

Section

1

1. Declaration of Conformity

Technical File Scopes

GMDN Codes Refer to the Parts List, Rev. 24 for a complete list of GMDN codes subject of this Technical File

Revision 24

MDD Class, Rule Class IIa, Rule 6 and Rule 9

Route of Compliance Annex II (excluding Section 4)

Notified Body / Number BSI / CE 2797
(Formerly - BSI / CE 0086)

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

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

1.1. Conformity Declaration Statement

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



William Heard
Regional Manager, Regulatory Affairs, EMEA

10-28-2020

Date

1.2. List of Devices by Catalog Number

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

MDD Technical File: SCOPES, Revision 24

Manufacturer name	Manufacturing location	EC QA Cert. number:	Product Code	Product Name	Class	GMDN code	TF	Rule	Annex	First DoC
ENDOSCOPES										
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3000AW	Arthroscope, 0°, 4 mm x 174 mm, HD	Ila	34856	SCOPES	6	II	7/1/2013
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3030AW	Arthroscopy, 30°, 4.0 mm x 175 mm, HD	Ila	34856	SCOPES	6	II	6/30/1998
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3030AWR	Endoscope, 30°, 4 x 175 mm, HD, Reverse Light Post	Ila	34856	SCOPES	6	II	3/16/2015
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3045AW	Arthroscope, 45°, 4 mm x 176 mm, HD	Ila	34856	SCOPES	6	II	7/1/2013
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3045AWR	Endoscope, 45°, 4 x 175 mm, HD, Reverse Light Post	Ila	34856	SCOPES	6	II	3/16/2015
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3070AW	Arthroscopy 70°, 4.0 mm x 175 mm, HD	Ila	34856	SCOPES	6	II	6/30/1998
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3070AWR	Endoscope, 70°, 4 x 177 mm, HD, Reverse Light Post	Ila	34856	SCOPES	6	II	3/16/2015
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3350-1930	Arthroscope 30°, 1.9 mm x 58 mm	Ila	34856	SCOPES	6	II	7/1/2013
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3350-2430	Arthroscope 30°, 2.4 mm x 72 mm	Ila	34856	SCOPES	6	II	7/1/2013
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3350-2470	Arthroscope 70°, 2.4 mm x 75 mm	Ila	34856	SCOPES	6	II	7/1/2013
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3350-2730	Arthroscope 30°, 2.7 mm x 72 mm	Ila	34856	SCOPES	6	II	7/1/2013
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3350-2770	Arthroscope 70°, 2.7 mm x 75 mm	Ila	34856	SCOPES	6	II	7/1/2013
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3350-2930	Centerline Carpal Tunnel Scope 30°, 2.9 mm x 133 mm	Ila	34856	SCOPES	6	II	7/1/2013
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3350-3030	Arthroscope 30°, 3 mm x 138 mm HD	Ila	34856	SCOPES	6	II	7/1/2013
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3350-3070	Arthroscope 70°, 3 mm x 140 mm, HD	Ila	34856	SCOPES	6	II	7/1/2013
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3350-3530	Sheathless Arthroscope, 30°, 3 mm x 153 mm, HD	Ila	34856	SCOPES	6	II	7/1/2013
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3350-3570	Sheathless Arthroscope, 70°, 3 mm x 153 mm, HD	Ila	34856	SCOPES	6	II	7/1/2013
