inc., 168 Brea Canyon Road, Walnut, California, 91789,USA" for Manufacture "Arthrex, Inc., 1360 Creekside Boulevard, Naples, Florida, 34108-1945, USA" for Manufacture "Arthrex Inc., 1250 Creekside Parkway, Naples, Florida, 34108, USA" for Manufacture "Arthrex California Technology, Inc., 460 Ward Drive, Santa Barbara, California, 93111, USA" for Manufacture "Arthrex, Inc., 6875 Arthrex Commerce Drive, Naples, Florida. 34120, USA" for Manufacture "Arthrex Logistics Center, 14550 Plantation Rd, Ft Myers, Florida, 33912, USA" for Inspection "Secant Medical Inc., 700 Park Avenue, Perkasio, Pennsylvania, 18944, USA" for Manufacture Change of name of Subcontractors: "Hansa Medical" to "FMI Hansa Medical Products LLC" "Kensey Nash Corporation" to "DSM Biomedical" "3-D Machining" to "3-D Medical Manufacturing" "Accellent Endoscopy" to "Accellent, Inc." Removal of Subcontractors:

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Date	Reference Number	Action
		"Symmetry Medical Avilla, Inc" "Marox Corporation" "Orchid BioCoat" "Philips Precision" Change of Name and address of EU representative: "Arthrex GmbH, Erwin-Hielscher-Strasse 9, 81249 München, Germany" EU Representative.
30 October 2014	8224290	Change of Scope: Include " partial joint resurfacing devices"; removal of "uni-compartmental knee devices" and Scope clarification of "general arthroscopic devices with measuring functions" to "general surgical devices with measuring functions" Addition of subcontractors: "Arthrex GmbH, Oskar-von-Miller Strasse 6, 85235, Odelzhausen, Germany" Activity: Manufacture "BBF Sterilisationsservice GmbH, Willy-Rüsch-Strasse 10/1, 71394, Kernen, Germany" Activity: Sterilisation "Carniaflex S.r.l., Via Nazionale 8, 33026, Paluzza, Italy" Activity: Manufacture "DOT GmbH, Charles-Darwin-Ring 1a, 18059 Rostock, Germany" Activity: Manufacture "Früh- Verpackungen AG, Allmendstrasse 47, 8320 Fehrltorf, Switzerland" Activity: Packaging "Hermann Medizintechnik GmbH, Württemberger Strasse 26, 78567 Fridingen, Germany" Activity: Manufacture

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 This certificate was issued electronically and is bound by the conditions of the contract.

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Date	Reference Number	Action
		"HG Medical GmbH, Gewerbegebiet 16, 82399, Raisting, Germany" Activity: Manufacture "Hofmann S.r.l., Via Carlo Carra 19, 20052 Monza, Italy" Activity: Manufacture "Icotec AG, Industriestrasse 12, 9450, Altstätten, Switzerland" Activity: Manufacture "INTERCUS GmbH, Zu den Pfarreichen 5, 07422, Bad Blankenburg, Germany" Activity: Manufacture "Karl Storz GmbH & Co. KG, Mittelstrasse 8, 78532, Tuttlingen, Germany" Activity: Manufacture "MediMet Precision Casting and Implants Technology GmbH, Ohle Ring 23, 21684, Stade-Wiepenkathen, Germany" Activity: Manufacture "Puracon GmbH, Isarstrasse 1, 83026, Rosenheim, Germany" Activity: Packaging "Synergy Health Däniken AG, Hogenweidstrasse 6, 4658, Däniken, Switzerland" Activity: Sterilisation "Synergy Health Radeberg GmbH, Juri-Gagarin-Strasse 15, 01454, Radeberg, Germany" Activity: Sterilisation
17 June 2016	8522587	Extension of scope to cover Total Joint Replacement devices and associated trials and instrumentation transferred from another Notified Body. Addition of subcontractors: "CoorsTek Medical, LLC, 221 Commercial Parkway, Molalla, Oregon, 97038, USA" Activity: Manufacture "CoorsTek Medical, LLC, 811 Northwoods Boulevard, Vandalia, Ohio, 45377-9468, USA" Activity: Inspection

