

## Sekcja

# 1

### 1. Deklaracja zgodności

**Dokumentacja techniczna** Wyroby do przetwarzania krwi i szpiku kostnego

**Kody GMDN** Pełną listę wszystkich kodów GMDN, o których mowa w niniejszej dokumentacji technicznej, można znaleźć w Wykazie Części, kor. 25

**Korekta** 25

**Klasa MDD, Reguła** Klasa IIa, Reguła 1, 2, 3, 6 i 12

**Ścieżka zgodności** Załącznik II (z wyłączeniem Sekcji 4)

**Jednostka Notyfikowana/  
Numer** BSI / CE 2797  
(wcześniej BSI / CE0086)

**Wytwórca** 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 93/42/EWG dotyczącej urządzeń medycznych.

*Ganga Kolli*

Ganga Kolli (1 maja 2024 15:44 EDT)

Ganga Kolli,  
Senior Manager, Dział Regulacji Prawnych

Data

#### 1.2. Lista urządzeń według numeru katalogowego

Lista urządzeń według numerów katalogowych znajduje się w części B.

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Końcowy raport z audytu

2024-05-01

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Dokument utworzony przez Sawen Aziz ([sawen.aziz@arthrex.com](mailto:sawen.aziz@arthrex.com))

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## Section

# 1

## 1. Declaration of Conformity

<b>Technical File</b>	<b>Blood and Bone Marrow Processing Devices</b>
<b>GMDN Codes</b>	<b>Refer to Parts List Rev. 25 for a complete list of all GMDN Codes subject of this technical file</b>
<b>Revision</b>	<b>25</b>
<b>MDD Class, Rule</b>	Class IIa, Rule 1, 2, 3, 6, and 12
<b>Route of Compliance</b>	Annex II (excluding Section 4)
<b>Notified Body / Number</b>	BSI / CE 2797 (Formerly - BSI / CE0086)
<b>Manufacturer</b>	Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108 USA
<b>EC Representative</b>	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.

Ganga Kolli

Ganga Kolli (May 1, 2024 15:44 EDT)

