



Część

1

1. Deklaracja zgodności

Karta techniczna Płytki, śruby, kliny i zszywki

Kody GMDN Pełna lista wszystkich kodów GMDN objętych niniejszą kartą techniczną znajduje się w Wykazie części, Wersja 41

Wersja 41

Klasa MDD, Reguła Klasa IIb, 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 Arthrex GmbH

Europejskiej Erwin-Hielscher-Strasse 9
81249 Monachium, Niemcy

1.1. Oświadczenie dotyczące Deklaracji Zgodności

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

Laura Medlin

Przedstawiciel ds. Zarządzania Regulacjami Prawnymi

02/02/2021

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 Plates, Screws, Wedges, and Staples

GMDN Codes Refer to Parts List, Rev. 41 for a complete list of all GMDN Codes subject of this Technical File

Revision 41

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.

Laura Medlin

Regulatory Management Representative

02/02/2021

Date

1.2. List of Devices by Catalog Number

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

| Manufacturer Name | Manufacturing Location | ECQA Cert. Number | Product Code | Product Name | Class | GMDN code | Technical File | Rule | Annex | First DoC |
|--|------------------------|-------------------|------------------|--|-------|-----------|----------------------------------|------|-------|------------|
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-1400H-45 | 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 | Peel Interference 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 Insert, 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 | Peel 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 | Peel 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 | Peel Tenodesis Screw, 8 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 SwivelLock 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 SwivelLock 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 SwivelLock 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 SwivelLock 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 SwivelLock 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 SwivelLock 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 SwivelLock 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 SwivelLock 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 SwivelLock 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 SwivelLock 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-15 | 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-25 | 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 | | | | | | | | | | |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13100-05.0 | 5.0 MM FEMORAL OPENING WEDGE OSTIOTOMY PLATE | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 1/1/2002 |

| 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-13710-15.0 | CONTOURLOCK HTO PLATE, STRAIGHT WEDGE 15MM LEFT | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 9/19/2008 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13710-17.5 | CONTOURLOCK HTO PLATE, STRIGHT WEDGE 17.5MM LEFT | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 9/19/2008 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13715-03.0 | CONTOURLOCK HTO PLATE, STRAIGHT WEDGE 3MM RGT | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 9/19/2008 |
| 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, STRIGHT 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, STRIGHT WEDGE 15MM 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 L | 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 L | 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-13725-10.0 | 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 SLD 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™ Arrow | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 6/1/2018 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13070A-S | Patella SuturePlate™ 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™ Star, Large | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 6/1/2018 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13070L-P | Patella SuturePlate™ Star, Pole Fracture, Large | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 7/5/2018 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13070L-P-S | Patella SuturePlate™ Star, Pole Fracture, Large, Sterile | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 7/5/2018 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13070M | Patella SuturePlate™ Star, Medium | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 6/1/2018 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13070M-P | Patella SuturePlate™ Star, Pole Fracture, Medium | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 7/5/2018 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13070M-P-S | Patella SuturePlate™ 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™ 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™ Star, Small | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 6/1/2018 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13070S-P | Patella SuturePlate™ Star, Pole Fracture, Small | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 6/1/2018 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13070S-P-S | Patella SuturePlate™ 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™ 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 |