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3350-4030	Arthroscope, 30°, 4 mm x 152.5 mm, HD	Ila	34856	SCOPES	6	II	7/1/2013
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3350-4030H	Hip Arthroscope, 30°, 3.5 mm x 205 mm, HD	Ila	34856	SCOPES	6	II	7/1/2013
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3350-4030R	Arthroscope 30°, 4 mm x 152.5 mm, HD, Reverse Light Post	Ila	34856	SCOPES	6	II	7/1/2013
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3350-4031	4K Arthroscope, 30°, 4 mm x 152.5 mm	Ila	34856	SCOPES	6	II	10/27/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3350-4070	Arthroscope 70°, 4 mm x 156 mm, HD	Ila	34856	SCOPES	6	II	7/1/2013
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3350-4070H	Hip Arthroscope 70°, 3.5 mm x 205 mm, HD	Ila	34856	SCOPES	6	II	7/1/2013
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3350-4071	4K Arthroscope, 70°, 4 mm x 156 mm	Ila	34856	SCOPES	6	II	10/27/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3350-5030	Sheathless Arthroscope, 30°, 4 mm x 134 mm, HD	Ila	34856	SCOPES	6	II	7/1/2013
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3350-5070	Sheathless Arthroscope 70°,4 mm x 138 mm, HD	Ila	34856	SCOPES	6	II	7/1/2013
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3350-5230	4K ARTHROSCOPE, 30°, 4.8 MM x 152.5 MM	Ila	34856	SCOPES	6	II	4/22/2016
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3350-5270	4K ARTHROSCOPE, 70°, 4.8 MM x 156 MM	Ila	34856	SCOPES	6	II	4/22/2016
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3350-5430	4K Sheathless Endoscope, 30°, 5.2 x 160 mm	Ila	34856	SCOPES	6	II	4/13/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3350-5470	4K Sheathless Endoscope, 70°, 5.2 x 162 mm	Ila	34856	SCOPES	6	II	4/13/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3351-1000	4K Laparoscope 0°, 10 mm x 330 mm, HD	Ila	12291	SCOPES	6	II	7/1/2013
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3351-1000L	4K Laparoscope 0°, 10 mm x 455 mm, Extended Length	Ila	12291	SCOPES	6	II	7/1/2013
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3351-1030	4K Laparoscope 30°, 10 mm x 330 mm, HD	Ila	12291	SCOPES	6	II	7/1/2013
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3351-1030L	4K Laparoscope 30°, 10 mm x 455 mm, Extended Length	Ila	12291	SCOPES	6	II	7/1/2013
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3351-1045	4K Laparoscope 45°, 10 mm x 333.5 mm, HD	Ila	12291	SCOPES	6	II	7/1/2013
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3351-1045L	4K Laparoscope 45°, 10 mm x 459 mm, HD, Extended Length	Ila	12291	SCOPES	6	II	7/1/2013
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3351-3000	Laparoscope 0°, 3 mm x 207 mm, HD	Ila	12291	SCOPES	6	II	7/1/2013
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3351-3030	Laparoscope 30°, 3 mm x 207 mm, HD	Ila	12291	SCOPES	6	II	7/1/2013
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3351-5500	Laparoscope 0°, 5.5 mm x 300 mm, HD	Ila	12291	SCOPES	6	II	7/1/2013
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3351-5500L	Laparoscope 0°, 5.5 mm x 424 mm, HD, Extended Length	Ila	12291	SCOPES	6	II	7/1/2013
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3351-5530	Laparoscope 30°, 5.5 mm x 300 mm, HD	Ila	12291	SCOPES	6	II	7/1/2013