Ganga Kolli

Sr. Manager Regulatory Affairs

Date

### 1.2. List of Devices by Catalog Number

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

EC QA Cert. number	Product Code	Product Name	Class	GMDN Code	TF	Rule	Annex:	First DoC:
CE 85507	ABS-10011	Arthrex ACP® Kit Series I	Ila	46923	Blood and Bone Marrow	1 & 3	II	11/30/2017
CE 85507	ABS-10014	Arthrex ACP® Double Syringe	Ila	46923	Blood and Bone Marrow	1 & 3	II	11/30/2017
CE 85507	ABS-10072	Arthrex Angel® cPRP & BMA Kit	Ila	16833	Blood and Bone Marrow	1 & 3	II	11/30/2017
CE 85507	ABS-10064	cPRP Processing Set, Arthrex Angel System	Ila	45669	Blood and Bone Marrow	2 & 3	II	5/4/2018
CE 85507	ABS-10066	Angel® Concentrated Platelet Rich Plasma (cPRP) System	Ila	16405	Blood and Bone Marrow	2, 3 & 12	II	5/4/2018
CE 85507	ABS-10066R	Angel® Concentrated Platelet Rich Plasma (cPRP) System	Ila	16405	Blood and Bone Marrow	2, 3 & 12	II	5/4/2018
CE 85507	ABS-10071	Arthrex Angel® PRP Kit	Ila	46923	Blood and Bone Marrow	6	II	5/4/2018
CE 85507	ABS-10080	Thrombinator™ System for use with Arthrex PRP Systems	Ila	47155	Blood and Bone Marrow	1 & 3	II	9/7/2018
CE 85507	ABS-10014-C	Arthrex ACP® Double Syringe (Croma Edition)	Ila	46923	Blood and Bone Marrow	1 & 3	II	8/16/2019
CE 85507	ABS-10014-E	Arthrex ACP® Double Syringe (PCT Edition)	Ila	46923	Blood and Bone Marrow	1 & 3	II	8/16/2019
CE 85507	ABS-10026	Counterweight for the Centrifugation of ACP-Double Syringe	Ila	56637	Blood and Bone Marrow	1 & 3	II	12/12/2019
CE 85507	ABS-10026-15	Arthrex ACP™ Sleeve for Counterweight ABS-10026	Ila	15682	Blood and Bone Marrow	1 & 3	II	12/12/2019
CE 85507	ABS-10027	Arthrex ACP™ Counterweight for Centrifugation of ACP Double Syringe, 15ml	Ila	15682	Blood and Bone Marrow	1 & 3	II	12/12/2019
CE 85507	AR-6431	Waste Collection Bag	Ila	58982	Blood and Bone Marrow	2	II	3/10/2020
CE 85507	ABS-1003	Funnel	Ila	47872	Blood and Bone Marrow	6	II	3/10/2020
CE 85507	ABS-1004	Mixing Syringe, 3cc with Luer Cap	Ila	44093	Blood and Bone Marrow	6	II	3/10/2020
CE 85507	ABS-2000	Mixing Syringe, 14cc with Luer Cap	Ila	44093	Blood and Bone Marrow	6	II	3/10/2020
CE 85507	ABS-1101-10S	Scoring Cutter for 10mm Round Cartiform	Ila	58804	Blood and Bone Marrow	6	II	3/10/2020
CE 85507	ABS-1101-20S	Scoring Cutter for 20mm Round Cartiform	Ila	58804	Blood and Bone Marrow	6	II	3/10/2020
CE 85507	ABS-1000-H	Delivery System, BioCartilage® Hip	Ila	44093	Blood and Bone Marrow	6	II	7/10/2020
CE 85507	ABS-1050	GraftNet™ Tissue Collector	Ila	60942	Blood and Bone Marrow	6	II	8/17/2020
CE 85507	ABS-2000-OT	IntraOsseous BioPlasty® (IOBP®), Core Decompression & Delivery Kit	Ila	44093	Blood and Bone Marrow	6	II	8/17/2020
CE 85507	ABS-2000-CT	IntraOsseous BioPlasty® (IOBP®), Core Decompression & Delivery Kit - Knee Closed Tip	Ila	44093	Blood and Bone Marrow	6	II	8/17/2020
CE 85507	ABS-2020-OT	IntraOsseous BioPlasty® (IOBP®), Core Decompression & Delivery Kit - Foot & Ankle Open Tip	Ila	44093	Blood and Bone Marrow	6	II	8/17/2020
CE 85507	ABS-2010-CT	IntraOsseous BioPlasty® (IOBP®), Core Decompression & Delivery Kit - Hip Closed Tip	Ila	44093	Blood and Bone Marrow	6	II	8/17/2020
CE 85507	ABS-2010-OT	IntraOsseous BioPlasty (IOBP), Core Decompression & Delivery Kit-Hip Open Tip	Ila	44093	Blood and Bone Marrow	6	II	1/25/2021