TF PLATE, SCREWS, WEDGE AND STAPLES, REVISION 41

| 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-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-13403P | 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-13402R | 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-14405P | PEEKPower, Humeral Fracture Plate, proximal 5-hole | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 12/10/2012 |
| PLATE Family | | | | | | | | | | |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13200M | PLATE, LOW PROFILE, FLAT T1 | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 8/23/2019 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13200M-02SL | PLT,LO-PRO,META OPEN WDG,T1,L2.5MM | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 10/23/2003 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13200M-02SR | Low Profile System, Metatarsal Opening Wedge Plate, Left, 2.5 mm, sterile, Titanium | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 2/19/2007 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13200M-02SL | PLT,LO-PRO,META OPEN WDG,T1,R2.5MM | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 10/23/2003 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13200M-02SR | Low Profile System, Metatarsal Opening Wedge Plate, Right, 2.5 mm, sterile, Titanium | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 2/19/2007 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13200M-02L | PLT,LO-PRO,META OPEN WDG,T1,L2MM | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 12/6/2002 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13200M-02L | Low Profile System, Metatarsal Opening Wedge Plate, Left, 2.0 mm, sterile, Titanium | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 2/19/2007 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13200M-02R | PLT,LO-PRO,META OPEN WDG,T1,R2MM | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 12/6/2002 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13200M-02R | Low Profile System, Metatarsal Opening Wedge Plate, Right, 2.0 mm, sterile, Titanium | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 2/19/2007 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13200M-03SL | PLT,LO-PRO,META OPEN WDG,T1,L3.5MM | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 10/23/2003 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13200M-03SL | Low Profile System, Metatarsal Opening Wedge Plate, Left, 3.5 mm, sterile, Titanium | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 2/19/2007 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13200M-03SR | PLT,LO-PRO,META OPEN WDG,T1,R3.5MM | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 10/23/2003 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13200M-03SR | Low Profile System, Metatarsal Opening Wedge Plate, Right, 3.5 mm, sterile, Titanium | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 2/19/2007 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13200M-04SL | PLT,LO-PRO,META OPEN WDG,T1,L3MM | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 12/6/2002 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13200M-04SL | Low Profile System, Metatarsal Opening Wedge Plate, Left, 3.0 mm, sterile, Titanium | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 2/19/2007 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13200M-04SR | PLT,LO-PRO,META OPEN WDG,T1,R3MM | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 12/6/2002 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13200M-04SR | Low Profile System, Metatarsal Opening Wedge Plate, Right, 3.0 mm, sterile, Titanium | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 2/19/2007 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13200M-04SL | PLT,LO-PRO,META OPEN WDG,T1,L4.5MM | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 10/23/2003 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13200M-04SL | Low Profile System, Metatarsal Opening Wedge Plate, Left, 4.5 mm, sterile, Titanium | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 2/19/2007 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13200M-04SR | PLT,LO-PRO,META OPEN WDG,T1,R4.5MM | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 10/23/2003 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13200M-04SR | Low Profile System, Metatarsal Opening Wedge Plate, Right, 4.5 mm, sterile, Titanium | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 2/19/2007 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13200M-05SL | PLT,LO-PRO,META OPEN WDG,T1,L5MM | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 12/6/2002 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13200M-05SL | Low Profile System, Metatarsal Opening Wedge Plate, Left, 5.5 mm, sterile, Titanium | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 2/19/2007 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13200M-05SR | PLT,LO-PRO,META OPEN WDG,T1,R5.5MM | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 12/6/2002 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13200M-05SR | Low Profile System, Metatarsal Opening Wedge Plate, Right, 5.5 mm, sterile, Titanium | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 2/19/2007 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13200M-06SL | PLT,LO-PRO,META OPEN WDG,T1,L6.5MM | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 2/19/2007 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13200M-06SL | Low Profile System, Metatarsal Opening Wedge Plate, Left, 6.5 mm, sterile, Titanium | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 2/19/2007 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13200M-06SR | PLT,LO-PRO,META OPEN WDG,T1,R6.5MM | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 2/19/2007 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13200M-06SR | Low Profile System, Metatarsal Opening Wedge Plate, Right, 6.5 mm, sterile, Titanium | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 2/19/2007 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13200M-07L | PLT,LO-PRO,META OPEN WDG,T1,L7MM | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 2/19/2007 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13200M-07L | Low Profile System, Metatarsal Opening Wedge Plate, Left, 7.0 mm, sterile, Titanium | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 2/19/2007 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13200M-07R | PLT,LO-PRO,META OPEN WDG,T1,R7MM | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 2/19/2007 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13200M-07R | Low Profile System, Metatarsal Opening Wedge Plate, Right, 7.0 mm, sterile, Titanium | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 2/19/2007 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13200M-08L | PLT,LO-PRO,META OPEN WDG,T1,L8.5MM | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 2/19/2007 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13200M-08L | Low Profile System, Metatarsal Opening Wedge Plate, Left, 8.5 mm, sterile, Titanium | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 2/19/2007 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13200M-08R | PLT,LO-PRO,META OPEN WDG,T1,R8.5MM | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 2/19/2007 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13200M-08R | Low Profile System, Metatarsal Opening Wedge Plate, Right, 8.5 mm, sterile, Titanium | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 2/19/2007 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13200M-09L | PLT,LO-PRO,META OPEN WDG,T1,L9.5MM | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 2/19/2007 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13200M-09L | Low Profile System, Metatarsal Opening Wedge Plate, Left, 9.5 mm, sterile, Titanium | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 2/19/2007 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13200M-09R | PLT,LO-PRO,META OPEN WDG,T1,R9.5MM | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 2/19/2007 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13200M-09R | Low Profile System, Metatarsal Opening Wedge Plate, Right, 9.5 mm, sterile, Titanium | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 2/19/2007 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13200M-10L | PLT,LO-PRO,META OPEN WDG,T1,L10MM | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 2/19/2007 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13200M-10L | Low Profile System, Metatarsal Opening Wedge Plate, Left, 10 mm, sterile, Titanium | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 2/19/2007 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13200M-10R | PLT,LO-PRO,META OPEN WDG,T1,R10MM | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 2/19/2007 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13200M-10R | Low Profile System, Metatarsal Opening Wedge Plate, Right, 10 mm, sterile, Titanium | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 2/19/2007 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13200M-11L | PLT,LO-PRO,META OPEN WDG,T1,L11MM | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 2/19/2007 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13200M-11L | Low Profile System, Metatarsal Opening Wedge Plate, Left, 11 mm, sterile, Titanium | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 2/19/2007 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13200M-11R | PLT,LO-PRO,META OPEN WDG,T1,R11MM | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 2/19/2007 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13200M-11R | Low Profile System, Metatarsal Opening Wedge Plate, Right, 11 mm, sterile, Titanium | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 2/19/2007 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13200M-12L | PLT,LO-PRO,META OPEN WDG,T1,L12MM | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 2/19/2007 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13200M-12L | Low Profile System, Metatarsal Opening Wedge Plate, Left, 12 mm, sterile, Titanium | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 2/19/2007 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13200M-12R | PLT,LO-PRO,META OPEN WDG,T1,R12MM | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 2/19/2007 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13200M-12R | Low Profile System, Metatarsal Opening Wedge Plate, Right, 12 mm, sterile, Titanium | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 2/19/2007 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13200M-13L | PLT,LO-PRO,META OPEN WDG,T1,L13MM | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 2/19/2007 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13200M-13L | Low Profile System, Metatarsal Opening Wedge Plate, Left, 13 mm, sterile, Titanium | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 2/19/2007 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13200M-13R | PLT,LO-PRO,META OPEN WDG,T1,R13MM | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 2/19/2007 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13200M-13R | Low Profile System, Metatarsal Opening Wedge Plate, Right, 13 mm, sterile, Titanium | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 2/19/2007 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13200M-14L | PLT,LO-PRO,META OPEN WDG,T1,L14MM | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 2/19/2007 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13200M-14L | Low Profile System, Metatarsal Opening Wedge Plate, Left, 14 mm, sterile, Titanium | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 2/19/2007 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13200M-14R | PLT,LO-PRO,META OPEN WDG,T1,R14MM | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 2/19/2007 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13200M-14R | Low Profile System, Metatarsal Opening Wedge Plate, Right, 14 mm, sterile, Titanium | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 2/19/2007 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13200M-15L | PLT,LO-PRO,META OPEN WDG,T1,L15MM | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 2/19/2007 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13200M-15L | Low Profile System, Metatarsal Opening Wedge Plate, Left, 15 mm, sterile, Titanium | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 2/19/2007 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13200M-15R | PLT,LO-PRO,META OPEN WDG,T1,R15MM | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 2/19/2007 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13200M-15R | Low Profile System, Metatarsal Opening Wedge Plate, Right, 15 mm, sterile, Titanium | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 2/19/2007 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13200M-16L | PLT,LO-PRO,META OPEN WDG,T1,L16.5MM | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 2/19/2007 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13200M-16L | Low Profile System, Metatarsal Opening Wedge Plate, Left, 16.5 mm, sterile, Titanium | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 2/19/2007 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13200M-16R | PLT,LO-PRO,META OPEN WDG,T1,R16.5MM | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 2/19/2007 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13200M-16R | Low Profile System, Metatarsal Opening Wedge Plate, Right, 16.5 mm, sterile, Titanium | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 2/19/2007 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13200M-17L | PLT,LO-PRO,META OPEN WDG,T1,L17MM | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 2/19/2007 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13200M-17L | Low Profile System, Metatarsal Opening Wedge Plate, Left, 17 mm, sterile, Titanium | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 2/19/2007 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13200M-17R | PLT,LO-PRO,META OPEN WDG,T1,R17MM | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 2/19/2007 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13200M-17R | Low Profile System, Metatarsal Opening Wedge Plate, Right, 17 mm, sterile, Titanium | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 2/19/2007 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13200M-18L | PLT,LO-PRO,META OPEN WDG,T1,L18MM | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 2/19/2007 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13200M-18L | Low Profile System, Metatarsal Opening Wedge Plate, Left, 18 mm, sterile, Titanium | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 2/19/2007 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13200M-18R | PLT,LO-PRO,META OPEN WDG,T1,R18MM | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 2/19/2007 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13200M-18R | Low Profile System, Metatarsal Opening Wedge Plate, Right, 18 mm, sterile, Titanium | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 2/19/2007 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13200M-19L | PLT,LO-PRO,META OPEN WDG,T1,L19MM | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 2/19/2007 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13200M-19L | Low Profile System, Metatarsal Opening Wedge Plate, Left, 19 mm, sterile, Titanium | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 2/19/2007 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13200M-19R | PLT,LO-PRO,META OPEN WDG,T1,R19MM | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 2/19/2007 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13200M-19R | Low Profile System, Metatarsal Opening Wedge Plate, Right, 19 mm, sterile, Titanium | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 2/19/2007 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13200M-20L | PLT,LO-PRO,META OPEN WDG,T1,L20MM | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 2/19/2007 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13200M-20L | Low Profile System, Metatarsal Opening Wedge Plate, Left, 20 mm, sterile, Titanium | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 2/19/2007 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13200M-20R | PLT,LO-PRO,META OPEN WDG,T1,R20MM | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 2/19/2007 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13200M-20R | Low Profile System, Metatarsal Opening Wedge Plate, Right, 20 mm, sterile, Titanium | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 2/19/2007 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13200M-2 | | | | | | | |

| 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-8007-25S | 3 HOLE DBL COMP PLATE, 25MM, STERILE | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 5/25/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8007-30 | 3 HOLE DBL COMP PLATE, 30MM | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 7/22/2013 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8007-30S | 3 HOLE DBL COMP PLATE, 30MM, STERILE | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 5/25/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8008-20 | 4 HOLE DBL COMP PLATE, STRAIGHT, 20MM | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 7/22/2013 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8008-20S | 4 HOLE DBL COMP PLT, STR, 20MM, STERILE | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 5/25/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8008-25 | 4 HOLE DBL COMP PLATE, STRAIGHT, 25MM | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 7/22/2013 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8008-25S | 4 HOLE DBL COMP PLT, STR, 25MM, STERILE | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 5/25/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8008-30 | 4 HOLE DBL COMP PLATE, STRAIGHT, 30MM | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 7/22/2013 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8008-30S | 4 HOLE DBL COMP PLT, STR, 30MM, STERILE | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 5/25/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8009-20 | 4 HOLE DBL COMP PLT SQUARE, 20MM | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 7/22/2013 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8009-20S | 4 HOLE DBL COMP PLT SQUARE, 20MM, STERILE | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 5/25/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8009-25 | 4 HOLE DBL COMP PLATE, SQUARE, 20MM | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 7/22/2013 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8009-25S | 4 HOLE DBL COMP PLT SQUARE, 25MM, STERILE | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 5/25/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8009-30 | 4 HOLE DBL COMP PLT SQUARE, 30MM | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 7/22/2013 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8009-30S | 4 HOLE DBL COMP PLT SQUARE, 30MM, STERILE | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 5/25/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8111 | Wedge Profile Plate | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 12/2/2008 |
| 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 | 3/9/2007 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8941 | LOW PROFILE LAPIDUS PLATE, TITANIUM | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 6/12/2013 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8941L | LOW PROFILE LAPIDUS PLATE, LONG | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 7/24/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8941LS | Low Profile Lapidus Plate, Long, TI, Sterile | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 5/20/2014 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8941PL | Plantar Lapidus Plate Left | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 12/20/2016 |
| 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 | 5/20/2014 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8941PR | Plantar Lapidus Plate Right | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 12/20/2016 |
| 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-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-S | 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-8942LM | 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-S | 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-8942RM | 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 |