MDD Technical File: SCOPES, Revision 24

Manufacturer name	Manufacturing location	EC QA Cert. number:	Product Code	Product Name	Class	GMDN code	TF	Rule	Annex	First DoC
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3351-5530L	Laparoscope 30°, 5.5 mm x 424 mm, HD, Extended Length	Ila	12291	SCOPES	6	II	7/1/2013
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3351-5545	Laparoscope 45°, 5.5 mm x 302 mm, HD	Ila	12291	SCOPES	6	II	7/1/2013
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3351-5545L	Laparoscope 45°, 5.5 mm x 425 mm, HD, Extended Length	Ila	12291	SCOPES	6	II	7/1/2013
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3352-5500	4K Laproscope, 0°, 5.5 x 300 mm, Hi-Mag	Ila	12291	SCOPES	6	II	8/25/2015
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3352-5500L	4K Laproscope, Ext Length, 0°, 5.5 x 424 mm, Hi-Mag	Ila	12291	SCOPES	6	II	8/25/2015
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3352-5530	4K Laproscope, 30°, 5.5 x 300 mm, Hi-Mag	Ila	12291	SCOPES	6	II	8/25/2015
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3352-5530L	4K Laproscope, Ext Length, 30°, 5.5 x 424 mm, Hi-Mag	Ila	12291	SCOPES	6	II	8/25/2015
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3352-5545	4K Laproscope, 45°, 5.5 x 302 mm, Hi-Mag	Ila	12291	SCOPES	6	II	8/25/2015
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3352-5545L	4K Laproscope, Ext Length, 45°, 5.5 x 425 mm, Hi-Mag	Ila	12291	SCOPES	6	II	8/25/2015
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3355-1930	C-Mount Arthroscope 30°, 1.9 mm x 58 mm	Ila	34856	SCOPES	6	II	12/23/2014
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3355-2430	C-Mount Arthroscope, 30°, 2.4mm x 72 mm	Ila	34856	SCOPES	6	II	11/4/2016
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3355-2470	C-Mount Arthroscope 70°, 2.4 mm x 75 mm	Ila	34856	SCOPES	6	II	12/21/2016
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3355-2730	C-Mount Arthroscope, 30°, 2.7 mm x 72 mm Length	Ila	34856	SCOPES	6	II	7/1/2013
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3355-2770	C-Mount Arthroscope, 70°, Ø 2.7 mm x 74 mm Length	Ila	34856	SCOPES	6	II	7/1/2013
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3355-3030	C-Mount Arthroscope, 30 degrees, 3 x 138 mm, HD	Ila	34856	SCOPES	6	II	10/13/2015
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3355-3070	C-Mount Arthroscope, 70 degrees, 3 x 138 mm, HD	Ila	34856	SCOPES	6	II	10/13/2015
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3355-4000	C-Mount Endoscope, 0°, 4 x 152.5 mm	Ila	34856	SCOPES	6	II	4/13/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3355-4030	C-Mount Arthroscope, 30°, Ø 4.0 mm x 152.5 mm Length	Ila	34856	SCOPES	6	II	7/1/2013
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3355-4030H	C-Mount Hip Arthroscope, 30°, 3.5 mm x 202 mm	Ila	34856	SCOPES	6	II	7/1/2013
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3355-4030R	C-Mount Arthroscope, 30°, Reverse Light Post, 4 x 152.5 mm	Ila	34856	SCOPES	6	II	4/13/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3355-4031	4K C-Mount Arthroscope, 30°, 4 mm x 152.5 mm	Ila	34856	SCOPES	6	II	10/27/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3355-4070	C-Mount Arthroscope, 70°, Ø 4.0 mm x 155.5 mm Length	Ila	34856	SCOPES	6	II	7/1/2013
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3355-4070H	C-Mount Hip Arthroscope, 70°, 3.5 mm x 206 mm	Ila	34856	SCOPES	6	II	7/1/2013
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3355-4071	4K C-Mount Arthroscope, 70°, 4 mm x 156 mm	Ila	34856	SCOPES	6	II	10/27/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3355-5230	4K C-MOUNT ARTHROSCOPE,30°,4.8 x 152.5MM	Ila	34856	SCOPES	6	II	4/22/2016
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3355-5270	4K C-MOUNT ARTHROSCOPE, 70°, 4.8 x 156MM	Ila	34856	SCOPES	6	II	4/22/2016
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3355-5430	4K C-Mount Arthroscope, 30°, 5 x 160 mm	Ila	34856	SCOPES	6	II	10/6/2015
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3355-5470	4K C-Mount Arthroscope, 70°, 5 x 162 mm	Ila	34856	SCOPES	6	II	10/6/2015
ENDOSCOPIC MEDICAL INSTRUMENTS										
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3016Q	Sheath, HI-Flow, w/Stabilizer, Q-Lock, 2 Stopcock	Ila	34856	SCOPES	6	II	6/30/1998
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3370-1900	Sheath Body, for 1.9 mm Scope Sheath System	Ila	34856	SCOPES	6	II	7/1/2013
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3370-2702	Sheath System, 2 Stopcock for 2.7 mm Scope	Ila	34856	SCOPES	6	II	7/1/2013
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3370-3000	Sheath Body, for 3 mm Scope Sheath System	Ila	34856	SCOPES	6	II	7/1/2013
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3370-3003	I/O Sheath Set for Synergy 3 mm Scope; Part A & B	Ila	37086	SCOPES	6	II	4/13/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3370-3003A	Inner Sheath for In/Outflow Synergy 3 mm Scope Sheath	Ila	37086	SCOPES	6	II	2/12/2016
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3370-3003B	Outer Sheath for In/Outflow Synergy 3 mm Scope Sheath	Ila	37086	SCOPES	6	II	2/12/2016
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3370-4001	Sheath System, 1 Stopcock for 4 mm Scope	Ila	34856	SCOPES	6	II	7/1/2013
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3370-4003A	Inner Sheath for In/Outflow Synergy 4mm Scope Sheath	Ila	37086	SCOPES	6	II	2/12/2016
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3370-4003B	Outer Sheath for In/Outflow Synergy 4 mm Scope Sheath	Ila	37086	SCOPES	6	II	2/12/2016
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3371-0300	Sheath Body, High-Flow, Fenestration, for 3 mm Scope Sheath System	Ila	34856	SCOPES	6	II	7/1/2013
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3371-0301	Sheath System High-Flow, Fenestration, 1 Stopcock for 3 mm Scope	Ila	34856	SCOPES	6	II	7/1/2013
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3371-0302	Sheath System, High-Flow, Fenestration, 2 Stopcock for 3 mm Scope	Ila	34856	SCOPES	6	II	7/1/2013
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3371-4000	Sheath Body, High-Flow, Fenestration, for 4 mm Scope Sheath System	Ila	34856	SCOPES	6	II	7/1/2013

