

Część

1

1. Deklaracja zgodności


Karta techniczna	Guziki i szwy
Kody GMDN	Szczegółowy wykaz wszystkich kodów GMDN dotyczących tego pliku technicznego znajduje się w Wykazie Części, Kor. 38
Wersja	38
Klasa MDD, Reguła	Klasa II B, Reguła 8
Ścieżka zgodności	Załącznik II (z wyłączeniem sekcji 4)
Jednostka	BSI / CE 2797
Notyfikowana / Numer	(wcześniej – BSI / CE 0086)
Producent	Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108 USA
Przedstawiciel w Unii Europejskiej	Arthrex GmbH Erwin Hielscher-Strasse 9 81249 Monachium, Niemcy

1.1. Oświadczenie dotyczące Deklaracji Zgodności

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



William Heard
(Podpis)
Dyrektor Regionalny ds. Regulacji, EMEA



Date
Data

1.2. Wykaz Urządzeń wg numerów katalogowych

Wykaz Urządzeń wg numerów katalogowych znajduje się w Części B.

Section

1

1. Declaration of Conformity

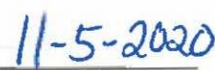
Technical File	Buttons and Suture
GMDN Codes	Refer to Parts List, Rev. 38 for a complete list of all GMDN Codes subject of this Technical File
Revision	38
MDD Class, Rule	Class IIb, Rule 8
Route of Compliance	Annex II (excluding Section 4)
Notified Body / Number	BSI / CE 2797 (Formerly - BSI / CE 0086)
Manufacturer	Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108 USA
EC Representative	Arthrex GmbH Erwin Hielscher - Strasse 9 81249 München, Germany

1.1. Conformity Declaration Statement

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



William Heard
Regional Manager, Regulatory Affairs, EMEA



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:
BUTTON Family										
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1588-15	RetroButton®, 12 mm x 15 mm Loop	IIb	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	IIb	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	IIb	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	IIb	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	IIb	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	IIb	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	IIb	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	IIb	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	IIb	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	IIb	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	IIb	45062	Buttons and Suture	8	II	3/22/2010
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-2260	Implant Delivery System, Distal Biceps	IIb	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	IIb	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	IIb	61671	Buttons and Suture	8	II	3/28/2011
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-2267	Button, Pec Repair, Large Eyelets	IIb	61671	Buttons and Suture	8	II	4/9/2013
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-2268	Implant Delivery System, Pec Repair	IIb	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	IIb	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	IIb	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	IIb	45062	Buttons and Suture	8	II	9/4/2013
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-2290	Implant System, Proximal Tenodesis	IIb	45062	Buttons and Suture	8	II	5/17/2013
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-2291	Proximal Tenodesis Button	IIb	45062	Buttons and Suture	8	II	5/17/2013
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-2296	Tenodesis Button, 2.6 x 7mm	IIb	61671	Buttons and Suture	8	II	5/27/2020
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-4550	Implant System, Meniscal Root Repair	IIb	13907	Buttons and Suture	8	II	6/14/2016
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-8920	Suture Button, 3.5 mm	IIb	61671	Buttons and Suture	8	II	12/24/2003
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-8922	Suture Button, 12 mm	IIb	61671	Buttons and Suture	8	II	12/24/2003
CINCH Family										
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-4500	Meniscal Cinch™	IIb	45062	Buttons and Suture	8	II	1/18/2008
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-4501	Meniscal Cinch™ II	IIb	45062	Buttons and Suture	8	II	10/19/2018
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-5800	SoftStitch™ Implant With #1 Nylon Monofilament	IIb	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	IIb	44093	Buttons and Suture	8	II	4/30/2003
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-13930DS	Meniscal Viper Repair- Large Disposables Kit	IIb	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	IIb	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	IIb	44093	Buttons and Suture	8	II	4/20/2018
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1676DS	Bio-Tenodesis Disposable Kit	IIb	44093	Buttons and Suture	8	II	2/16/2007
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1676DS-1	Bio-Tenodesis Disposable Kit	IIb	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)	IIb	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)	IIb	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)	IIb	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)	IIb	13907	Buttons and Suture	8	II	7/12/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-4068-25TLF	SutureLasso, 25° Tight Curve Left, Small Diameter (SD), w/FiberStick	IIb	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	IIb	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	IIb	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	IIb	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	IIb	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	IIb	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	IIb	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	IIb	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	IIb	13907	Buttons and Suture	8	II	6/28/2001
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7202-1	FiberWire with needles	IIb	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	IIb	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)	IIb	13907	Buttons and Suture	8	II	12/20/2018
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