| 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-8948-04S | Plate, Low Profile, Cotton, Titanium, 4 mm, sterile | IIb | 61689 | 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 | 9/13/2008 |
| 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 | 9/13/2008 |
| 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 | CALCAINEUS 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 | CALCAINEUS 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 | CALCAINEUS 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, Sterile | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 3/29/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8952DFLS | Dorsal Midfoot Fusion Plate, 3mm, Large, Medium | 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, Sterile | 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, Small | 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, Sterile | 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 | LP MEDIAL COLUMN PLATE, 3.5MM, LARGE, RIGHT | 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 | 5/23/2013 |
| 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 | 11/10/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8952MC-MLS | LP MEDIAL COLUMN PLATE, 3.5MM, MEDIUM, RIGHT | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 5/23/2013 |
| 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 | 11/10/2017 |
| 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 | 5/23/2013 |
| 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 | 11/10/2017 |
| 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 | 5/23/2013 |
| 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 | 11/10/2017 |
| 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 | 5/23/2013 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8952ML-05LST | 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-05R | 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-05RST | 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-8952MS-04 | 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-04S | 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 |

| 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-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 |
| 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-03S | 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-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-8952XS | X-Plate, Large, Sterile | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 7/24/2017 |
| 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-8952XM5 | 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-8952XS | 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-8953-00S | Low Profile Opening Wedge Locking Plate, 2.5 mm, Sterile | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 6/12/2013 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8953-02 | PLATE, POW, LOCKING, Ti, 2 MM | IIb | 61688 | 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 | 7/11/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8953-02S | 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-8953-03 | 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 | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 6/12/2013 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8953-03S | Low Profile Opening Wedge Locking Plate, 3.5 mm, Sterile | IIb | 61689 | 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 | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 6/12/2013 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8953-04S | Low Profile Opening Wedge Locking Plate, 4.5 mm, Ti, Sterile | IIb | 61689 | 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 | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 6/12/2013 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8953-05S | Low Profile Opening Wedge Locking Plate, 5.5 mm, Ti, Sterile | IIb | 61689 | 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 | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 7/24/2017 |
| 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-8953-06S | 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-8953-07 | 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-L5 | 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-S5 | 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-L5 | 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-S5 | 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-8954MTS | Low Profile T-Plate, 3.5 mm, 4 Hole, Ti, Sterile | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 11/5/2013 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8954PL-L | Calcaneal Fracture perimeter plate, large, left | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 3/9/2018 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8954PL-L5 | Calcaneal Fracture Perimeter Plate, Large, Left, Ti, Sterile | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 7/12/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8954PL-M | Calcaneal Fracture perimeter plate, medium, left | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 8/24/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8954PL-M5 | Calcaneal Fracture Perimeter Plate, medium, left | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 7/12/2013 |

| 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-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 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8954PR-MS | Calcaneal Fracture Perimeter Plate, Medium, Right, Ti, Sterile | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 8/24/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8954PR-S | Calcaneal Fracture perimeter plate, small, right | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 7/1/2013 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8954PR-SS | Calcaneal Fracture Perimeter Plate, Small, Right, Ti, Sterile | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 8/24/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8954PR-XS | Calcaneal Fracture perimeter plate, x-small, right | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 7/1/2013 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8954PR-XSS | Calcaneal Fracture Perimeter Plate, X-Small, Right, Ti, Sterile | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 8/24/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8954YL-L | CALC FX PERC PLATE, LONG | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 11/5/2013 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8954YL-LS | Calc FX Perc Plate, Ant Proc/Post Tuber, Left, Long, Ti, Sterile | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 8/24/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8954YL-S | CALC FX PERC PLATE, STD | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 11/5/2013 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8954YL-SS | Calc FX Perc Plate, Ant Proc/Post Tuber, Left, Standard, Ti, Sterile | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 8/24/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8954YR-L | CALC FX PERC PLATE, LONG | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 11/5/2013 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8954YR-LS | Calc FX Perc Plate, Ant Proc/Post Tuber, Right, Long, Ti, Sterile | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 8/24/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8954YR-S | CALC FX PERC PLATE, STD | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 11/5/2013 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8954YR-SS | Calc FX Perc Plate, Ant Proc/Post Tuber, Right, Standard, Ti, Sterile | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 8/24/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8956-01 | Universal 5th Metatarsal Hook Plate | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 9/25/2013 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8956-01S | Universal 5th Metatarsal Hook Plate, Ti, Sterile | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 8/24/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8956L-02 | Universal 5th Metatarsal Hook Plate, Left | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 2/13/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8956L-02S | Universal 5th Metatarsal Hook Plate, Left, Sterile | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 2/13/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8956R-03 | Universal 5th Metatarsal Hook Plate, Right | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 2/13/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8956R-03S | Universal 5th Metatarsal Hook Plate, Right, Sterile | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 2/13/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8957-01 | Mesh Plate, Long, Titanium, Non-Sterile | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 10/2/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8957-01S | Mesh Plate, Long, Titanium, Sterile | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 10/2/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8957-02 | Mesh Plate, Long, Stainless Steel, Non-Sterile | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 10/2/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8957-02S | Mesh Plate, Long, Stainless Steel, Sterile | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 10/2/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8957-03 | Mesh Plate, Short, Titanium, Non-Sterile | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 10/2/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8957-03S | Mesh Plate, Short, Titanium, Sterile | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 10/2/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8957-04S | Mesh Plate, Short, Stainless Steel, Sterile | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 10/2/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8958-01 | Two Hole Plate, Stainless Steel, Non-Sterile | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 3/29/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8958-01S | Two Hole Plate, Stainless Steel, Sterile | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 3/29/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8958-02 | Two Hole Plate, Titanium, Non-Sterile | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 3/29/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8958-02S | Two Hole Plate, Titanium, Sterile | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 3/29/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8963A-03 | Anterior Distal Tibia Plate, SS, 3H | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 12/31/2020 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8963A-03S | Anterior Distal Tibia Plate, 3 Hole | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 4/6/2016 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8963A-04 | Anterior Distal Tibia Plate, SS, 4H | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 4/6/2016 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8963A-05 | Anterior Distal Tibia Plate, SS, 5H | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 12/31/2020 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8963A-05S | Anterior Distal Tibia Plate, 5 Hole | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 4/6/2016 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8963A-06 | Anterior Distal Tibia Plate, SS, 6H | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 4/6/2016 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8963A-07 | Anterior Distal Tibia Plate, SS, 7H | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 12/31/2020 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8963A-07S | Anterior Distal Tibia Plate, 7 Hole | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 4/6/2016 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8963A-08 | Anterior Distal Tibia Plate, SS, 8H | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 4/6/2016 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8963A-09 | Anterior Distal Tibia Plate, SS, 9H | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 4/6/2016 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8963A-09S | Anterior Distal Tibia Plate, 9 Hole | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 12/31/2020 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8963A-10 | Anterior Distal Tibia Plate, SS, 10H | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 4/6/2016 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8963A-11 | Anterior Distal Tibia Plate, SS, 11H | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 4/6/2016 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8963A-12 | Anterior Distal Tibia Plate, SS, 12H | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 4/6/2016 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8963A-13 | Anterior Distal Tibia Plate, SS, 13H | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 4/6/2016 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8963AL-04 | Anterolateral Distal Tibia Plate, SS, Left, 4H | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 4/6/2016 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8963AL-04S | Anterolateral Distal Tibia Plate, Left, 4 Hole | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 4/6/2016 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8963AL-05 | Anterolateral Distal Tibia Plate, SS, Left, 5H | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 4/6/2016 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8963AL-06 | Anterolateral Distal Tibia Plate, SS, Left, 6H | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 12/31/2020 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8963AL-06S | Anterolateral Distal Tibia Plate, Left, 6 Hole | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 4/6/2016 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8963AL-07 | Anterolateral Distal Tibia Plate, SS, Left, 7H | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 4/6/2016 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8963AL-08 | Anterolateral Distal Tibia Plate, SS, Left, 8H | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 4/6/2016 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8963AL-08S | Anterolateral Distal Tibia Plate, Left, 8 Hole | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 12/31/2020 |