MDD Technical File: SCOPES, Revision 24

Manufacturer name	Manufacturing location	EC QA Cert. number:	Product Code	Product Name	Class	GMDN code	TF	Rule	Annex	First DoC
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3371-4000H	Sheath Body, High-Flow, Fenestration, for 4 mm Hip Scope Sheath System	Ila	34856	SCOPES	6	II	7/1/2013
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3371-4002H	Sheath System, High-Flow, Fenestration, 2 Stopcock for 3.5 mm Hip Scope	Ila	34856	SCOPES	6	II	7/1/2013
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3372-0301	SHEATH, HF, 1 STOPCOCK FOR 3MM SCOPE	Ila	37086	SCOPES	6	II	7/17/2015
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3372-0302	SHEATH, HF, 2 STOPCOCK FOR 3MM SCOPE	Ila	37086	SCOPES	6	II	7/17/2015
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3372-1901	SHEATH, 1 STOPCOCK FOR 1.9MM SCOPE	Ila	37086	SCOPES	6	II	11/5/2015
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3372-1902	SHEATH, 2 STOPCOCK FOR 1.9MM SCOPE	Ila	37086	SCOPES	6	II	11/5/2015
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3372-2401	SHEATH, 1 STOPCOCK FOR 2.4MM SCOPE	Ila	37086	SCOPES	6	II	11/5/2015
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3372-2402	SHEATH, 2 STOPCOCK FOR 2.4MM SCOPE	Ila	37086	SCOPES	6	II	11/5/2015
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3372-2701	SHEATH, 1 STOPCOCK FOR 2.7MM SCOPE	Ila	37086	SCOPES	6	II	11/5/2015
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3372-2702	SHEATH, 2 STOPCOCK FOR 2.7MM SCOPE	Ila	37086	SCOPES	6	II	11/5/2015
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3372-3001	SHEATH, 1 STOPCOCK FOR 3MM SCOPE	Ila	37086	SCOPES	6	II	7/17/2015
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3372-3002	SHEATH, 2 STOPCOCK FOR 3MM SCOPE	Ila	37086	SCOPES	6	II	7/17/2015
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3372-4001	Sheath, HF, 1 Stopcock for 4mm Scope	Ila	37086	SCOPES	6	II	10/6/2015
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3372-4002	Sheath, HF, 2 Stopcock for 4mm Scope	Ila	37086	SCOPES	6	II	10/6/2015
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3373-0301	SHEATH,HF,TAP/FEN,1 STPCK FOR 3MM SCOPE	Ila	37086	SCOPES	6	II	11/5/2015
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3373-0302	SHEATH,HF,TAP/FEN,2 STPCK FOR 3MM SCOPE	Ila	37086	SCOPES	6	II	11/5/2015
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3373-4001	SHEATH,HF,TAP/FEN,1 STPCK FOR 4MM SCOPE	Ila	37086	SCOPES	6	II	11/5/2015
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3373-4001H	SHTH,HIP,TAP/FEN 1 STPCK F/3.5MM HIP SCP	Ila	34856	SCOPES	6	II	7/17/2015
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3373-4002	SHEATH,HF,TAP/FEN,2 STPCK FOR 4MM SCOPE	Ila	37086	SCOPES	6	II	11/5/2015
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3373-4002H	SHTH,HIP,TAP/FEN 2 STPCK F/3.5MM HIP SCP	Ila	34856	SCOPES	6	II	7/17/2015
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3373-5001	SHEATH, HF, TAP/FEN, 1 STOPCOCK FOR 4.8 MM SCOPE	Ila	37086	SCOPES	6	II	4/22/2016
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3373-5002	SHEATH, HF, TAP/FEN, 2 STOPCOCK FOR 4.8 MM SCOPE	Ila	37086	SCOPES	6	II	4/22/2016
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3374-4001	Sheath, Fenestrated, 1 Stopcock for 4mm Scope	Ila	37086	SCOPES	6	II	10/6/2015
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3374-4002	Sheath, Fenestrated, 2 Stopcock for 4mm Scope	Ila	37086	SCOPES	6	II	10/6/2015
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3375-5007	CONICAL OBTURATOR F/TAP/ FEN HF 4.8MM SCOPE SHEATH	Ila	34856	SCOPES	6	II	2/22/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3380-0401	Bridge System, Sealed, 1 Stopcock for 4.0 mm Scope	Ila	34856	SCOPES	6	II	7/1/2013
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3380-0402	Sealed Bridge for 4.0 mm Scope, 2 Stopcock	Ila	34856	SCOPES	6	II	7/1/2013
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3380-3001	Bridge for 3.0 mm Scope, 1 Stopcock	Ila	34856	SCOPES	6	II	7/1/2013
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3380-3002	Bridge for 3.0 mm Scope, 2 Stopcock	Ila	34856	SCOPES	6	II	7/1/2013
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3380-4001	Bridge for 4.0 mm Scope, 1 Stopcock	Ila	34856	SCOPES	6	II	7/1/2013
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3380-4001H	Bridge System, 1 Stopcock, for 3.5 mm Hip Scope	Ila	34856	SCOPES	6	II	7/1/2013
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3380-4002	Bridge for 4.0 mm Scope, 2 Stopcock	Ila	34856	SCOPES	6	II	7/1/2013
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3380-4002H	Bridge for 3.5 mm Hip Scope, 2 Stopcock	Ila	34856	SCOPES	6	II	7/1/2013
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3380-4003H	Bridge, XL, Quick Connect, 1 Stopcock for 3.5mm Hip Scope	Ila	37090	SCOPES	6	II	10/6/2015
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3380-4004H	Bridge, XL, Quick Connect, 2 Stopcock for 3.5mm Hip Scope	Ila	37090	SCOPES	6	II	10/6/2015
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3420-3.0	METAL CANNULA, 3.0MM	Ila	46696	SCOPES	6	II	4/22/2016
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3420-4.5	METAL CANNULA, 4.5MM	Ila	46696	SCOPES	6	II	4/22/2016
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3420-4.75	METAL CANNULA, 4.75MM	Ila	46696	SCOPES	6	II	4/22/2016
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3420-5.0	METAL CANNULA, 5.0MM	Ila	46696	SCOPES	6	II	4/22/2016
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3420-5.5	METAL CANNULA, 5.5MM	Ila	46696	SCOPES	6	II	4/22/2016
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3420-6.5	METAL CANNULA, 6.5MM	Ila	46696	SCOPES	6	II	4/22/2016
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3420H-4.5	Metal Cannula, XL, Hip, 4.5 mm	Ila	46696	SCOPES	6	II	10/6/2015
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3420H-5.0	Metal Cannula, XL, Hip, 5.0 mm	Ila	46696	SCOPES	6	II	10/6/2015
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3420H-5.5	Metal Cannula, XL, Hip, 5.5 mm	Ila	46696	SCOPES	6	II	10/6/2015