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USA

Date	Reference Number	Action
		"DiSanto Technology Inc., 10 Constitution Boulevard South, Shelton, Connecticut, 06484, USA" Activity: Manufacture "Millstone Medical Outsourcing, LLC, 580 Commerce Drive, Fall River, Massachusetts, 02720, USA" Activity: Packaging "Orchid Orthopedic Solutions, 13963 Fir Street, Oregon City, Oregon, 97045, USA" Activity: Manufacture "Orthoplastics Ltd., Unit A, Beech Industrial Estate, Bacup, Lancashire, OL13 9EL, UK" Activity: Manufacture "PCC Structural, Inc., SSBO, 13340 SE 84th Avenue, Clackamas, Oregon, 97015, USA" Activity: Manufacture "SQ Products AG, Sumpfstrasse 5, 6312 Steinhausen, Switzerland" Activity: Manufacture
12 August 2016	8502608	Addition of Autocam Corporation and Orchid Orthopedics Switzerland GmbH for manufacturing activity. Name change of subcontractors from Food Technology Service, Inc to Sterigenics U.S., LLC. Add "Other critical processes" activity to for existing subcontractor; Dot GmbH. Change activity of BBF Sterilisationservice from sterilization to Gamma sterilization Name clarification of subcontractor from 'Früh- Verpackungen AG' to 'Früh Verpackungstechnik AG'.
02 January 2018	8712710	Addition of critical subcontractor Arthrex Inc., 6861 Arthrex Commerce Drive, Ave Maria, FL 34142 for EO Sterilization activities.

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 Issued To: **Arthrex, Inc.**
1370 Creekside Boulevard
Naples
Florida
34108-1945
USA

Date	Reference Number	Action
17 April 2018	8926564	Extension of scope to include blood cell separators, centrifuges, and sterile disposable processing sets.
21 February 2019	7781012	Traceable to NB 0086. Administrative Subcontractor Service wording update from <i>'Inspection'</i> to <i>'Final Inspection'</i> for Arthrex Logistics Center, 14550 Plantation Rd, Ft Myers, Florida, 33912, USA Administrative Subcontractor Service wording update from <i>'Inspection'</i> to <i>'Final Inspection'</i> for CoorsTek Medical, LLC, 811 Northwoods Boulevard, Vandalia, Ohio, 45377-9468, USA Administrative Subcontractor Service wording update from <i>'Sterilization'</i> to <i>'ETO Sterilization'</i> for International Sterilization Laboratories, 217 Sampey Road, Groveland, Florida, 34736, USA Administrative Subcontractor Service wording update from <i>'Sterilization'</i> to <i>'ETO Sterilization'</i> for Isomedix Operations, Inc., 3459 South Clinton Avenue, South Plainfield, New Jersey, 07080, USA Administrative Subcontractor Service wording update from <i>'Sterilization'</i> to <i>'Gamma Sterilization'</i> for Steris Isomedix Services, Inc. 9 Apollo Drive, Whippany, New Jersey 07981, USA Administrative Subcontractor Service wording update from <i>'Sterilization'</i> to <i>'Gamma Sterilization'</i> for STERIS Isomedix Services, 1000 South Sarah Place, Ontario, California 91761, USA Administrative Subcontractor Service wording update from <i>'Sterilization'</i> to <i>'Gamma Sterilization'</i> for Tri-State Centurian, 3310 S. Main Street, Salisbury, North Carolina 28147, USA