| 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-89633ML-04S | Medial Distal Tibia Plate, Left, 6 Hole | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 12/31/2020 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-89633ML-07 | Medial Distal Tibia Plate, SS, Left, 7H | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 4/6/2016 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-89633ML-08 | Medial Distal Tibia Plate, SS, Left, 8H | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 4/6/2016 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-89633ML-08S | Medial Distal Tibia Plate, Left, 8 Hole | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 12/31/2020 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-89633ML-09 | Medial Distal Tibia Plate, SS, Left, 9H | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 4/6/2016 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-89633ML-10 | Medial Distal Tibia Plate, SS, Left, 10H | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 4/6/2016 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-89633ML-10S | Medial Distal Tibia Plate, Left, 10 Hole | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 12/31/2020 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-89633ML-11 | Medial Distal Tibia Plate, SS, Left, 11H | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 4/6/2016 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-89633ML-12 | Medial Distal Tibia Plate, SS, Left, 12H | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 12/31/2020 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-89633ML-12S | Medial Distal Tibia Plate, Left, 12 Hole | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 4/6/2016 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-89633ML-13 | Medial Distal Tibia Plate, SS, Left, 13H | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 4/6/2016 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-89633ML-14 | Medial Distal Tibia Plate, SS, Left, 14H | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 12/31/2020 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-89633ML-14S | Medial Distal Tibia Plate, Left, 14 Hole | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 4/6/2016 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-89633ML-15 | Medial Distal Tibia Plate, SS, Left, 15H | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 4/6/2016 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-89633ML-16 | Medial Distal Tibia Plate, SS, Left, 16H | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 4/6/2016 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-89633ML-16S | Medial Distal Tibia Plate, Left, 16 Hole | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 12/31/2020 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-89633MR-04 | Medial Distal Tibia Plate, SS, Right, 4H | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 4/6/2016 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-89633MR-04S | Medial Distal Tibia Plate, Right, 4 Hole | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 4/6/2016 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-89633MR-05 | Medial Distal Tibia Plate, SS, Right, 5H | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 12/31/2020 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-89633MR-06 | Medial Distal Tibia Plate, SS, Right, 6H | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 4/6/2016 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-89633MR-06S | Medial Distal Tibia Plate, Right, 6 Hole | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 12/31/2020 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-89633MR-07 | Medial Distal Tibia Plate, SS, Right, 7H | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 4/6/2016 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-89633MR-08 | Medial Distal Tibia Plate, SS, Right, 8H | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 4/6/2016 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-89633MR-08S | Medial Distal Tibia Plate, Right, 8 Hole | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 12/31/2020 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-89633MR-09 | Medial Distal Tibia Plate, SS, Right, 9H | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 4/6/2016 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-89633MR-10 | Medial Distal Tibia Plate, SS, Right, 10H | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 4/6/2016 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-89633MR-10S | Medial Distal Tibia Plate, Right, 10 Hole | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 12/31/2020 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-89633MR-11 | Medial Distal Tibia Plate, SS, Right, 11H | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 4/6/2016 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-89633MR-12 | Medial Distal Tibia Plate, SS, Right, 12H | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 12/31/2020 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-89633MR-12S | Medial Distal Tibia Plate, Right, 12 Hole | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 4/6/2016 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-89633MR-13 | Medial Distal Tibia Plate, SS, Right, 13H | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 4/6/2016 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-89633MR-14 | Medial Distal Tibia Plate, SS, Right, 14H | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 12/31/2020 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-89633MR-14S | Medial Distal Tibia Plate, Right, 14 Hole | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 4/6/2016 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-89633MR-15 | Medial Distal Tibia Plate, SS, Right, 15H | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 4/6/2016 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-89633MR-16 | Medial Distal Tibia Plate, SS, Right, 16H | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 12/31/2020 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-89633P-03 | Posterior Distal Tibia Plate, SS, 3H | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 4/6/2016 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-89633P-03S | Posterior Distal Tibia Plate, 3 Hole | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 12/31/2020 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-89633P-04 | Posterior Distal Tibia Plate, SS, 4H | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 4/6/2016 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-89633P-05 | Posterior Distal Tibia Plate, SS, 5H | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 12/31/2020 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-89633P-05S | Posterior Distal Tibia Plate, 5 Hole | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 4/6/2016 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-89633P-06 | Posterior Distal Tibia Plate, SS, 6H | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 4/6/2016 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-89633P-07 | Posterior Distal Tibia Plate, SS, 7H | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 12/31/2020 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-89633P-07S | Posterior Distal Tibia Plate, 7 Hole | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 4/6/2016 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-89633P-08 | Posterior Distal Tibia Plate, SS, 8H | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 4/6/2016 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-89633P-09 | Posterior Distal Tibia Plate, SS, 9H | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 12/31/2020 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-89633P-10 | Posterior Distal Tibia Plate, SS, 10H | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 4/6/2016 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-89633P-11 | Posterior Distal Tibia Plate, SS, 11H | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 4/6/2016 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-89633P-12 | Posterior Distal Tibia Plate, SS, 12H | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 4/6/2016 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-89633P-13 | Posterior Distal Tibia Plate, SS, 13H | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 4/6/2016 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-89633PL-04 | Postero Dist Fib Pit, SS, 4H | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 12/31/2020 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-89633PL-04S | Postero Dist Fib Pit, 4 Hole | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 4/6/2016 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-89633PL-05 | Postero Dist Fib Pit, SS, 5H | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 12/31/2020 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-89633PL-05S | Postero Distal Distal Fibula Plate, 5 Hole | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 4/6/2016 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-89633PL-06 | Postero Dist Fib Pit, SS, 6H | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 12/31/2020 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-89633PL-06S | Postero Dist Fib Pit, 6 Hole | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 4/6/2016 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-89633PL-07 | Postero Dist Fib Pit, SS, 7H | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 12/31/2020 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-89633PL-08 | Postero Dist Fib Pit, SS, 8H | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 4/6/2016 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-89633PL-08S | Postero Distal Distal Fibula Plate, 8 Hole | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 12/31/2020 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-89633PL-09 | Postero Dist Fib Pit, SS, 9H | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 4/6/2016 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-89633PL-10 | Postero Dist Fib Pit, SS, 10H | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 4/6/2016 |