MDD Technical File: SCOPES, Revision 24

Manufacturer name	Manufacturing location	EC QA Cert. number:	Product Code	Product Name	Class	GMDN code	TF	Rule	Annex	First DoC
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3420H-6.5	Metal Cannula, XL, Hip, 6.5 mm	Ila	46696	SCOPES	6	II	10/6/2015
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3425-3.0	Metal Cannula, Fenestrated, 2.0mm	Ila	46696	SCOPES	6	II	2/12/2016
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3425-4.5	METAL CANNULA, FENESTRATED, 4.5MM	Ila	46696	SCOPES	6	II	4/22/2016
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3425-4.75	METAL CANNULA, FENESTRATED, 4.75MM	Ila	46696	SCOPES	6	II	4/22/2016
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3425-5.0	METAL CANNULA, FENESTRATED, 5.0MM	Ila	46696	SCOPES	6	II	4/22/2016
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3425-5.5	METAL CANNULA, FENESTRATED, 5.5MM	Ila	46696	SCOPES	6	II	4/22/2016
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3425-6.5	METAL CANNULA, FENESTRATED, 6.5MM	Ila	46696	SCOPES	6	II	4/22/2016
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3020	Switching Stick, 4 mm	Ila	47457	SCOPES	6	II	12/9/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3020-01	15 INCH SWITCHING STICK	Ila	47457	SCOPES	6	II	12/9/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3020-02	18 INCH SWITCHING STICK	Ila	47457	SCOPES	6	II	12/9/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3020-03	SWITCHING STICK, LONG, NON-CANNULATED, 3.5 MM x 15"	Ila	47457	SCOPES	6	II	12/9/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3020-04	SWITCHING STICK, LONG, NON-CANNULATED, 3.5 MM x 18"	Ila	47457	SCOPES	6	II	12/9/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3020-05	SWITCHING STICK 4.8mm x 15in	Ila	47457	SCOPES	6	II	12/9/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3020-07	SWITCHING STICK 4.6mm x 15in	Ila	47457	SCOPES	6	II	12/9/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3020-08	SWITCHING STICK 3.0mm x 15in	Ila	47457	SCOPES	6	II	12/9/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3020-09	SWITCHING STICK 3.3mm x 10in	Ila	47457	SCOPES	6	II	12/9/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3026	SWITCHING STICK, EXTRA LONG, 4MM	Ila	47457	SCOPES	6	II	12/9/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3027	Switching Stick Inserter	Ila	47457	SCOPES	6	II	12/9/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3375-0301	Obturator Conical for 3.0 mm HF Scope Sheath System	Ila	35692	SCOPES	6	II	12/9/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3375-0302	Trocar Sharp for 3.0 mm HF Scope Sheath System	Ila	61424	SCOPES	6	II	12/9/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3375-0307	Obturator Conical, Low-Pro for 3.0 mm HF Scope Sheath System	Ila	35692	SCOPES	6	II	12/9/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3375-0311	Obturator conical for 3.0 mm HF Scope Sheath System	Ila	35692	SCOPES	6	II	12/9/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3375-0312	Sharp Trocar for 3.0 mm HF Scope Sheath System	Ila	61424	SCOPES	6	II	12/9/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3375-0317	Obturator Conical, Low-Pro, for 3 mm HF Scope Sheath System	Ila	35692	SCOPES	6	II	12/9/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3375-1901	Obturator Conical for 1.9 mm Scope Sheath System	Ila	35692	SCOPES	6	II	12/9/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3375-1902	Trocar Sharp, for 1.9 mm Scope Sheath System	Ila	61424	SCOPES	6	II	12/9/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3375-1907	Obturator Conical, Low-Pro, for 1.9 mm Scope Sheath System	Ila	35692	SCOPES	6	II	12/9/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3375-2401	Obturator Conical for 2.4 mm Scope Sheath System	Ila	35692	SCOPES	6	II	12/9/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3375-2402	Trocar Sharp, for 2.4 mm Scope Sheath System	Ila	61424	SCOPES	6	II	12/9/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3375-2407	Obturator Conical, Low-Pro, for 2.4 mm Sheath System	Ila	35692	SCOPES	6	II	12/9/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3375-2701	Obturator Conical, for 2.7 mm Scope Sheath System	Ila	35692	SCOPES	6	II	12/9/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3375-2702	Trocar Sharp, for 2.7 mm Scope Sheath System	Ila	61424	SCOPES	6	II	12/9/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3375-2707	Obturator Conical, Low-Pro, for 2.7 mm Scope Sheath System	Ila	35692	SCOPES	6	II	12/9/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3375-3001	Obturator Conical for 3.0 mm Scope Sheath System	Ila	35692	SCOPES	6	II	12/9/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3375-3002	Trocar Sharp, for 3.0 mm Scope Sheath System	Ila	61424	SCOPES	6	II	12/9/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3375-3005	Conical Obturator for In/Outflow Synergy 3 mm Scope Sheath	Ila	35692	SCOPES	6	II	12/9/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3375-3006	Sharp Trocar Trocar for In/Outflow Synergy 3mm Scope Sheath	Ila	37086	SCOPES	6	II	12/9/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3375-3007	Obturator Conical, Low-Pro, for 3.0 mm Scope Sheath System	Ila	35692	SCOPES	6	II	12/9/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3375-4001	Obturator Conical, for 4 mm Scope Sheath System	Ila	35692	SCOPES	6	II	12/9/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3375-4001H	Obturator Conical, for 3.5 mm Hip HF Scope Sheath System	Ila	35692	SCOPES	6	II	12/9/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3375-4002	Trocar Sharp, for 4.0 mm HF Scope Sheath System	Ila	61424	SCOPES	6	II	12/9/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3375-4002H	Trocar Sharp, for 3.5 mm Hip HF Scope Sheath System	Ila	34856	SCOPES	6	II	12/9/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3375-4003	Obturator Cannulated, for 4 mm HF Scope Sheath System	Ila	35692	SCOPES	6	II	12/9/2019

