

# Sekcja

# 1

## 1. Deklaracja zgodności

Dokumentacja techniczna	Urządzenia elektrochirurgiczne (RF)
Kody GMDN	Pełną listę wszystkich kodów GMDN, o których mowa w niniejszej dokumentacji technicznej, można znaleźć w Wykazie Kor. 15
Korekta	15
Klasa MDD, Reguła	Klasa IIb, Reguła 9
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

2/8/2022

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	Electrosurgical (RF) Devices
GMDN Codes	Refer to Parts List, Rev. 15 for a complete list of all GMDN Codes subject of this Technical File
Revision	15
MDD Class, Rule	Class IIb, 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.



David Rogers  
Director, Regulatory Affairs

Date

8/2/2022

**1.2. List of Devices by Catalog Number**

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

Manufacturer name:	Manufacturing location:	EC QA Cert. number:	Product Code:	Product Name:	Class:	GMDN Code	TF	Rule:	Annex:	First DoC:
<b>Electrosurgical Consoles</b>										
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-9800	Arthrex Synergy Console	IIb	56296	ELECTROSURGICAL	9	II	5/17/2016
<b>Electrosurgical Control Accessories</b>										
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-9800-F	Synergy Footswitch	IIb	36336	ELECTROSURGICAL	9	II	5/17/2016
<b>Ablation Bipolar Disposables</b>										
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-9811	APOLLO RF 90 DEGREE MULTIPOINT ABLATOR	IIb	61872	ELECTROSURGICAL	9	II	5/17/2016
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-9825	Apollo RF Hook, Non-Aspirating 90 degrees	IIb	61872	ELECTROSURGICAL	9	II	12/22/2016
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-9821	Apollo RF XL90, Aspirating Ablator 90 Extra Larger	IIb	61872	ELECTROSURGICAL	9	II	1/30/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-9815	Apollo RF™ MP50, Aspirating Ablator 50°, Multi-Port	IIb	61872	ELECTROSURGICAL	9	II	11/17/2017
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-9835	Apollo RF™ H50, Aspirating Ablator 50°	IIb	61872	ELECTROSURGICAL	9	II	9/21/2018
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-9845	Apollo RF® SJ50, Aspirating Ablator 50, short	IIb	61872	ELECTROSURGICAL	9	II	10/15/2020
<b>Ablation Monopolar Disposables</b>										
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-9705-90	OPES ABLATOR, 90 DEG.TOOTHBRUSH, LOW PROFILE	IIb	58039	ELECTROSURGICAL	9	II	9/4/2003
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-9703A-90	OPES ASPIRATING ABLATOR 3MM 90 DEG LOW PROFILE	IIb	58039	ELECTROSURGICAL	9	II	9/1/2004
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-9705A-90	OPES ASPIRATING ABLATOR TOOTHBRUSH 90 DEG LP	IIb	58039	ELECTROSURGICAL	9	II	9/1/2004
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-9803A-50	ARTHREX COOLCUT-50 ABLATOR	IIb	58039	ELECTROSURGICAL	9	II	12/11/2008
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-9801	COOLCUT HOOK ELECTRODE	IIb	58039	ELECTROSURGICAL	9	II	2/9/2010
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-9802M-45	COOLCUT MENISCECTOMY-45 DEG	IIb	58039	ELECTROSURGICAL	9	II	2/9/2010
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-9802M-90	COOLCUT MENISCECTOMY-90 DEG	IIb	58039	ELECTROSURGICAL	9	II	2/9/2010
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-9803-30	COOLCUT -30 NON-ASPIRATING	IIb	58039	ELECTROSURGICAL	9	II	2/9/2010
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-9803-50	COOLCUT -50 NON-ASPIRATING	IIb	58039	ELECTROSURGICAL	9	II	2/9/2010
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-9803-90	COOLCUT 90 NON-ASPIRATING	IIb	58039	ELECTROSURGICAL	9	II	2/9/2010
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-9803A-30	COOLCUT 30 ASPIRATING	IIb	58039	ELECTROSURGICAL	9	II	2/9/2010
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-9803A-90	ARTHREX COOLCUT-90 ABLATOR	IIb	58039	ELECTROSURGICAL	9	II	2/9/2010
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-9808	COOLCUT BALL ELECTRODE	IIb	58039	ELECTROSURGICAL	9	II	2/9/2010
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-9808-45	COOLCUT BALL ELECTRODE, 45 DEG	IIb	58039	ELECTROSURGICAL	9	II	2/9/2010
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-9808SJ	COOLCUT SMALL JOINT BALL	IIb	58039	ELECTROSURGICAL	9	II	2/9/2010
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-9808SJ-45	COOLCUT 45 DEG SMALL JOINT BALL	IIb	58039	ELECTROSURGICAL	9	II	2/9/2010
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-9809SJ-45	COOLCUT SMALL JOINT ABLATOR, 45 DEG	IIb	58039	ELECTROSURGICAL	9	II	2/9/2010
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-9809SJ-90	COOLCUT SMALL JOINT ABLATOR, 90 DEG	IIb	58039	ELECTROSURGICAL	9	II	2/9/2010
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-9610	DISPOSABLE PENCIL KIT	IIb	58039	ELECTROSURGICAL	9	II	4/20/2011
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-9610SGP	DISPOSABLE SPLIT ADULT RETURN ELECTRODE W CABLE	IIb	58039	ELECTROSURGICAL	9	II	4/20/2011
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-9606H-90	ARTHROSCOPY ELECTRODE, HOOK 90 DEGREE	IIb	58039	ELECTROSURGICAL	9	II	11/1/2011
Arthrex, Inc.	Naples, FL USA	CE 85507	AR-9802C	CoolCut Calibrator	IIb	58039	ELECTROSURGICAL	9	II	11/30/2012