| 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-0L | MaxForce™ MTP Compression Plate, Long, 0° Valgus, 0° Dorsiflex, Left | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 8/20/2020 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-9944L-0R | MaxForce™ MTP Compression Plate, Long, 0° Valgus, 0° Dorsiflex, Right | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 8/20/2020 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-9944L-5L | MaxForce™ MTP Compression Plate, 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-0L | MaxForce™ MTP Compression Plate, Revision, 0° Valgus, 0° Dorsiflex, Left | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 8/20/2020 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-9944X-0R | MaxForce™ MTP Compression Plate, Revision, 0° Valgus, 0° Dorsiflex, Right | 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, 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 | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 8/20/2020 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-9963APLL-04 | Posteriorlateral 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 | Posteriorlateral 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 | Posteriorlateral 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 | Posteriorlateral 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 | Posteriorlateral Anatomic Distal Fibula Plate, Left, 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 | Posteriorlateral 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 | Posteriorlateral 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 | Posteriorlateral 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 | Posteriorlateral 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 | Posteriorlateral 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 | Posteriorlateral 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 | Posteriorlateral 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 | Posteriorlateral 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 | Posteriorlateral 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 | Posteriorlateral 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 | Posteriorlateral 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 | Posteriorlateral 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 | Posteriorlateral 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 | Posteriorlateral 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 | Posteriorlateral 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 | Posteriorlateral Distal Fibula Plate, Locking, Ti, 10 Hole, Sterile | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 2/2/2021 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-9963PLL-04S | Posteriorlateral 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 | Posteriorlateral 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 | Posteriorlateral 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 | Posteriorlateral 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 | Posteriorlateral 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 Arthroereisis 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 Arthroereisis 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 Arthroereisis 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 Arthroereisis 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 Arthroereisis 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 Arthroereisis 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-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, Ti, 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, 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 | Dorsal Distal Radius Plate, Ti, Standard, Right, 4 H, Sterile | 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 |

| 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-1330PW-1B5 | Fracture Screw with Washer, 3.0 mm x XX mm, sterile | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 8/10/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-1330PW-205 | Fracture Screw with Washer, 3.0 mm x XX mm, sterile | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 8/10/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-1330PW-225 | Fracture Screw with Washer, 3.0 mm x XX mm, sterile | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 8/10/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-1330PW-245 | Fracture Screw with Washer, 3.0 mm x XX mm, sterile | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 8/10/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-1330PW-265 | Fracture Screw with Washer, 3.0 mm x XX mm, sterile | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 8/10/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-1330PW-285 | Fracture Screw with Washer, 3.0 mm x XX mm, sterile | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 8/10/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-1330PW-305 | Fracture Screw with Washer, 3.0 mm x XX mm, sterile | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 8/10/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-1330PW-405 | Fracture Screw with Washer, 3.0 mm x XX mm, sterile | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 8/10/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-1330PW-455 | Fracture Screw with Washer, 3.0 mm x XX mm, sterile | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 8/10/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-1330PW-505 | Fracture Screw with Washer, 3.0 mm x XX mm, sterile | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 8/10/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13416T | PEEKPower, Locking Screw for HTO Plate, 5.0 mm x 16.0 mm | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 8/10/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13416TS | PEEKPower, Locking Screw for HTO Plate, 5.0 mm x 16.0 mm | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 8/1/2008 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13420T | PEEKPower, Locking Screw for HTO Plate, 5.0 mm x 20.0 mm | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 11/22/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13420TS | PEEKPower, Locking Screw for HTO Plate, 5.0 mm x 20.0 mm | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 8/1/2008 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13424T | PEEKPower, Locking Screw for HTO Plate, 5.0 mm x 24.0 mm | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 11/22/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13424TS | PEEKPower, Locking Screw for HTO Plate, 5.0 mm x 24.0 mm | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 11/22/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13426T | PEEKPower, Locking Screw for HTO Plate, 5.0 mm x 26.0 mm | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 4/30/2008 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13426TS | PEEKPower, Locking Screw for HTO Plate, 5.0 mm x 26.0 mm | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 4/30/2008 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13428T | PEEKPower, Locking Screw for HTO Plate, 5.0 mm x 28.0 mm | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 11/22/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13428TS | PEEKPower, Locking Screw for HTO Plate, 5.0 mm x 28.0 mm | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 4/30/2008 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13430T | PEEKPower, Locking Screw for HTO Plate, 5.0 mm x 30.0 mm | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 11/22/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13430TS | PEEKPower, Locking Screw for HTO Plate, 5.0 mm x 30.0 mm | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 4/30/2008 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13432T | PEEKPower, Locking Screw for HTO Plate, 5.0 mm x 32.0 mm | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 11/22/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13432TS | PEEKPower, Locking Screw for HTO Plate, 5.0 mm x 32.0 mm | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 4/30/2008 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13434T | PEEKPower, Locking Screw for HTO Plate, 5.0 mm x 34.0 mm | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 11/22/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13434TS | PEEKPower, Locking Screw for HTO Plate, 5.0 mm x 34.0 mm | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 4/30/2008 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13436T | PEEKPower, Locking Screw for HTO Plate, 5.0 mm x 36.0 mm | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 11/22/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13436TS | PEEKPower, Locking Screw for HTO Plate, 5.0 mm x 36.0 mm | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 4/30/2008 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13438T | PEEKPower, Locking Screw for HTO Plate, 5.0 mm x 38.0 mm | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 11/22/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13438TS | PEEKPower, Locking Screw for HTO Plate, 5.0 mm x 38.0 mm | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 4/30/2008 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13440T | PEEKPower, Locking Screw for HTO Plate, 5.0 mm x 40.0 mm | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 11/22/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13440TS | PEEKPower, Locking Screw for HTO Plate, 5.0 mm x 40.0 mm | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 4/30/2008 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13442T | PEEKPower, Locking Screw for HTO Plate, 5.0 mm x 42.0 mm | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 11/22/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13442TS | PEEKPower, Locking Screw for HTO Plate, 5.0 mm x 42.0 mm | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 4/30/2008 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13444T | PEEKPower, Locking Screw for HTO Plate, 5.0 mm x 44.0 mm | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 11/22/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13444TS | PEEKPower, Locking Screw for HTO Plate, 5.0 mm x 44.0 mm | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 4/30/2008 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13446T | PEEKPower, Locking Screw for HTO Plate, 5.0 mm x 46.0 mm | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 11/22/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13446TS | PEEKPower, Locking Screw for HTO Plate, 5.0 mm x 46.0 mm | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 4/30/2008 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13448T | PEEKPower, Locking Screw for HTO Plate, 5.0 mm x 48.0 mm | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 11/22/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13448TS | PEEKPower, Locking Screw for HTO Plate, 5.0 mm x 48.0 mm | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 4/30/2008 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13450T | PEEKPower, Locking Screw for HTO Plate, 5.0 mm x 50.0 mm | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 11/22/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13450TS | PEEKPower, Locking Screw for HTO Plate, 5.0 mm x 50.0 mm | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 4/30/2008 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13455T | PEEKPower, Locking Screw for HTO Plate, 5.0 mm x 55.0 mm | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 11/22/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13455TS | PEEKPower, Locking Screw for HTO Plate, 5.0 mm x 55.0 mm | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 4/30/2008 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13460T | PEEKPower, Locking Screw for HTO Plate, 5.0 mm x 60.0 mm | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 11/22/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13460TS | PEEKPower, Locking Screw for HTO Plate, 5.0 mm x 60.0 mm | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 4/30/2008 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13465T | PEEKPower, Locking Screw for HTO Plate, 5.0 mm x 65.0 mm | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 11/22/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13465TS | PEEKPower, Locking Screw for HTO Plate, 5.0 mm x 65.0 mm | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 4/30/2008 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13470T | PEEKPower, Locking Screw for HTO Plate, 5.0 mm x 70.0 mm | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 11/22/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13470TS | PEEKPower, Locking Screw for HTO Plate, 5.0 mm x 70.0 mm | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 4/30/2008 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13475T | PEEKPower, Locking Screw for HTO Plate, 5.0 mm x 75.0 mm | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 11/22/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13475TS | PEEKPower, Locking Screw for HTO Plate, 5.0 mm x 75.0 mm | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 4/30/2008 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13480T | PEEKPower, Locking Screw for HTO Plate, 5.0 mm x 80.0 mm | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 11/22/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13480TS | PEEKPower, Locking Screw for HTO Plate, 5.0 mm x 80.0 mm | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 4/30/2008 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13485T | PEEKPower, Locking Screw for HTO Plate, 5.0 mm x 85.0 mm | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 11/22/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13485TS | PEEKPower, Locking Screw for HTO Plate, 5.0 mm x 85.0 mm | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 4/30/2008 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13490T | PEEKPower, Locking Screw for HTO Plate, 5.0 mm x 90.0 mm | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 11/22/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13490TS | PEEKPower, Locking Screw for HTO Plate, 5.0 mm x 90.0 mm | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 4/30/2008 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13524T | PEEKPower, Cortical Compression Screw for HTO Plate, 4.5 mm x 24 mm | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 7/14/2008 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13524TS | PEEKPower, Cortical Non-Locking Screw for HTO Plate, 4.5mm x 24mm,sterile | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 8/10/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-13528T | PEEKPower, Cortical Compression Screw for HTO Plate, 4.5 mm x 28 mm | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 7/14/2008 |