MDD Technical File: SCOPES, Revision 24

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Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3375-4003H	Obturator Cannulated , for 3,5 mm HF Scope Sheath System	Ila	35692	SCOPES	6	II	12/9/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3375-4004	Obturator Blunt, for 4.0 mm HF Scope Sheath System	Ila	35692	SCOPES	6	II	12/9/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3375-4005	Obturator conical for 4.0 mm Scope Sheath System I/O	Ila	35692	SCOPES	6	II	12/9/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3375-4007	Obturator Conical, Low-Pro, for 4.0 mm Sheath System	Ila	35692	SCOPES	6	II	12/9/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3375-4007H	Obturator Conical, Low-Pro, for 3.5 mm HIP HF Scope Sheath System	Ila	35692	SCOPES	6	II	12/9/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3375-4011	Obturator Conical for 4.0 mm Scope Sheath System	Ila	35692	SCOPES	6	II	12/9/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3375-4012	Trocar Sharp for 4.0 mm Scope Sheath System	Ila	61424	SCOPES	6	II	12/9/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3375-4017	Obturator Conical, Low-Pro, for 4 mm Scope Sheath System	Ila	35692	SCOPES	6	II	12/9/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3375-4021	Conical Obturator for Fen 4mm Scope Sheath w/ Handle	Ila	35692	SCOPES	6	II	12/9/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3375-4022	Sharp Trocar for Fen 4mm Scope Sheath w/ Handle	Ila	35692	SCOPES	6	II	12/9/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3375-4027	Conical Obturator for Fen 4mm Scope Sheath	Ila	35692	SCOPES	6	II	12/9/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3375-5001	CONICAL OBTURATOR FOR TAP/FEN HF 4.8MM SCOPE SHEATH W/ HANDLE	Ila	35692	SCOPES	6	II	12/9/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3375-5002	SHARP TROCAR FOR TAP/FEN HF 4.8MM SCOPE SHEATH W/ HANDLE	Ila	35692	SCOPES	6	II	12/9/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3375-5003	CANNULATED OBTURATOR FOR TAP/FEN HF 4.8MM SCOPE SHEATH W/HANDLE	Ila	35692	SCOPES	6	II	12/9/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3421-3.0	BLUNT OBTURATOR FOR 3.0MM METAL CANNULA	Ila	58753	SCOPES	6	II	12/9/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3421-4.5	BLUNT OBTURATOR FOR 4.5MM METAL CANNULA	Ila	58753	SCOPES	6	II	12/9/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3421-4.75	BLUNT OBTURATOR FOR 4.75MM METAL CANNULA	Ila	58753	SCOPES	6	II	12/9/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3421-5.0	BLUNT OBTURATOR FOR 5.0MM METAL CANNULA	Ila	58753	SCOPES	6	II	12/9/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3421-5.5	BLUNT OBTURATOR FOR 5.5MM METAL CANNULA	Ila	58753	SCOPES	6	II	12/9/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3421-6.5	BLUNT OBTURATOR FOR 6.5MM METAL CANNULA	Ila	58753	SCOPES	6	II	12/9/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3421H-4.5	Cannulated Obturator, XL, Hip, 4.5 mm	Ila	35692	SCOPES	6	II	12/9/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3421H-5.0	Cannulated Obturator, XL, Hip, 5.0 mm	Ila	35692	SCOPES	6	II	12/9/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3421H-5.5	Cannulated Obturator, XL, Hip, 5.5 mm	Ila	35692	SCOPES	6	II	12/9/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3421H-6.5	Cannulated Obturator, XL, Hip, 6.5 mm	Ila	35692	SCOPES	6	II	12/9/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3422-3.0	TROCAR FOR 3.0MM METAL CANNULA	Ila	61424	SCOPES	6	II	12/9/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3422-4.5	TROCAR FOR 4.5MM METAL CANNULA	Ila	47457	SCOPES	6	II	12/9/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3422-4.75	TROCAR FOR 4.75MM METAL CANNULA	Ila	61424	SCOPES	6	II	12/9/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3422-5.0	TROCAR FOR 5.0MM METAL CANNULA	Ila	61424	SCOPES	6	II	12/9/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3422-5.5	TROCAR FOR 5.5MM METAL CANNULA	Ila	61424	SCOPES	6	II	12/9/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3422-6.5	TROCAR FOR 6.5MM METAL CANNULA	Ila	61424	SCOPES	6	II	12/9/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-6520-15	SWITCHING STICK, LONG, CANNULATED	Ila	47457	SCOPES	6	II	12/9/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-6520-16	SWITCHING STICK, LONG, CANNULATED, 3.5 MM x 15"	Ila	47457	SCOPES	6	II	12/9/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3300	INFLOW/OUTFLOW SHEATH SET F/STORZ 4MM SCOPE	Ila	47457	SCOPES	6	II	4/28/2020
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3301	CONICAL OBTURATOR F/ IN/OUT STORZ 4MM SCOPE SHEATH	Ila	47457	SCOPES	6	II	4/28/2020
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3320-01	SHEATH, HI-FLOW, TAP/FEN, 2 STOPCOCKS F/ STORZ 4MM SCOPE	Ila	47457	SCOPES	6	II	4/28/2020
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3320-02	SHEATH, HI-FLOW, TAP/FEN, 1 STOPCOCK F/ STORZ 4MM SCOPE	Ila	47457	SCOPES	6	II	4/28/2020
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3321	CONICAL OBTURATOR,F/TAP/FEN HF 4MM STORZ SCOPE SHEATH	Ila	47457	SCOPES	6	II	4/28/2020
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3322	TROCAR FOR TAP/FEN HF 4MM STORZ SCOPE SHEATH	Ila	47457	SCOPES	6	II	4/28/2020
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3323	CANNULATED OBTURATOR FOR TAP/FEN HF 4MM STORZ SCOPE SHEATH	Ila	47457	SCOPES	6	II	4/28/2020
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3324	BLUNT FOR TAP/FEN HF 4MM STORZ SCOPE SHEATH	Ila	47457	SCOPES	6	II	4/28/2020
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3415-4.5	METAL CANNULA, 4.5MM, W/ DAM	Ila	47457	SCOPES	6	II	4/28/2020
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3415-5.0	METAL CANNULA, 5.0MM, W/ DAM	Ila	47457	SCOPES	6	II	4/28/2020
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3415-5.5	METAL CANNULA, 5.5MM, W/ DAM	Ila	47457	SCOPES	6	II	4/28/2020

