

Sekcja

1

1. Deklaracja zgodności

Dokumentacja techniczna POMPA

Kody GMDN Pełną listę wszystkich kodów GMDN, o których mowa w niniejszej dokumentacji technicznej, można znaleźć w Wykazie Kor. 18

Korekta 18

Klasa MDD, Reguła Klasa IIa, Reguła 2, Reguła 9 i Reguła 11

Ścieżka zgodności Załącznik II (z wyłączeniem Sekcji 4)

**Jednostka Notyfikowana/
Numer** BSI / CE 2797
(poprzednio BSI / CE 0086)

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

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

1.1. Oświadczenie do Deklaracji Zgodności

Niżej podpisany oświadcza, że wymienione powyżej urządzenia medyczne są zgodne z odpowiednimi sekcjami dyrektywy dotyczącej urządzeń medycznych 93/42/EWG.



David Rogers,
Dyrektor ds. Regulacji

1/8/2022

Data

1.2. Lista urządzeń według numeru katalogowego

Lista urządzeń według numerów katalogowych znajduje się w części B.

Section

1

1. Declaration of Conformity

Technical File	PUMP
GMDN Codes	Refer to Parts List, Rev. 18 for a complete list of all GMDN Codes subject of this technical file
Revision	18
MDD Class, Rule	Class IIa, Rule 2, Rule 9 and Rule 11
Route of Compliance	Annex II (excluding Section 4)
Notified Body/ Number	BSI / CE 2797 (Formerly - BSI / CE 0086)
Manufacturer	Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108 USA
EC Representative	Arthrex GmbH Erwin-Hielscher-Strasse 9 81249 München, Germany

1.1. Conformity Declaration Statement

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



David Rogers
Director, Regulatory Affairs

8/1/2022

Date

1.2. List of Devices by Catalog Number

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

Manufacturer name:	Manufacturing location:	EC QA Cert. number:	Product Code	Product Name:	Class:	GMDN	TF	Rule:	Annex:	First DoC:
Arthroscopy Pumps										
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-6480	DUALWAVE ARTHROSCOPY FLUID MANAGEMENT System	Ila	36003	PUMP	11	II	1/27/2009
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-6482	DUALWAVE REMOTE	Ila	36003	PUMP	9	II	1/27/2009
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-6483	DUALWAVE FOOT PEDAL	Ila	36336	PUMP	9	II	1/27/2009
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-6485	Synergy Continous Wave 4 Arthroscopic Pump	Ila	36003	PUMP	11	II	6/23/2017
Pump Accessories										
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-6200	Y-Inflow Tubing 7.0 mm	Ila	36003	PUMP	2	II	6/17/1997
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-6200A	Suction Tubing	Ila	36003	PUMP	2	II	6/17/1997
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-6215	TUBING ADAPTER, 'Y' DOUBLE SPIKED (10-BOX)	Ila	46102	PUMP	2	II	9/1/2003
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-6220	TUBING, EXTENSION 6FT. (20-BOX)	Ila	46102	PUMP	2	II	1/10/2007
Arthrex, Inc.	Naples, FL USA	CE 85507	ZB-6200	Y-Inflow Tubing 7.0 mm (nonsterile)	Ila	46102	PUMP	2	II	8/17/2007
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-6410	MAIN PUMP TUBING	Ila	46102	PUMP	2	II	1/1/2002
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-6415	One Piece Main Pump and Patient Extension Tubing for AR-6450, AR-6475 and AR-6480	Ila	36003	PUMP	2	II	6/17/1997
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-6415CL	One Piece Main Pump and Patient Extension Tubing with Care Lock Bag Connection for AR-6450, AR-6475 and AR-6480	Ila	36003	PUMP	2	II	6/17/1997
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-6411	ReDeuce PUMP TUBING W/CONNECTOR, 8' LONG	Ila	46102	PUMP	2	II	10/27/2006
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-6421	ReDeuce PATIENT TUBING W/CONNECTOR, 8' LONG	Ila	46102	PUMP	2	II	12/21/2006
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-6420	Main Pump Tubing for AR-6450, AR-6475 and AR-6480	Ila	46102	PUMP	2	II	8/17/2007
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-6420CL	Main Pump Tubing with Care Lock Bag Connection for AR-6450, AR-6475 and AR-6480	Ila	46102	PUMP	2	II	8/17/2007
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-6430	DUALWAVE OUTFLOW CASSETTE/TUBE SET	Ila	46102	PUMP	2	II	2/3/2009
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-6435	DUALWAVE Outflow Tube Set	Ila	46102	PUMP	2	II	9/27/2012
Arthrex, Inc.	Naples, FL USA	CE 85507	ZB-6425	Patient Extension Tubing with Luer Lock Connection (nonsterile)	Ila	46102	PUMP	2	II	4/17/2014
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-6425	Patient Extension Tubing with Luer Lock Connection	Ila	46102	PUMP	2	II	8/17/2007
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-6437	Inflow/Outflow Single Use, EU	Ila	46102	PUMP	2	II	9/13/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-6436	Inflow/Outflow Single Use	Ila	46102	PUMP	2	II	9/13/2019
Arthrex, Inc.	Naples, FL USA	CE 85507	ZB-6415	One Piece Main Pump and Patient Extension Tubing for AR-6450, AR-6475 and AR-6480 (nonsterile)	Ila	46102	PUMP	2	II	9/2/2020
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-4004T	Arthrovac Suction Tubing	Ila	46102	PUMP	2	II	9/2/2020
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-6412	Gravity Tubing	Ila	46102	PUMP	2	II	9/28/2020
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-6414	Gravity Tubing, 4 Spike	Ila	46102	PUMP	2	II	9/28/2020
Kit/Sets NS Insts										
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-4004	ArthroVac™ Floor Suction System, Reusable	Ila	35582	PUMP	2	II	4/17/2015
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-4004P	ArthroVac™ Felt Pads for Floor Suction System	Ila	44011	PUMP	2	II	6/23/2017
Tools for NS Insts										
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-6477-01	Pump Mounting Screw, 1/4"-20 3/4"Thumb	Ila	61952	PUMP	2	II	12/2/2005