| 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-8930-125 | Arthrex QuickFix™ Screw, TI, 2 mm x 12 mm, sterile, IM | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 5/19/2008 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8930-13 | QUICKFIX SCREW, 2 X 13 MM | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 3/9/2007 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8930-135 | Arthrex QuickFix™ Screw, TI, 2 mm x 13 mm, sterile, IM | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 5/19/2008 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8930-14 | QUICKFIX SCREW, 2 X 14 MM | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 3/9/2007 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8930-145 | Arthrex QuickFix™ Screw, TI, 2 mm x 14 mm, sterile, IM | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 5/19/2008 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8931-13 | QUICKFIX SCREW, 3 X 13 MM | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 3/9/2007 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8931-135 | Arthrex QuickFix™ Screw, TI, 3 mm x 13 mm, sterile, IM | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 5/19/2008 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8931-15 | QUICKFIX SCREW, 3 X 15 MM | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 3/9/2007 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8931-155 | Arthrex QuickFix™ Screw, TI, 3 mm x 15 mm, sterile, IM | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 5/19/2008 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8931-17 | QUICKFIX SCREW, 3 X 17 MM | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 3/9/2007 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8931-175 | Arthrex QuickFix™ Screw, TI, 3 mm x 17 mm, sterile, IM | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 5/19/2008 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8931-195 | Arthrex QuickFix™ Screw, TI, 3 mm x 19 mm, sterile, IM | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 3/9/2007 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8933-10 | LOW PROFILE SCREW, TI, 3.0MM X 10MM, CORTICAL | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 5/19/2008 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8933-12 | LOW PROFILE SCREW, TI, 3.0MM X 12MM, CORTICAL | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 3/9/2007 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8933-125 | Low Profile Screw, Cortical, 3 x 12mm, Titanium, Sterile | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 5/25/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8933-14 | LOW PROFILE SCREW, TI, 3.0MM X 14MM, CORTICAL | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 9/19/2008 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8933-145 | Low Profile Screw, Cortical, 3 x 14mm, Titanium, Sterile | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 5/25/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8933-16 | LOW PROFILE SCREW, TI, 3.0MM X 16MM, CORTICAL | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 9/19/2008 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8933-165 | Low Profile Screw, Cortical, 3 x 16mm, Titanium, Sterile | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 5/25/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8933-18 | LOW PROFILE SCREW, TI, 3.0MM X 18MM, CORTICAL | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 9/19/2008 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8933-185 | Low Profile Screw, Cortical, 3 x 18mm, Titanium, Sterile | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 5/25/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8933-20 | LOW PROFILE SCREW, TI, 3.0MM X 20MM, CORTICAL | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 3/4/2009 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8933-205 | Low Profile Screw, Cortical, 3 x 20 mm, Sterile | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 7/11/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8933-22 | LOW PROFILE SCREW, TI, 3.0MM X 22MM, CORTICAL | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 3/4/2009 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8933-225 | Low Profile Screw, Cortical, 3 x 22mm, Titanium, Sterile | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 5/25/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8933-24 | LOW PROFILE SCREW, TI, 3.0MM X 24MM, CORTICAL | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 9/10/2010 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8933-245 | Low Profile Screw, Cortical, 3 x 24 mm, Sterile | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 7/11/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8933-26 | LOW PROFILE SCREW, TI, 3.0MM X 26MM, CORTICAL | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 7/24/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8933-285 | Low Profile Screw, Cortical, 3 x 26 mm, TI, Sterile | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 6/12/2013 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8933-28 | LOW PROFILE SCREW, TI, 3.0MM X 28MM, CORTICAL | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 7/24/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8933-285 | Low Profile Screw, Cortical, 3 x 28 mm, TI, Sterile | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 6/12/2013 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8933-30 | LOW PROFILE SCREW, TI, 3.0MM X 30MM, CORTICAL | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 7/24/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8933-305 | Low Profile Screw, Cortical, 3 x 30 mm, TI, Sterile | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 6/12/2013 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8933-32 | LOW PROFILE SCREW, TI, 3.0MM X 32MM, CORTICAL | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 7/24/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8933-325 | Low Profile Screw, Cortical, 3 x 32 mm, TI, Sterile | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 6/12/2013 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8933-34 | LOW PROFILE SCREW, TI, 3.0MM X 34MM, CORTICAL | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 7/24/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8933-345 | Low Profile Screw, Cortical, 3 x 34 mm, TI, Sterile | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 6/12/2013 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8933-36 | LOW PROFILE SCREW, TI, 3.0MM X 36MM, CORTICAL | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 7/24/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8933-365 | Low Profile Screw, Cortical, 3 x 36 mm, TI, Sterile | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 6/12/2013 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8933-38 | LOW PROFILE SCREW, TI, 3.0MM X 38MM, CORTICAL | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 7/24/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8933-385 | Low Profile Screw, Cortical, 3 x 38 mm, TI, Sterile | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 6/12/2013 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8933-40 | LOW PROFILE SCREW, TI, 3 x 40 mm, TI, Sterile | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 10/2/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8933-42 | Low Profile Screw, 3.0 x 42 mm, Cortical, Titanium | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 4/4/2008 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8933-42PT | LOW PROFILE SCREW, TI, 3 X 42MM, CANN, PART THD | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 10/2/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8933-44 | Low Profile Screw, 3.0 x 44 mm, Cortical, Titanium | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 4/4/2008 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8933-44PT | LOW PROFILE SCREW, TI, 3 X 44MM, CANN, PART THD | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 10/2/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8933-46 | Low Profile Screw, 3.0 x 46 mm, Cortical, Titanium | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 4/4/2008 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8933-48 | LOW PROFILE SCREW, TI, 3 X 46MM, CANN, PART THD | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 10/2/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8933-48PT | LOW PROFILE SCREW, TI, 3 X 48MM, CANN, PART THD | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 4/4/2008 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8933-50 | Low Profile Screw, 3.0 x 50 mm, Cortical, Titanium | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 3/29/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8933-50PT | LOW PROFILE SCREW, TI, 3 X 50MM, CANN, PART THD | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 3/29/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8933HV-10 | Low Profile VA Locking, 3.0 x 10 mm, Hybrid | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 4/4/2008 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8933HV-12 | Low Profile VA Locking, 3.0 x 12 mm, Hybrid | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 3/29/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8933HV-14 | Low Profile VA Locking, 3.0 x 14 mm, Hybrid | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 3/29/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8933HV-16 | Low Profile VA Locking, 3.0 x 16 mm, Hybrid | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 3/29/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8933HV-18 | Low Profile VA Locking, 3.0 x 18 mm, Hybrid | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 3/29/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8933HV-20 | Low Profile VA Locking, 3.0 x 20 mm, Hybrid | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 3/29/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8933HV-22 | Low Profile VA Locking, 3.0 x 22 mm, Hybrid | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 3/29/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8933HV-24 | Low Profile VA Locking, 3.0 x 24 mm, Hybrid | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 3/29/2017 |