Manufacturer name	Manufacturing location	EC QA Cert. number:	Product Code	Product Name	Class	GMDN code	TF	Rule	Annex	First DoC
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3416-4.5	BLUNT OBTURATOR FOR 4.5MM METAL CANNULA W/DAM	IIa	47457	SCOPES	6	II	4/28/2020
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3416-5.0	BLUNT OBTURATOR FOR 5.0MM METAL CANNULA W/DAM	IIa	47457	SCOPES	6	II	4/28/2020
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3416-5.5	BLUNT OBTURATOR FOR 5.5MM METAL CANNULA W/DAM	IIa	47457	SCOPES	6	II	4/28/2020
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3490-02	BRIDGE,2 STOPCOCKS,FOR 4MM STORZ SCOPE	IIa	47457	SCOPES	6	II	4/28/2020
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3490-03	BRIDGE,HIP,2 STOPCOCKS,FOR 4MM STORZ SCOPE	IIa	47457	SCOPES	6	II	4/28/2020
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3491-01	BRIDGE,FOR SEALED CANNULA,1 STOPCOCK,4MM STORZ SCOPE	IIa	47457	SCOPES	6	II	4/28/2020
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3491-02	BRIDGE,FOR SEALED CANNULA,2 STOPCOCK,4MM STORZ SCOPE	IIa	47457	SCOPES	6	II	4/28/2020
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3300A	INNER SHEATH FOR 4mm STORZ SCOPE, PART A	IIa	47457	SCOPES	6	II	4/28/2020
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3300B	OUTER SHEATH FOR 4mm STORZ SCOPE, PART B	IIa	47457	SCOPES	6	II	4/28/2020
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3370-0007	INFLOW STOPCOCK FOR INFLOW SHEATH	IIa	47457	SCOPES	6	II	4/28/2020
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3370-0005	OUTFLOW STOPCOCK FOR OUTFLOW SHEATH	IIa	47457	SCOPES	6	II	4/28/2020
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3370-0001	Stopcock, Single, Spare, for Synergy HD3 Sheath	IIa	34856	SCOPES	6	II	7/1/2013
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3370-0002	Stopcock, Double, Spare, for Synergy HD3 Sheath	IIa	34856	SCOPES	6	II	7/1/2013
				Camera Heads NS Insts						
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3210-0011	4K Synergy UHD4 Trimano Camera Holder	IIa	32288	SCOPES	6	II	12/9/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3210-0018	HD SynergyUHD4 Camera Head, autoclavable	IIa	35958	SCOPES	6	II	12/9/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3210-0021	HD Synergy UHD4 C-Mount Camera Head, autoclavable	IIa	35958	SCOPES	6	II	12/9/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3210-0022	HD Synergy UHD4 C-Mount Camera Head, 0 degree, autoclavable	IIa	35958	SCOPES	6	II	12/9/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3210-0023	Camera Head, Synergy HD4K	IIa	35958	SCOPES	6	II	12/9/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3210-0025	Camera Head, Synergy HD4K, C-MT	IIa	35958	SCOPES	6	II	12/9/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3210-0026	4K Synergy UHD4 C-Mount Camera Head, 0 degree, autoclavable	IIa	35958	SCOPES	6	II	12/9/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3210-0028	4K Synergy UHD4 C-Mount w/20 foot cable, autoclavable	IIa	35958	SCOPES	6	II	12/9/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3210-0029	4K Synergy UHD4 C-Mount w/20 foot cable, autoclavable	IIa	35958	SCOPES	6	II	12/9/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3210-0030	4K Synergy UHD4 C-Mount Broadband Camera Head, autoclavable	IIa	35958	SCOPES	6	II	12/9/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3210-0031	4K Synergy UHD4 Ultra, Autoclavable	IIa	35958	SCOPES	6	II	12/9/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3210-0032	4K Synergy UHD4 Ultra C-Mount, Autoclavable	IIa	35958	SCOPES	6	II	12/9/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3370-0006	Starfish Scope Rotation Attachment	IIa	37090	SCOPES	6	II	12/9/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3370-0008	Arthrex C-MNT Starfish Scope Rotation Attachment	IIa	37090	SCOPES	6	II	12/9/2019
				Displays and Consoles NS Insts						
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3200-0020	CCU Arthrex Synergy UHD4, Matrix	IIa	35958	SCOPES	6	II	12/9/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3200-0021	CCU Arthrex Synergy UHD4	IIa	35958	SCOPES	6	II	12/9/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3200-1040	Synergy System Integration Cable Kit	IIa	47487	SCOPES	6	II	12/9/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3200-0022	CCU, Arthrex Synergy UHD4, Matrix, HCRI (For China Only)	IIa	35958	SCOPES	6	II	12/9/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3200-0023	CCU, Arthrex Synergy UHD4, HCRI (For China Only)	IIa	35958	SCOPES	6	II	12/9/2019
				Tools For NS Insts						
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3355-0001	C-Mount Wrench, Synergy	IIa	32871	SCOPES	6	II	12/9/2019
				NanoScope Camera System						
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3200-0030	NanoScope Console	IIa	35958	SCOPES	6	II	12/9/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3210-0040	NanoScope™ Handpiece	IIa	44093	SCOPES	6	II	1/28/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3210-0041	NanoScope Sheath Accessory Kit	IIa	44093	SCOPES	6	II	4/28/2020
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3210-0042	NanoScope Operative Camera Kit	IIa	44093	SCOPES	6	II	7/31/2020