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-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-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® #1/4 metric (38" long), Braided PB Blue Suture	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 (TM) 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/ØMOND PNT ST. NDL	IIb	13907	Buttons and Suture	8	II	11/17/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7232-05	2-0 FiberLoop with Needle, Blue	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 w/ Curved Needle	IIb	85507	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 Striaght Straight 20"	IIb	13907	Buttons and Suture	8	II	7/6/2006
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	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	#2 FiberLoop w/curved needle	IIb	13907	Buttons and Suture	8	II	9/22/2008
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7234C-1	FIBERLOOP	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	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	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	IIb	13907	Buttons and Suture	8	II	8/16/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7237	FiberTape, 2 mm	IIb	13907	Buttons and Suture	8	II	8/11/2003
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7237-1	FiberTape	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	
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,BLU W/NDLS,17" TAPE LGTH	IIb	13907	Buttons and Suture	8	II	12/22/2017

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-7237-7	FiberTape, 2 mm, 7 inches long	IIb	13907	Buttons and Suture	8	II	6/16/2008
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7237-7-1	FiberTape, 2 mm, 7 inches long (single pack)	IIb	13907	Buttons and Suture	8	II	4/9/2014
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7237-7T	TigerTape, 2 mm, 7 inches long	IIb	13907	Buttons and Suture	8	II	6/16/2008
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7237-7T-1	TigerTape, 2 mm, 7 inches long (single 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	0 FiberLoop, Blue	IIb	13907	Buttons and Suture	8	II	1/18/2008
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7253-1	FIBERLOOP	IIb	13907	Buttons and Suture	8	II	8/16/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7253T	TigerLoop™ 0/3.5 metric	IIb	13907	Buttons and Suture	8	II	3/28/2011
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7254	FiberWire® #0/3.5 metric (38" long), Braided PB Suture Blue	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	IIb	13907	Buttons and Suture	8	II	12/20/2018
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	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	IIb	61690	Buttons and Suture	8	II	10/27/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7267-1	FiberTape Cerclage Suture	IIb	61690	Buttons and Suture	8	II	3/22/2018
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7267T	TigerTape Cerclage Suture	IIb	61690	Buttons and Suture	8	II	10/27/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7267T-1	TigerTape Cerclage Suture	IIb	61690	Buttons and Suture	8	II	3/22/2018
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7270	Fiberchain, #2 FiberWire with 10 loops 7 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-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-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-7298	Univert Apex Suture Kit (SutureLasso)	IIb	37839	Buttons and Suture	8	II	6/15/2015
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7299-11	#0 (3.5 metric)FiberWire, Blue	IIb	13907	Buttons and Suture	8	II	4/3/2012
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-7299-12	#0 (3.5 metric)FiberWire, White	IIb	13907	Buttons and Suture	8	II	4/3/2012
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 (5 pack)	IIb	13907	Buttons and Suture	8	II	12/20/2018
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, White/Blue with Needle (1 pack)	IIb	13907	Buttons and Suture	8	II	11/5/2020
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

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-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-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-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-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-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
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-8925T	Syndesmosis TightRope XP, Titanium Kit	IIb	45062	Buttons and Suture	8	II	2/16/2018
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-8911DS	Mini TightRope® Repair Implant, Cannulated, Stainless Steel	IIb	44093	Buttons and Suture	8	II	7/20/2006
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-8913DS	Mini TightRope® Implant with Insertter	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
Knee										
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-1588RT	ACL TightRope® RT	IIb	45062	Buttons and Suture	8	II	9/10/2010
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-1588TN	TightRope® ABS, Implant (no button)	IIb	13907	Buttons and Suture	8	II	12/17/2010

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-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-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-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-2658TR	Knotless Distal Clavicle Plate Button TightRope®	IIb	61688	Buttons and Suture	8	II	6/30/2017