| Manufacturer Name | Manufacturing Location | EC QA Cert. Number | Product Code | Product Name | Class | GMVDN code | Technical File | Rule | Annex | First DoC |
|-------------------|------------------------|--------------------|--------------|--|-------|------------|----------------------------------|------|-------|-----------|
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-89351-325 | Low Profile Locking Screw, Titanium, 3.5 x 32 mm, sterile | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 5/19/2008 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-89351-34 | LOCKING SCREW, TITANIUM 3.5MM X 34MM | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 3/9/2007 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-89351-34S | Low Profile Locking Screw, Titanium, 3.5 x 34 mm, sterile | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 5/19/2008 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-89351-36 | LOCKING SCREW, TITANIUM 3.5MM X 36MM | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 3/9/2007 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-89351-36S | Low Profile Locking Screw, Titanium, 3.5 x 36 mm, sterile | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 5/19/2008 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-89351-38 | LOCKING SCREW, TITANIUM 3.5MM X 38MM | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 3/9/2007 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-89351-38S | Low Profile Locking Screw, Titanium, 3.5 x 38 mm, sterile | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 5/19/2008 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-89351-40 | LOCKING SCREW, TITANIUM 3.5MM X 40MM | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 3/9/2007 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-89351-40S | Low Profile Locking Screw, Titanium, 3.5 x 40 mm, sterile | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 5/19/2008 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-89351-42 | LOCKING SCREW, TITANIUM 3.5MM X 42MM | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 3/9/2007 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-89351-42S | Low Profile Locking Screw, Titanium, 3.5 x 42 mm, sterile | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 5/19/2008 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-89351-44 | LOCKING SCREW, TITANIUM 3.5MM X 44MM | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 3/9/2007 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-89351-44S | Low Profile Locking Screw, Titanium, 3.5 x 44 mm, sterile | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 5/19/2008 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-89351-46 | LOW PROFILE LOCKING SCREW, TI, 3.5MM X 46MM | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 6/12/2013 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-89351-46S | Low Profile Locking Screw, 3.5 x 46 mm, Sterile | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 11/4/2016 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-89351-48 | LOW PROFILE LOCKING SCREW, TI, 3.5MM X 48MM | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 6/12/2013 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-89351-48S | Low Profile Locking Screw, 3.5 x 48 mm, Sterile | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 11/4/2016 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-89351-50 | LOW PROFILE LOCKING SCREW, TI, 3.5MM X 50MM | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 6/12/2013 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-89351-50S | Low Profile Locking Screw, 3.5 x 50 mm, Sterile | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 11/4/2016 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-89351-52 | LOW PROFILE LOCKING SCREW, 3.5 X 52MM | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 6/12/2013 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-89351-52S | Low Profile Locking Screw, 3.5 x 52 mm, Sterile | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 11/4/2016 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-89351-54 | LOW PROFILE LOCKING SCREW, 3.5 X 54MM | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 6/12/2013 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-89351-54S | Low Profile Locking Screw, 3.5 x 54 mm, Sterile | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 11/4/2016 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-89351-55 | Low Profile Locking Screw, 3.5 x 55 mm, TI | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 2/2/2018 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-89351-55S | Low Profile Locking Screw, 3.5 x 55 mm, Sterile | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 11/4/2016 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-89351-56 | LOW PROFILE LOCKING SCREW, 3.5 X 56MM | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 6/12/2013 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-89351-56S | Low Profile Locking Screw, 3.5 x 56 mm, Sterile | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 11/4/2016 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-89351-58 | LOW PROFILE LOCKING SCREW, 3.5 X 58MM | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 6/12/2013 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-89351-58S | Low Profile Locking Screw, 3.5 x 58 mm, Sterile | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 11/4/2016 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-89351-60S | LOW PROFILE LOCKING SCREW, TI, 3.5MM X 60MM | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 6/12/2013 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-89351-60S | Low Profile Locking Screw, 3.5 x 60 mm, Sterile | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 11/4/2016 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-89351-65 | Low Profile Locking Screw, 3.5 x 65 mm, TI | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 2/2/2018 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-89351-70 | Low Profile Locking Screw, 3.5 x 70 mm, TI | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 2/2/2018 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-89351-75 | Low Profile Locking Screw, 3.5 x 75 mm, TI | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 2/2/2018 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-89351-80 | Low Profile Locking Screw, 3.5 x 80 mm, TI | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 2/2/2018 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8940-10 | Low Profile Screw, TI, 4.0 mm x 10 mm | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 2/2/2018 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8940-12 | Low Profile Screw, TI, 4.0 mm x 12 mm | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 2/2/2018 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8940-14 | LOW PROFILE SCREW, TITANIUM, 4.0MM X 14MM | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 2/2/2018 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8940-14S | Low Profile Screw, Titanium, Non-Locking, 4.0 x 14 mm, sterile | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 2/2/2018 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8940-16 | LOW PROFILE SCREW, TITANIUM, 4.0MM X 16MM | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 3/9/2007 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8940-16S | Low Profile Screw, Titanium, Non-Locking, 4.0 x 16 mm, sterile | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 5/19/2008 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8940-18 | LOW PROFILE SCREW, TITANIUM, 4.0MM X 18MM | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 3/9/2007 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8940-18S | Low Profile Screw, Titanium, Non-Locking, 4.0 x 18 mm, sterile | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 5/19/2008 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8940-20 | LOW PROFILE SCREW, TITANIUM, 4.0MM X 20MM | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 3/9/2007 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8940-20S | Low Profile Screw, Titanium, Non-Locking, 4.0 x 20 mm, sterile | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 5/19/2008 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8940-22 | LOW PROFILE SCREW, TITANIUM, 4.0MM X 22MM | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 3/9/2007 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8940-22S | Low Profile Screw, Titanium, Non-Locking, 4.0 x 22 mm, sterile | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 5/19/2008 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8940-24 | LOW PROFILE SCREW, TITANIUM, 4.0MM X 24MM | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 3/9/2007 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8940-24S | Low Profile Screw, Titanium, Non-Locking, 4.0 x 24 mm, sterile | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 5/19/2008 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8940-26 | LOW PROFILE SCREW, TITANIUM, 4.0MM X 26MM | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 3/9/2007 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8940-26S | Low Profile Screw, Titanium, Non-Locking, 4.0 x 26 mm, sterile | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 5/19/2008 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8940-28 | LOW PROFILE SCREW, TITANIUM, 4.0MM X 28MM | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 3/9/2007 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8940-28S | Low Profile Screw, Titanium, Non-Locking, 4.0 x 28 mm, sterile | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 5/19/2008 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8940-30 | LOW PROFILE SCREW, TITANIUM, 4.0MM X 30MM | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 3/9/2007 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8940-30S | Low Profile Screw, Titanium, Non-Locking, 4.0 x 30 mm, sterile | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 5/19/2008 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8940-32 | LOW PROFILE SCREW, TITANIUM, 4.0MM X 32MM | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 3/9/2007 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8940-32S | Low Profile Screw, Titanium, Non-Locking, 4.0 x 32 mm, sterile | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 5/19/2008 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8940-34 | LOW PROFILE SCREW, TITANIUM, 4.0MM X 34MM | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 3/9/2007 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8940-34S | Low Profile Screw, Titanium, Non-Locking, 4.0 x 34 mm, sterile | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 5/19/2008 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8940-36 | LOW PROFILE SCREW, TITANIUM, 4.0MM X 36MM | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 3/9/2007 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8940-36S | Low Profile Screw, Titanium, Non-Locking, 4.0 x 36 mm, sterile | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 5/19/2008 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8940-38 | LOW PROFILE SCREW, TITANIUM, 4.0MM X 38MM | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 3/9/2007 |