CE 85507	ABS-2001-OT	IntraOsseous BioPlasty (IOBP), Core Decompression & Delivery Kit-Knee Open Tip	Ila	44093	Blood and Bone Marrow	6	II	1/25/2021
CE 85507	ABS-1000-L	Delivery System, BioCartilage®, Large with 4.5" Tuohy Needle, Obturator, 3cc Mixing Syringe, Female Luer Cap, Funnel, Foam Tip Applicator, and Fat Pad Retractor	Ila	44093	Blood and Bone Marrow	6	II	2/23/2021
CE 85507	ABS-1000-S	Delivery System, BioCartilage®, Small with 3.0" Tuohy Needle, Obturator, 3cc Mixing Syringe, Female Luer Cap, Funnel, Foam Tip Applicator, and Fat Pad Retractor	Ila	44093	Blood and Bone Marrow	6	II	2/23/2021
CE 85507	AR-1101THK-13	Vortex™ Threaded Bone Marrow Recovery System, 13G	Ila	16833	Blood and Bone Marrow	6	II	4/9/2021
CE 85507	AR-1101THK-8	Vortex™ Threaded Bone Marrow Recovery System, 8G	Ila	16833	Blood and Bone Marrow	6	II	4/9/2021
CE 85507	AR-1101TH-13OT	Vortex™ Threaded Bone Marrow Recovery Needle, 13G, Open Tip	Ila	46350	Blood and Bone Marrow	6	II	4/9/2021
CE 85507	AR-1101TH-8OT	Vortex™ Threaded Bone Marrow Recovery Needle, 8G, Open Tip	Ila	46350	Blood and Bone Marrow	6	II	4/9/2021
CE 85507	AR-1101TH-13CT	Vortex™ Threaded Bone Marrow Recovery Needle, 13G, Closed Tip	Ila	46350	Blood and Bone Marrow	6	II	4/9/2021
CE 85507	AR-1101TH-8CT	Vortex™ Threaded Bone Marrow Recovery Needle, 8G, Closed Tip	Ila	46350	Blood and Bone Marrow	6	II	4/9/2021
CE 85507	ABS-10013	ACP Max PRP System (w/o ACD-A)	Ila	46350	Blood and Bone Marrow	6	II	3/1/2024
CE 85507	ABS-10013-B	ACP Max™ PRP System	Ila	46923	Blood and Bone Marrow	1 & 3	II	5/25/2021
CE 85507	ABS-10013-E	ACP Max™ PRP System (PCT)	Ila	46923	Blood and Bone Marrow	1 & 3	II	5/25/2021
CE 85507	ABS-10062-TH8CT	BMA kit, 8G closed tip, w/o ACD-A	Ila	16833	Blood and Bone Marrow	1 & 3	II	5/25/2021
CE 85507	ABS-10062-TH8OT	BMA kit, 8G open tip, w/o ACD-A	Ila	16833	Blood and Bone Marrow	1 & 3	II	5/25/2021
CE 85507	ABS-10062-TH13CT	BMA kit, 13G closed tip, w/o ACD-A	Ila	16833	Blood and Bone Marrow	1 & 3	II	5/25/2021
CE 85507	ABS-10062-TH13OT	BMA kit, 13G open tip, w/o ACD-A	Ila	16833	Blood and Bone Marrow	1 & 3	II	5/25/2021
CE 85507	ABS-10062K-TH8CT	BMA and Angel processing kit, 8G closed tip, w/o ACD-A	Ila	16833	Blood and Bone Marrow	1 & 3	II	5/25/2021
CE 85507	ABS-10062K-TH8OT	BMA and Angel processing kit, 8G open tip, w/o ACD-A	Ila	16833	Blood and Bone Marrow	1 & 3	II	5/25/2021
CE 85507	ABS-10062K-TH13CT	BMA and Angel processing kit, 13G closed tip, w/o ACD-A	Ila	16833	Blood and Bone Marrow	1 & 3	II	5/25/2021
CE 85507	ABS-10062K-TH13OT	BMA and Angel processing kit, 13G open tip, w/o ACD-A	Ila	16833	Blood and Bone Marrow	1 & 3	II	5/25/2021
CE 85507	AR-1001-TH-PWR	BMA needle adapter	Ila	16833	Blood and Bone Marrow	1 & 3	II	5/25/2021

EC QA Cert. number	Product Code	Product Name	Class	GMDN Code	TF	Rule	Annex:	First DoC:
CE 85507	ABS-10017	ACP Max Counterbalance	Ila	62346	Blood and Bone Marrow	1	II	5/9/2023
CE 85507	ABS-1052	Graf tNet XL Bone Collection Device	Ila	60942	Blood and Bone Marrow	6	II	4/29/2024
CE 85507	AR-S4000K-S	Endoscopic Spine Access Kit	Ila	44093	Blood and Bone Marrow	6	II	4/29/2024






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Final Audit Report

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