Manufacturer name	Manufacturing location	EC QA Cert. number:	Product Code	Product Name	Class	GMDN code	TF	Rule	Annex	First DoC
Nano Insts										
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-10911D	NanoBiter Straight Tip, Straight Shaft, Disposable	Ila	57874	SCOPES	6	II	7/7/2020
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-10922D	NanoBiter 15° Up Tip, 15° Up Curved Shaft, Disposable	Ila	57874	SCOPES	6	II	7/7/2020
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-10913D	NanoGrasper Tip, Straight Shaft, Disposable	Ila	57874	SCOPES	6	II	7/7/2020
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-10915D	NanoScissor Tip, Straight Shaft, Disposable	Ila	57874	SCOPES	6	II	7/7/2020
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-10901D	NanoBiter Straight Tip, 70mm, Disposable	Ila	57874	SCOPES	6	II	7/7/2020
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-10902D	NanoBiter 15° Up Tip, 70mm, Disposable	Ila	57874	SCOPES	6	II	7/7/2020
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-10903D	NanoGrasper Tip, 70mm, Disposable	Ila	57874	SCOPES	6	II	7/7/2020
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-10905D	NanoScissor Tip, 70mm, Disposable	Ila	57874	SCOPES	6	II	7/7/2020
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-10911D-1	NanoBiter Straight Tip, Straight Shaft, Disposable	Ila	57874	SCOPES	6	II	7/7/2020
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-10922D-1	NanoBiter 15° Up Tip, 15° Up Curved Shaft, Disposable	Ila	57874	SCOPES	6	II	7/7/2020
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-10913D-1	NanoGrasper Tip, Straight Shaft, Disposable	Ila	57874	SCOPES	6	II	7/7/2020
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-10915D-1	NanoScissor Tip, Straight Shaft, Disposable	Ila	57874	SCOPES	6	II	7/7/2020
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-10901D-1	NanoBiter Straight Tip, 70mm, Disposable	Ila	57874	SCOPES	6	II	7/7/2020
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-10902D-1	NanoBiter 15° Up Tip, 70mm, Disposable	Ila	57874	SCOPES	6	II	7/7/2020
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-10903D-1	NanoGrasper Tip, 70mm, Disposable	Ila	57874	SCOPES	6	II	7/7/2020
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-10905D-1	NanoScissor Tip, 70mm, Disposable	Ila	57874	SCOPES	6	II	7/7/2020
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-10100N	NanoScope Probe	Ila	35948	SCOPES	6	II	7/7/2020
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1090NH	NanoGrip, NanoScope Optics Handle	Ila	65126	SCOPES	6	II	9/29/2020
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-1090NH-1	NanoGrip, NanoScope Optics Handle	Ila	65126	SCOPES	6	II	9/29/2020
Fluorescence Endoscopic Imaging System										
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3200-0025	SynergyID Console	Ila	35958	SCOPES	6	II	7/31/2020
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3210-0033	4K SynergyID Camera Head, Autoclavable	Ila	35958	SCOPES	6	II	7/31/2020
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3200-1018	Synergy ^{ID} Laser Light Source	Ila	35958	SCOPES	6	II	7/31/2020
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3351-1001	4K Laparoscope, 0° 10 x 330 mm, NIR	Ila	12291	SCOPES	6	II	7/31/2020
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3351-1031	4K Laparoscope, 30° 10 x 330 mm, NIR	Ila	12291	SCOPES	6	II	7/31/2020
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3351-1046	4K Laparoscope, 45° 10 x 333 mm, NIR	Ila	12291	SCOPES	6	II	7/31/2020
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3352-5501	4K Laparoscope, 0°, 5.5 x 300 mm, Hi-Mag, NIR	Ila	12291	SCOPES	6	II	7/31/2020
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3352-5531	4K Laparoscope, 30°, 5.5 x 300 mm, Hi-Mag, NIR	Ila	12291	SCOPES	6	II	7/31/2020
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-3352-5546	4K Laparoscope, 45°, 5.5 x 302 mm, Hi-Mag, NIR	Ila	12291	SCOPES	6	II	7/31/2020