| 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-8940-345 | Low Profile Screw, Titanium, Non-Locking, 4.0 x 38 mm, sterile | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 5/19/2008 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8940-40 | Low Profile Screw, Titanium, Non-Locking, 4.0MM x 40MM | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 3/9/2007 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8940-40S | Low Profile Screw, Titanium, Non-Locking, 4.0 x 40 mm, sterile | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 5/19/2008 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8940-42 | Low Profile Screw, Titanium, 4.0MM X 42MM | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 3/9/2007 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8940-42S | Low Profile Screw, Titanium, Non-Locking, 4.0 x 42 mm, sterile | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 5/19/2008 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8940-44 | Low PROFILE SCREW, TITANIUM, 4.0MM X 44MM | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 3/9/2007 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8940-44S | Low Profile Screw, 4 x 44 mm, sterile | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 5/19/2008 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8940-46 | Low PROFILE SCREW, Ti, 4.0MM X 46MM | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 6/12/2013 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8940-46S | Low Profile Screw, 4 x 46 mm | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 5/25/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8940-48 | Low PROFILE SCREW, Ti, 4.0MM X 48MM | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 6/12/2013 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8940-48S | Low Profile Screw, 4 x 48 mm | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 5/25/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8940-50 | Low PROFILE SCREW, Ti, 4.0MM X 50MM | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 6/12/2013 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8940-50S | Low Profile Screw, 4 x 50 mm | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 5/25/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8940-52 | Low PROFILE SCREW, 4 X 52MM | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 5/25/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8940-52S | Low Profile Screw, 4 x 52 mm | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 6/12/2013 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8940-54 | Low PROFILE SCREW, 4 X 54MM | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 5/25/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8940-54S | Low Profile Screw™, 4 x 54 mm, sterile | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 6/12/2013 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8940-56 | Low PROFILE SCREW, 4 X 56MM | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 5/25/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8940-56S | Low Profile Screw, 4 x 56 mm | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 6/12/2013 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8940-58 | Low PROFILE SCREW, 4 X 58MM | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 5/25/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8940-58S | Low Profile Screw, 4 x 58 mm | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 6/12/2013 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8940-60 | Low PROFILE SCREW, Ti, 4.0MM X 60MM | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 5/25/2017 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8940-60S | Low Profile Screw, 4 x 60 mm | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 6/12/2013 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8945-20FT | Low PROFILE SCREW, Ti, 4.5 X 20MM, CANNULATED | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 9/15/2009 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8945-20FTS | Low Profile Screw™, Ti, 4.5 mm x 20 mm, Cannulated, Fully Threaded, sterile | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 4/4/2008 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8945-20PT | Low PRO SCREW, Ti, 4.5 X 20MM, CANN PARTIALLY THD | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 12/11/2008 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8945-20PTS | Low Profile Screw™, Ti, 4.5 mm x 20.0 mm, Cannulated, Partially Threaded, sterile | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 9/15/2009 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8945-22FT | Low PROFILE SCREW, Ti, 4.5 X 22MM, CANNULATED | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 4/4/2008 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8945-22FTS | Low Profile Screw™, Ti, 4.5 mm x 22 mm, Cannulated, Fully Threaded, sterile | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 12/11/2008 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8945-22PT | Low PRO SCREW, Ti, 4.5 X 22MM, CANN PARTIALLY THD | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 9/15/2009 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8945-22PTS | Low Profile Screw™, Ti, 4.5 mm x 22.0 mm, Cannulated, Partially Threaded, sterile | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 4/4/2008 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8945-24FT | Low PROFILE SCREW, Ti, 4.5 X 24MM, CANNULATED | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 9/15/2009 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8945-24FTS | Low Profile Screw™, Ti, 4.5 mm x 24 mm, Cannulated, Fully Threaded, sterile | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 4/4/2008 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8945-24PT | Low PRO SCREW, Ti, 4.5 X 24MM, CANN PARTIALLY THD | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 12/11/2008 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8945-24PTS | Low Profile Screw™, Ti, 4.5 mm x 24.0 mm, Cannulated, Partially Threaded, sterile | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 9/15/2009 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8945-26FT | Low PROFILE SCREW, Ti, 4.5 X 26MM, CANNULATED | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 4/4/2008 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8945-26FTS | Low Profile Screw™, Ti, 4.5 mm x 26 mm, Cannulated, Fully Threaded, sterile | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 12/11/2008 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8945-26PT | Low PRO SCREW, Ti, 4.5 X 26MM, CANN PARTIALLY THD | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 9/15/2009 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8945-26PTS | Low Profile Screw™, Ti, 4.5 mm x 26.0 mm, Cannulated, Partially Threaded, sterile | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 4/4/2008 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8945-28FT | Low PROFILE SCREW, Ti, 4.5 X 28MM, CANNULATED | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 12/11/2008 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8945-28FTS | Low Profile Screw™, Ti, 4.5 mm x 28 mm, Cannulated, Fully Threaded, sterile | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 9/15/2009 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8945-28PT | Low PRO SCREW, Ti, 4.5 X 28MM, CANN PARTIALLY THD | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 4/4/2008 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8945-28PTS | Low Profile Screw™, Ti, 4.5 mm x 28.0 mm, Cannulated, Partially Threaded, sterile | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 12/11/2008 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8945-30FT | Low PROFILE SCREW, Ti, 4.5 mm x 30MM, CANNULATED | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 9/15/2009 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8945-30FTS | Low Profile Screw™, Ti, 4.5 mm x 30 mm, Cannulated, Fully Threaded, sterile | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 4/4/2008 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8945-30PT | Low PRO SCREW, Ti, 4.5 X 30MM, CANN PARTIALLY THD | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 12/11/2008 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8945-30PTS | Low Profile Screw™, Ti, 4.5 mm x 30.0 mm, Cannulated, Partially Threaded, sterile | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 9/15/2009 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8945-32FT | Low PROFILE SCREW, Ti, 4.5 X 32MM, CANNULATED | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 4/4/2008 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8945-32FTS | Low Profile Screw™, Ti, 4.5 mm x 32 mm, Cannulated, Fully Threaded, sterile | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 12/11/2008 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8945-32PT | Low PRO SCREW, Ti, 4.5 X 32MM, CANN PARTIALLY THD | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 9/15/2009 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8945-32PTS | Low Profile Screw™, Ti, 4.5 mm x 32.0 mm, Cannulated, Partially Threaded, sterile | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 4/4/2008 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8945-34FT | Low PROFILE SCREW, Ti, 4.5 X 34MM, CANNULATED | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 12/11/2008 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8945-34FTS | Low Profile Screw™, Ti, 4.5 mm x 34 mm, Cannulated, Fully Threaded, sterile | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 9/15/2009 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8945-34PT | Low PRO SCREW, Ti, 4.5 X 34MM, CANN PARTIALLY THD | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 4/4/2008 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8945-34PTS | Low Profile Screw™, Ti, 4.5 mm x 34.0 mm, Cannulated, Partially Threaded, sterile | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 12/11/2008 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8945-36FT | Low Profile Screw, Cannulated, Partially Threaded, 4.5 x 35 mm | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 8/23/2019 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8945-36FTS | Low PROFILE SCREW, Ti, 4.5 X 36MM, CANNULATED | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 9/15/2009 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8945-36PT | Low Profile Screw™, Ti, 4.5 mm x 36 mm, Cannulated, Fully Threaded, sterile | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 4/4/2008 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8945-36PTS | Low PRO SCREW, Ti, 4.5 X 36MM, CANN PARTIALLY THD | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 12/11/2008 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8945-38FT | Low Profile Screw™, Ti, 4.5 mm x 38.0 mm, Cannulated, Fully Threaded, sterile | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 9/15/2009 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8945-38FTS | Low PROFILE SCREW, Ti, 4.5 X 38MM, CANNULATED | IIb | 61689 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 4/4/2008 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8945-38PT | Low Profile Screw™, Ti, 4.5 mm x 38 mm, Cannulated, Fully Threaded, sterile | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 12/11/2008 |
| Arthrex, Inc. | Naples, FL | CE 85507 | AR-8945-38PTS | Low Profile Screw™, Ti, 4.5 mm x 38 mm, Cannulated, Fully Threaded, sterile | IIb | 61688 | PLATE, SCREWS, WEDGE and STAPLES | 8 | II | 9/15/2009 |

| 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-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 |