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17 June 2019	9759171	Subcontractor change: Removal of: Arthrex Inc., Carniflex S.r.l., Coorstek Medical LLC, Coorstek Medical LLC, Intercus Isomedix Operations Inc, Karl Storz GmbH, Secant Medical LLC, Steris Isomedix Services Change to Name/Address/Activity: 3-D Medical Manufacturing, name change to Tecomet Riviera Beach Accelent Inc., name change to Lake Region Medical Arthrex 6875, name and address change to 6875 Arthrex Commerce Drive, Ave Maria, Florida 34142, USA Astro Medical Devices, name change to Integrated Medical Solutions, Inc Autocam Corporation, name and address change to Autocam Medical, LLC, 4162 East Paris Ave SE, Kentwood, Michigan, 49512, USA Coastal life technologies, Inc., name and address change to Viant San Antonio, Inc., 7027 Fairgrounds Parkway, San Antonio, TX 78238 USA Di Santo Technology Inc., name change to Oerlikon AM Medical Inc. DSM Biomedical, name change to DSM Biomedical Inc. d.b.a. DSM Biomedical, d.b.a. Actamax Surgical Materials, LLC. FMI Hansa Medical Products LLC, name and address change to Structure Medical LLC, 3511 Plover Avenue, Naples, Florida, 34117 USA Hofmann S.R.L, address change to Via Carlo Carra 19, 20900 Monza (MB), Italy Medimet Precision Casting and Implants, name change to Medimet GmbH Orchid Orthopaedics Switzerland GmbH, address change to Tafernstrasse 39, 5405 Baden-Dattwil, Switzerland Orchid Unique DBA Orchid Bridgeport, name change to Orchid Bridgeport Orthoplastics Ltd, address change to Grove Mill, Todmorden Road, Bacup, Lancashire, OL13 9EF, UK

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Date	Reference Number	Action
		RK Manufacturing Corp, address change to 34 Executive Drive Danbury, Connecticut 06810, USA Sterilization Services of Georgia, Inc., name and address change to Sterilization Services of Georgia 6005 Boatrock Blvd. Atlanta, Georgia 30336 USA Steris Isomedix Services, Inc., name change to Isomedix Operations, Inc. Activity, Gamma Sterilization Steris Isomedix Services, 2072 Southport Road, name change to Isomedix Operations, Inc. Activity, Gamma Sterilization Tri-State Centurion Sterilization, name change to Centurion Medical Products Corporation Additions: Arthrex Inc., Bioiks d.o.o. also trading as Bioprod d.o.o., Cintron Medical Corporation, Cirtec Medical Corporation, Coronati Consulting, Sr.l., D&R Products Co. Inc., Eptam Plastics LTD, Gebr. Brasseler GmbH & Co. KG, Gb Implantat-Technologie GmbH, Invivio Ltd, Lenkbar, LLC, Mangar Industries, Inc., Memry Corporation, Metal Craft Machine & Engineering, Inc., Micropulse, Inc., MTD Micro Molding Inc., USHIO America, Inc., Nextphase Medical Devices LLC, NN, Inc. Precision Engineered Products Group – Vandalia, LLC, Orchid Orthopedic Solutions Chealsea LLC, Orchid Orthopedic Solutions, dba Orchid Lansing, Perryman Company Plastic Ingenuity, Inc., Praxis Powder Technology, Inc., Raumedic AG Sites Medical, Southeastern Technology, Sparton Medical Systems Colorado, LLC, Steril Milano S.r.l., Surgical Specialties Mexico S. DE R.L DE C.V., Tecomet, Inc., Texmo Precision Coatings, Transcoject GmbH
12 March 2020	3154295	Change to add Arthrex Manufacturing Inc, 130 Arthrex Drive, Pendleton, South Carolina 29670, USA

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Date	Reference Number	Action
Current	3424027	Removal of Steril Milano S.r.l as a critical subcontractor

To: Agentia Medicamentului si Dispozitivelor Medicale

We, **SPORTMED SYSTEMS SRL**, as distributor of **ARTHREX GmbH**, having a registered office at 85, Carol Davila St., 5th district, Bucharest, Romania, assign "GBG-MLD" SRL, having a registered office at Str. Albisoara 64/2, Chisinau MD -2005, Moldova, as **authorized representative** in correspondence with the conditions of directive 93/42/EEC, 98/79/EEC and 90/385/EEC.

We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova.

Place: Bucharest , Date: 23.11.2023

Signed: _____

